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COMBATING THE OPIOID CRISIS: PREVENTION AND PUBLIC HEALTH SOLUTIONS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTEENTH CONGRESS

SECOND SESSION

MARCH 21 & 22, 2018

Serial No. 115–112

Printed for the use of the Committee on Energy and Commerce
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[1] The statement can be found at: *https://docs.house.gov/meetings/IF/IF14/20180321/108049/HHRG-115-IF14-20180321-SD037.pdf.*

COMBATING THE OPIOID CRISIS: PREVENTION AND PUBLIC HEALTH SOLUTIONS, DAY 1

WEDNESDAY, MARCH 21, 2018

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

The subcommittee met, pursuant to call, at 10:02 a.m., in room 2123, Rayburn House Office Building, Hon. Michael Burgess, M.D. (chairman of the subcommittee) presiding.

Present: Representatives Burgess, Guthrie, Upton, Shimkus, Blackburn, Latta, Lance, Griffith, Bilirakis, Long, Bucshon, Brooks, Mullin, Hudson, Collins, Carter, Walden (ex officio), Green, Engel, Schakowsky, Butterfield, Matsui, Castor, Luján, Kennedy, Degette, and Pallone (ex officio).

Also Present: Representatives Walberg, McKinley, McNerney, and Dingell.

Staff Present: Mike Bloomquist, Staff Director; Adam Buckalew, Professional Staff Member, Health; Daniel Butler, Staff Assistant; Zachary Dareshori, Legislative Clerk, Health; Jordan Davis, Director of Policy and External Affairs; Paul Edattel, Chief Counsel, Health; Margaret Tucker Fogarty, Staff Assistant; Adam Fromm, Director of Outreach and Coalitions; Ali Fulling, Legislative Clerk, Oversight and Investigations, Digital Commerce and Consumer Protection; Caleb Graff, Professional Staff Member, Health; Jay Gulshen, Legislative Associate, Health; Ed Kim, Policy Coordinator, Health; Mary Martin, Chief Counsel, Energy/Environment; Mark Ratner, Policy Coordinator; Kristen Shatynski, Professional Staff Member, Health; Jennifer Sherman, Press Secretary; Danielle Steele, Counsel, Health; Austin Stonebraker, Press Assistant; Hamlin Wade, Special Advisor, External Affairs; Everett Winnick, Director of Information Technology; Jacquelyn Bolen, Minority Professional Staff; Jeff Carroll, Minority Staff Director; Waverly Gordon, Minority Health Counsel; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Jourdan Lewis, Minority Staff Assistant; Tim Robinson, Minority Chief Counsel; Andrew Souvall, Minority Director of Communications, Outreach and Member Services; Kimberlee Trzeciak, Minority Senior Health Policy Advisor; and C.J. Young, Minority Press Secretary.

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

The chair at this time would like to recognize the chairman of the full committee, Mr. Walden of Oregon, 5 minutes for an opening statement, please.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. WALDEN. Thank you, Mr. Chairman. And thank you for your great leadership on this issue.

Today marks the second of three legislative hearings advancing collaborative bipartisan legislative solutions to help combat the opioid crisis.

The impressive plague of opioid addiction and substance use disorder in our country requires an unprecedented response. And while this committee spearheaded the legislative efforts in CARA and Cures under Chairman Upton that has already devoted a record amount of Federal resource to address this crisis, we know we must do more to meet the growing demand.

This epidemic knows no geographic, no political, nor any socioeconomic bounds. I have held roundtables in my district in Oregon. Places like Hermiston and Grants Pass and Medford. When you talk to providers, to patients, to families, you can feel the sting of this crisis in every community.

President Trump rightly called it the crisis next door, and earlier this week, rolled out an ambitious plan. I was pleased to see that several of his proposals overlap with the work of this committee. And I know that working across the aisle and with the administration, we can arm agencies, healthcare providers, researchers, and patients with the tools they need. We stand ready to work with the President and his administration to put a stop to this crisis once and for all.

Over the span of 2 days, the Energy and Commerce Committee will consider a range of bills from members on both sides of the aisle, some 25 different pieces of legislation covering the full spectrum of prevention and public health, and we will hear from 19 witnesses.

The bills we consider today will strengthen the Food and Drug Administration's ability to understand several aspects of the opioid crisis, including the risk of long-term opioid use and how authorities can better intercept dangerous illicit products of international mail facilities.

We will hear about legislation that will facilitate the efficient development of treatments for substance use disorders and legislation that will encourage alternatives to opioids for the treatment of pain. These are two areas of medicine that have suffered from a lack of innovation and development, and I am optimistic that we can take tailored steps to encourage progress in the right direction.

Representative Latta's amendment in the nature of a substitute to H.R. 4284, Indexing Narcotics, Fentanyl, and Opioids, or the INFO Act, would create a public and easily accessible electronic dashboard that would link to all the nationwide efforts and strategies to combat this opioid crisis, as well as create an inner agency substance use disorder coordinating committee to review and coordinate research services and prevention activities across all rel-

evant Federal agencies. This will be a tremendous resource for patients, their families, and for our local communities.

Representative Mullin's amendment in the nature of a substitute to H.R. 3545, the Overdose Prevention and Patient Safety Act, which would allow for limited sharing of substance use disorder treatment records between health providers and place strong discrimination provisions in statute to protect people seeking or receiving substance use disorder treatment. I understand this issue is deeply sensitive, but it is important that we have a thoughtful discussion about ensuring that patients seeking these services receive parity and the same quality treatment that is provided to patients with other chronic disorders. Substance use disorder is a medical illness and we must treat it that way. Removing the stigma of addiction is one of the most important things we as Members of Congress can do to respond to this national emergency and will dramatically change how we prevent and treat this complex disease.

Representative McKinley's H.R. 5176, Preventing Overdoses While in Emergency Room, would provide resources for hospitals to develop discharge protocols for patients who have had an opioid overdose, such as the provision of naloxone upon discharge and referrals to treatment and other services that best fit the patients' needs.

I would also like to thank my colleague, Representative Griffith, for leading a discussion draft that would authorize Federal spport for a number of innovative activities in state-based prescription drug monitoring programs.

These are just a handful of the solutions that our Republican and Democrat colleagues have brought forth.

I would like to thank our four panels of witnesses that will be here today, hopefully, weather permitting. And I look forward to your feedback on these important issues.

And with that, I would yield the balance of my time, I believe, to Mr. Guthrie.

[The prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

Today marks the second of three legislative hearings advancing collaborative, bipartisan legislative solutions to help combat the opioid crisis.

The unprecedented plague of opioid addiction and substance use disorder in our country requires an unprecedented response. While this committee spearheaded the legislative efforts in CARA and Cures that has already devoted a record amount of federal resources to address this crisis, we can and must do more to meet this growing need.

This epidemic knows no geographic, political, or socio-economic bounds. I've held roundtables in my district in Oregon—places like Hermiston, Grants Pass, and Medford—when you talk to providers, patients, and their families, you can feel the sting of this crisis in the community.

President Trump rightly called it the "Crisis Next Door," and earlier this week, rolled out an ambitious plan. I was pleased to see that several of his proposals overlap with the work of this committee and I know that working across the aisle and with the administration we can arm agencies, health care providers, researchers, and patients with the tools they need. We stand ready to work with the President and his administration to put a stop to this crisis once and for all.

Over the span of 2 days, we will consider a range of bills from Members on both sides of the aisle—25 bills, in fact, covering the full spectrum of prevention and public health—and we will hear from 19 witnesses.

The bills we will consider today will strengthen the Food and Drug Administration's (FDA) ability to understand several aspects of the opioid crisis, including: the risks of long-term opioid use and how authorities can better intercept dangerous illicit products at international mail facilities.

We will hear about legislation that will facilitate the efficient development of treatments for substance use disorders, and legislation that will encourage alternatives to opioids for the treatment of pain. These are two areas of medicine that have suffered from a lack of innovation and development and I am optimistic that we can take tailored steps to encourage progress with the right solutions.

Rep. Latta's amendment in the nature of a substitute to H.R. 4284, Indexing Narcotics, Fentanyl, and Opioids (INFO) Act would create a public and easily accessible electronic dashboard linking to all of the nationwide efforts and strategies to combat the opioid crisis, as well as create an Interagency Substance Use Disorder Coordinating Committee to review and coordinate research, services, and prevention activities across all relevant federal agencies. This will be a tremendous resource for patients, their families, and our local communities.

Rep. Mullin's amendment in the nature of a substitute to H.R. 3545, the Overdose Prevention and Patient Safety Act, which would allow for limited sharing of substance use disorder treatment records between health providers and place strong discrimination prohibitions in statute to protect people seeking and receiving substance use disorder treatment. I understand this issue is a deeply sensitive one, but it is important that we have a thoughtful discussion about ensuring that patients seeking these services receive parity and the same quality treatment that is provided to patients with other chronic disorders. Substance use disorder is a medical illness and we must treat it that way. Removing the stigma of addiction is one of the most important things we as members of Congress can do to respond to this national emergency and will dramatically change how we prevent and treat this complex disease.

Rep. McKinley's H.R. 5176, Preventing Overdoses While in Emergency Rooms (POWER) Act, would provide resources for hospitals to develop discharge protocols for patients who have had an opioid overdose, such as the provision of naloxone upon discharge and referrals to treatment and other services that best fit the patient's needs.

I'd also like to thank my colleague Rep. Griffith for leading a discussion draft that would authorize federal support for a number of innovative activities in state-based prescription drug monitoring programs (PDMPs).

These are just a handful of the solutions that our colleagues, Republicans and Democrat, have brought forward.

I'd like to thank our four panels of witnesses for being here today andtomorrow, and I look forward to your feedback on these important issues.

Mr. GUTHRIE. Thank you, Mr. Chairman. Thanks, Dr. Burgess, for moving forward with this leadership.

I have introduced, with Ranking Member Green, the Comprehensive Opioid Recovery's Act, to approve treatment for those suffering from opioid addiction. The treatment system is fractured and complex, and patients with opioid use disorder are not afforded the same comprehensive coordinated care that patients with other chronic diseases receive. We must help all Americans who suffer from opioid addiction.

The bill creates a new treatment structure that provides coordinated evidence-based and patient-centered care. This bill will also generate meaningful data that can be used to inform standards and best practices moving forward.

Thank you again, and I yield back.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back.

The chair now recognizes the gentleman from Texas, Mr. Green, 5 minutes for an opening statement, please.

OPENING STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. GREEN. Thank you, Mr. Chairman, for holding the hearing today. I want to thank Dr. Gottlieb and our other witnesses from the Department of Health and Human Services and engaged stakeholders for joining us today on this snowy morning.

One hundred and fifteen Americans die from overdosing on opioids every day. The misuse of and addiction to opioids, including the prescription pain relievers, heroine, synthetic opioids like fentanyl, is a serious national crisis that affects public health as well as the social and economic welfare of communities throughout America.

The Centers for Disease Control and Prevention estimates that the total economic burden of prescription opioid misuse in the United States is $78.5 billion a year, including your cost of healthcare, loss of productivity, addiction treatment, and criminal justice involvement.

It is imperative that Congress and our public health agencies advance policies that will help our fellow Americans struggling with opioid addiction and prevent abuse and misuse from happening in the first place.

One of the bills I am working on concurrently is a discussion draft that would authorize the Food and Drug Administration to consider the potential for misuse and abuse when assessing the risk and benefits of a controlled substance for purposes of approval.

It is important that our committee craft legislation on the opioid crisis. And we give FDA clear authority to consider potential misuse and abuse of a product when risk outweigh the benefits.

I hope to hear from our panelists today on how we can best tailor our proposal that will clarify the FDA authority, while ensuring that it is targeting the controlled substances that are fueling the opioid crisis.

The second bill I am working on is with both Congressman Guthrie, Luján, and Bucshon, is the Comprehensive Opioid Recovery Centers Act, H.R. 5327. This bill creates a grant program administered to the Department of HHS to fund designated centers where individuals can obtain comprehensive patient-centered care for the treatment of their addiction and other substance use disorders.

Using the Comprehensive Opioid Recovery Centers Act, each grantee would be required to provide, either directly or through agreement with other entities, a set of range coordinated evidence-based treatment recovery services.

Grantees would also be required to monitor and report on the effectiveness of the programs, as well as provide outreach to their communities on services they are providing.

I have been a lifelong proponent of increasing access to healthcare in our communities. It is surprising to me to learn how confusing and limited the options are for patients with substance use disorder. I am hoping this legislation will help transform our treatment system and help patients move easily, navigate their options for care.

I look forward to asking questions of our panelists as to how to make sure the purpose of this bill is carried out in the most effective way.

While our committee is examining how best to combat opioid abuse, I need to remind my colleagues on the critical importance of ensuring Affordable Care Act coverage for the essential benefits as part of the solution to this crisis.

We cannot help Americans struggling with opioid abuse if they don't have health insurance coverage or have coverage that does not provide the full range of essential health services that are supposed to be guaranteed under the Affordable Care Act.

I would like to share some concerns before I conclude. Many members of our committee, including myself, are concerned about the number of bills we are considering during our 2-day hearing.

While we all agree on the magnitude of the opioid crisis and the importance of concrete congressional action, I am concerned that we will only be able to give brief attention to many bills before us today and tomorrow due to the number of bills we are considering, 25 in total.

While many of the bills are non-controversial and bipartisan, there are bills that need to be improved before they are ready for consideration before the House of Representatives, and I hope the chairman will commit to work with us on our concerns before bringing these bills up for markup.

And I yield back the balance of my time.

[The prepared statement of Mr. Green follows:]

PREPARED STATEMENT OF HON. GENE GREEN

Mr. Chairman, thank you for holding today's hearing on the opioid crisis and public health solutions.

I thank our witnesses with the Department of Health and Human Services and engaged stakeholders for joining us today on this snowy morning.

One-hundred fifteen (115) Americans die from overdosing on opioids every day. The misuse of, and addiction, to opioids—including prescription pain relievers, heroin, and synthetic opioids like fentanyl—is a serious national crisis that affects public health, as well as the social and economic welfare of communities throughout America.

The Centers for Disease Control and Prevention estimates that the total "economic burden" of prescription opioid misuse in the United States is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.

It is imperative that Congress and our federal public health agencies advance policies that will help our fellow Americans struggling with opioid addiction and prevent abuse and misuse from happening in the first place.

One of the bills I am working on, currently a discussion draft, would authorize the Food and Drug Administration (FDA) to consider the potential for misuse and abuse when assessing the risks and benefits of controlled substances for purposes of approval.

It is important that as our committee crafts legislation on the opioid crisis, we give FDA clear authority to consider potential misuse and abuse of a product when the risks outweigh the benefits.

I hope to hear from our panelists today how we can best tailor my proposal that will clarify FDA authority while ensuring that it is targeting the controlled substances that are fueling the opioid crisis.

The second bill I am working on, with Congressman Guthrie, Luján and Bucshon, is the Comprehensive Opioid Recovery Centers Act, H.R. 5327. This bill creates a grant program administered through the Department of Health and Human Services to fund designated centers where individuals can obtain comprehensive patient-centered care for the treatment of opioid addiction and other substance use disorders.

Under the Comprehensive Opioid Recovery Centers Act, each grantee would be required to provide, either directly or through agreement with other entities, a set range of coordinated evidence-based treatment and recovery services.

Grantees would also be required to monitor and report on the effectiveness of these programs as well as provide outreach to their communities on the services they are providing.

I've been a longtime proponent of increasing access to health care in our communities. It was surprising to me to learn how confusing and limited the options are for patients with substance use disorder. I'm hoping this piece of legislation will help transform our treatment system and help patients more easily navigate their options for care.

I look forward to asking questions of our panelists as to how to make sure the purpose of this bill is carried out in the most effective way.

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We cannot help American struggling with opioid abuse if they do not have health coverage, or have coverage that does not provide the full range of essential health services that are supposed to be guaranteed under the Affordable Care Act.

I would like to share some concerns before I conclude. Many Members of our committee, including myself, are concerned about the number of bills we are considering during our two-day hearing.

While we all agree on the magnitude of the opioid crisis and the importance of concrete congressional action, I am concerned that we will only be able to give brief attention to many of the bills before us today and tomorrow due to the number of bills we are considering, 25 in total.

While many of bills are non-controversial and bipartisan, there are bills that need to be improved before they are ready for consideration before the full House of Representatives. I hope the Chairman will commit to work with us on our concerns before bringing these bills to a markup.Thank you, Mr. Chairman. I yield the remainder of my time.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back.

The chair recognizes himself for 5 minutes for an opening statement, and acknowledge that we are convening our second of three hearings to consider legislation addressing the opioid epidemic.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

The efforts in the Comprehensive Addiction Recovery Act and 21st Century Cures have been impactful, but there is more that Congress must do to tackle the crisis.

As to Cures, I would like to point out a recent story which reported that some of the money approved by Congress remains untouched, mostly at the Substance Abuse and Mental Health Services Administration. If true, this should trouble all of us here, because in communities across America, individuals are suffering from addiction, overdose, lost loved ones. We cannot allow agency inertia to get in the way of delivering those dollars where they are, in fact, needed. This epidemic is in our hospitals, in our living rooms, and on our streets. Our partners at the Federal agencies must elevate to the challenge and deliver these vital resources for the States and communities that have been most impacted by this crisis.

As has previously been mentioned, this hearing is divided over 2 days this week. We will focus on prevention and public health aspects of the crisis. We are today going to hear the role of the Food and Drug Administration and other segments of the Department of Health and Human Services, including the Substance Abuse and Mental Health Services Administration and the Centers for Disease Control and Prevention, how they interact and how Congress can do a better job in enabling these agencies to do their work.

Today's hearing is a result of the Member Day that the Health Subcommittee held last October where over 50 Members of Congress, yes, this subcommittee, yes, the full committee, but any Member of Congress was invited in to tell their story. And we did hear their personal stories about how the epidemic has affected their communities. I do want to commend these members and their staffs and our committee staff for developing many of the policies under consideration today, 25. I acknowledge that that is a large number, but the crisis demands that we provide the attention necessary. These bills today range from amending laws relating to the confidentiality of substance use disorder and patient data, to establishing comprehensive opiate recovery centers, to streamlining and enhancing the tools for the Food and Drug Administration to intercept illegal products in international mail facilities. I would like to be able to describe each bill in detail, but that task would take up more time than I have allotted myself.

But I just want to point out that this challenge in front of us does require a multifaceted approach. For example, Representative Latta's bill, the INFO Act, embodies an all-encompassing approach by directing the Department of Health and Human Services to create a public and easily accessible electronic dashboard linking to all nationwide efforts and strategies to combat the crisis.

An all-hands-on-deck approach also means that we should help interested stakeholders, such as biopharmaceutical manufacturers, make the necessary investments in novel treatments for the market. A bill that I am sponsoring will require the Food and Drug Administration to provide more clarity through guidance on how these stakeholders can utilize the accelerated approval and breakthrough therapy programs to expedite the availability of innovative therapies for pain and addiction.

I am sure that many Members of Congress, especially those who sit on this subcommittee, have heard from doctors, they have heard from pharmacists in their districts about the inefficiencies of the State-run prescription drug monitoring programs. Representative Griffith's bill would realign prescription drug monitoring programs under the Centers for Disease Control to coordinate efforts to improve data collection into physician workflow. Passage of this bill would allow doctors to make better informed decisions leading to more effective treatment for patients.

When narcotics, when opiates go unused, they frequently sit in someone's medicine cabinet and instead of being properly discarded and their disposal secured. Representative Hudson's bill addresses this problem from the packaging and disposal angle. His bill would direct the Food and Drug Administration to work with manufacturers to establish programs for an efficient return or destruction of unused schedule II drugs, with an emphasis on opiates.

Many of us have seen the Centers for Disease Control's most recent report on emergency departments' admissions. There were 30 percent increase from July 2016 through September 2017. Two bills up for consideration would reverse that trend.

I again want to welcome our witnesses. And I will yield the balance of my time to Mrs. Blackburn from Tennessee.

[The prepared statement of Mr. Burgess follows:]

PREPARED STATEMENT OF HON. MICHAEL C. BURGESS

This morning, we convene for our second of three hearings to consider legislation addressing the opioid epidemic. While our efforts in the Comprehensive Addiction and Recovery Act and 21st Century Cures have been impactful, there is much more that Congress can do to tackle this crisis. As to Cures, I would like to point out a recent story which reported that most of the money approved by Congress remains untouched, mostly at the Substance Abuse and Mental Health Services Administration. If true, this should trouble all of us here because in communities across America, individuals and families are suffering from addiction, overdose, and loss of loved ones.

This epidemic is in our hospitals, in our living rooms, and on our streets. Our partners at federal agencies must rise up to the challenge and deliver these vital resources for the states and communities most hurt by this crisis.

This hearing, which will be split between today and tomorrow, focuses on the prevention and public health aspects of the crisis, particularly addressing the role that the Food and Drug Administration, and other segments of the Department of Health and Human Services, including the Substance Abuse and Mental Health Services Administration, can play, and how Congress can enable these agencies to better do its job.

Today's hearing is the result of the Member Day the Health Subcommittee held last October, where over 50 bipartisan Members of Congress—both on and off the Energy and Commerce Committee—shared their personal stories on how the opioid epidemic has devastated their communities. I commend these members, their staffs, and our committee staffs for developing many of the policies under consideration today. Twenty-five. This is the total number of bills being reviewed. They range from amending laws relating to confidentiality of substance use disorder patient data, to establishing comprehensive opioid recovery centers, to streamlining and enhancing the tools for FDA to intercept illegal products in international mail facilities. While I wish I could describe each bill in detail, that task itself may take the full two days we have slotted for this hearing.

The opioid epidemic requires a multi-pronged, comprehensive approach involving almost all facets of our society. For example, Rep. Latta's bill, the INFO Act, embodies an all-encompassing approach by directing the Department of Health and Human Services to create a public and easily accessible electronic dashboard linking to all nationwide efforts and strategies to combat the crisis.

An all-hands-on approach also means we should help interested stakeholders, such as biopharmaceutical manufacturers, make the necessary investments in novel treatments for the market. A bill I am sponsoring will require the Food and Drug Administration to provide more clarity through a guidance on how these stakeholders can utilize the accelerated approval and breakthrough therapy programs to expedite the availability of innovative therapies for pain and addiction.

I am sure that many members of Congress, especially those who sit on this Subcommittee, have heard from physicians and pharmacists in their district about the inefficiencies of state-run prescription drug monitoring programs, or PDMPs. Rep. Griffith's bill would realign PDMPs under the Centers for Disease Control and Prevention to coordinate efforts that will improve data collection and integration into physician workflow. Passage of this bill would allow physicians to make better informed decisions, leading to more effective treatment for their patients.

When opioids go unused, they frequently sit in people's medicine cabinets instead of being properly disposed, increasing the likelihood of diversion. Rep. Hudson's bill fights this problem from the packaging and disposal angle. His bill would direct the Food and Drug Administration to work with manufacturers to establish programs for efficient return or destruction of unused Schedule II drugs, with an emphasis on opioids.

Many of us have seen the Center for Disease Control and Prevention's most recent report on emergency department admissions due to opioid overdoses where there was a thirty percent increase from July 2016 through September 2017. Two bills up for consideration today aim to reverse this trend. A bill introduced by Rep. Pascrell would establish a demonstration program to test alternative pain management protocols to limit the use of opioids in hospital emergency departments. Another bill, introduced by Rep. McKinley, would assist hospitals in developing protocols on discharging patients after they overdose.

Clearly, we have our work cut out for us over the next 2 days as we examine the policies within these bills. But, it will be a worthwhile exercise that will produce a well-thought-out and well-vetted package of legislation to aid our public health workforce in overcoming this public health crisis.

I again want to welcome our witnesses and thank you for being here. I look forward to your testimony.

Mrs. BLACKBURN. Thank you, Mr. Chairman.

And another report that I saw yesterday was the AEI report that goes through the cost per capita of the opioid epidemic. It is $2,000 per person in Tennessee, is what it is costing us. But I think the emotional cost is something that we will want to visit with you all today about too.

Yesterday, I talked with a friend who was recounting how, 12 years ago, I sat with her, cried with her, talked with her as she discovered a high school child had an opioid addiction and how things have changed and the attention that is paid to the issue now. And it is a heart-wrenching issue. And we thank you all for being here and working with us on the issue.

And I yield back.

Mr. BURGESS. The gentlelady yields back.

And the chair will yield back.

The chair now recognizes the ranking member of the full committee, Mr. Pallone, 5 minutes for an opening statement, please.

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

Mr. PALLONE. Thank you, Mr. Chairman.

Today, we continue a series of hearings to address the complex opioid abuse crisis that is devastating lives across the country. While we have worked together to pass CARA and the 21st Century Cures Act, more must be done. And that is why I am pleased that Congress agreed in the budget agreement to provide a total of $6 billion in additional funding for efforts to respond to the epidemic for fiscal years 2018 and 2019. Without this funding commitment, many of the laws we have passed and the bills being discussed during this hearing are nothing more than empty words.

Over the next 2 days, we have a lot of bills to consider, and I hope we can have a thorough conversation about all of them. However, I am concerned that it will be difficult to properly address all of the bills since there are so many. In going forward, it would be nice if the Republican majority scheduled multiple hearings so that we have the time to fully evaluate the proposed solutions.

The bills we will consider during the next 2 days are diverse and span multiple disciplines, and that is essential because there is no single solution to the opioid crisis. No single individual, group, field of study, or agency can solve this problem alone. Everyone must do their part.

And one of the major ways we can impact the prevalence of opioids available for abuse is to limit the importation of synthetic opioids that have infiltrated our international mailing facilities, and that is why I have introduced a bill, the SCREEN Act, to expand FDA's authority to crack down on the counterfeit drugs entering the country. Currently, FDA has limited authority to act on parcels with mislabeled, unlabeled, or counterfeit drug products. This bill will provide greater oversight of packages in international mail facilities allowing the FDA to refuse importation or destroy illegal drugs being shipped into the country and recall and prevent

distribution of products that pose a danger to public health. Importantly, it will also authorize resources for FDA to expand capacity to meet this challenge.

It is unfortunate that the chairman chose not to notice this bill for today's hearing since I have been working on this issue for years, and I hope that we can still consider this bill as we move forward.

We are also reviewing other important bills, such as H.R. 3692, the Addiction Treatment Access Improvement Act of 2017, which will increase the number of providers that can treat patients through the DATA 2000 waiver. Also, H.R. 5140, the Tribal Addiction and Recovery Act, which would provide funding to Tribes and Tribal organizations for substance use disorder prevention and treatment efforts in Indian Country. And a discussion draft that would enhance and improve State-run prescription drug monitoring programs, known as NASPER.

I am not able to speak on every bill in such a short amount of time, but I do want to highlight the concerns I have with one of the bills under discussion today, and that is H.R. 3545, the Overdose Prevention and Patient Safety Act, which I think could dangerously erect a barrier to patients seeking and remaining in treatment and, therefore, harm our efforts to respond to this crisis. It would be nice if we could eliminate discrimination for good in this country by simply passing a law that makes discrimination illegal. But, unfortunately, that is simply not the case. And, therefore, I do not think the additions to the underlying text of the bill cures the issue of the risk of stigma, discrimination, and negative health and life outcomes that could result from a rollback of regulations that protect a patient's privacy.

So I look forward to discussing each of these bills during this and future hearings continuing to work towards finding solutions to this very severe opioid crisis.

And I yield the remainder of my time to the gentlewoman from California, Ms. Matsui.

[The prepared statement of Mr. Pallone follows:]

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I look forward to discussing each of the bills during this and future hearings and continuing to work towards finding solutions to the opioid crisis.

I yield back.

Ms. MATSUI. Thank you very much, Mr. Pallone. And thank you, Mr. Chairman, for holding this hearing. And thank you to the witnesses for being here today.

I am pleased that we are taking on the issue of the opioid epidemic in our committee. We are examining a lot of bills today, and I think we are ahead of some of the other committees in the House and Senate in doing so. I am glad we are moving forward, but do want to make sure that we do it in a way that avoids unintended consequences.

It is important that we take a comprehensive look at all aspects of this problem, from opioid manufacturing and distribution, to prescribing, to research and alternatives for pain management, to access of substance use treatment and services.

As we examine all the different factors that contributed to where we are today, I hope we approach solutions with a shared sense of responsibility. I know that the policy pendulum often swings to extremes. So I think we need to be careful to avoid creating new problems as we try to solve the problems facing us today.

Lastly, as we examine an array of targeted solutions with FDA, CDC, and SAMHSA today, I hope we take a holistic look at this epidemic and assure we are making a coordinated effort to provide solutions for families and prevent future strategies.

With that, thank you, and I yield back.

Mr. BURGESS. The chair thanks the gentlelady. The gentlelady yields back.

And that concludes member opening statements. The chair would like to remind members that, pursuant to committee rules, all members' opening statements will be made part of the record.

And we do want to thank our witnesses for being here today and taking the time to testify before the subcommittee. Each witness will have an opportunity to give a summary of their opening statement. That will be followed by questions from members.

Our first panel today, we will hear from Dr. Scott Gottlieb, the Commissioner of the Food and Drug Administration; Dr. Anne Schuchat, Acting Director, Center for Disease Control and Prevention; and Dr. Christopher M. Jones, Director of the National Mental Health, Substance Use Policy Laboratory, Substance Abuse and Mental Health Services Administration, and a Pharmacist, as I understand, and from Georgia.

So we welcome all of you to our witness table today.

Dr. Gottlieb, you are recognized for 5 minutes, please.

STATEMENT OF SCOTT GOTTLIEB, M.D., COMMISSIONER, FOOD AND DRUG ADMINISTRATION; ANNE SCHUCHAT, M.D., ACTING DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION; AND CHRISTOPHER M. JONES, PHARMD, MPH, DIRECTOR OF THE NATIONAL MENTAL HEALTH AND SUBSTANCE USE POLICY LABORATORY, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

STATEMENT OF SCOTT GOTTLIEB, M.D.

Dr. GOTTLIEB. Good morning, Chairman Burgess, Ranking Member Green, and members of the subcommittee. Thank you for the opportunity to discuss FDA's role in combating the ongoing crisis of opioid addiction.

Confronting this epidemic remains one of my highest priorities. I am committed to reexamining all of our authorities and further steps FDA can take, and I am grateful for this committee's commitment to the role FDA has in combating the epidemic and for your interest and additional tools that could enhance FDA's ability to respond, such as those that would support our work in the interdiction of illegal drugs, including narcotics, inside the international mail facilities.

To address this crisis, FDA is working across three broad domains. First, we are taking steps to improve our medical technology. This means better drugs to treat addiction through medication-assisted treatment and new pain remedies that are resistant to manipulation and misuse or aren't as addictive as traditional opioids.

Second, we are pursuing measures to reduce the rate of new addiction. This means trying to reduce overall prescribing and the number of pills that get dispensed with each prescription. So among other things, we are taking new steps to require sponsors to provide education to providers and other healthcare practitioners. We are also exploring ways to change how opioids are packaged to allow better management of their prescribing.

One of the things we are considering is steps to require sponsors to ensure prescribers provide specific documentation for prescription above a specified amount. Such a framework would be based on evidence-based guidelines that define the proper length of treatment for a given indication.

Third, we are ramping up our efforts aimed at the interdiction of illegal drugs, including narcotics. This includes new authorities and resources aimed at our work in the international mail facilities. There is a virtual flood of dangerous products entering the United States through mail packages that expose Americans to

dangerous pills. We are dealing with sophisticated bad actors that are aware of the gaps and weaknesses in our tools and try to exploit them.

Primary responsibility for imported narcotics falls to Customs and Border Protection. Anything believed to contain controlled substances goes to CBP before packages are sent to us at FDA. But we are still seeing more and more controlled substances hitting our investigators. In fact, in one recent 6-month period where FDA inspected 5,800 packages, 376 contained controlled substances, including opioids.

I am increasingly worried that those sneaking opioids through the mail will disguise them as ordinary drugs to evade detection. It is estimated that less than one-tenth of 1 percent of the packages that contain drugs actually undergo the physical inspection. The risk is that many illicit drugs are slipping through our grasp.

As you know, we have prioritized our work in the IMFs and invested to strengthen our presence and capabilities there, but there is more that we must do. We have increased our staffing and are seeking support to grow our footprint for interdiction work still further.

Additional staffing is critical. But to maximize what we can do, I want to focus on some additional authorities that we have discussed with Congress. These include certain detention and destruction authorities.

First, our operations at the IMFs routinely see packages of unlabeled or partially labeled pills coming through the facilities, some in boxes and blister packs, and many simply in thousands of loose pills and huge boxes. We are required to open every package, document the contents, and find supporting evidence of the article's intended use as a drug in order to detain, refuse, or destroy that article. Where the evidence is insufficient, under our existing standard for destruction, we often simply refuse entry and send the package back to its source. It is not uncommon for our investigators to see the same package again and again as shippers resend the same box a second and even third time.

This process is not a deterrent. If FDA had the authority to detain, refuse, and destroy unlabeled imported products that are found to contain active ingredients or analogues that are FDA-approved drugs, we could more quickly remove potentially dangerous products from the supply chain.

Second, this is also a numbers game. The bad actors can send in hundreds or thousands of small parcels via international mail to individual recipients in the U.S. These shipments are wholesale quantities of illegal, often counterfeit drugs, that are intended for further domestic distribution, and each package may violate FDA law. But they know that FDA can't examine or stop them all, because current law requires us to detain and pursue legal proceedings against each package separately. They simply overwhelm our system with volume. Improving FDA's authority so we can more efficiently detain or refuse bulk shipments of individual packages from a single source would create a big difference and better protect Americans from dangerous imported substances.

And, third, while substances already scheduled are generally referred to CBP at the border, when FDA-regulated articles contain

substances that haven't yet been scheduled, FDA is responsible for that product. This is an issue with the high volume of synthetic narcotics coming primarily from China. Right now, we can't refuse or destroy these unlabeled products or those without a drug claim, such as fentanyl analogues, simply because they are articles of concern to DEA.

Extending FDA's ability to refuse, detain, or destroy products in this gap right before DEA's scheduling takes place would keep dangerous articles that currently are not easily detained off the streets. These are just some of the tools that could enhance our mission.

I appreciate your support and your interest in our work in this effort, and I look forward to working close with you to help safe lives.

[The prepared statement of Dr. Gottlieb follows:]

STATEMENT

OF

SCOTT GOTTLIEB, M.D.

COMMISSIONER OF FOOD AND DRUGS

FOOD AND DRUG ADMINISTRATION

BEFORE THE

COMMITTEE ON ENERGY AND COMMERCE

SUBCOMMITTEE ON HEALTH

UNITED STATES HOUSE OF REPRESENTATIVES

"COMBATTING THE OPIOID CRISIS:

PREVENTION AND PUBLIC HEALTH SOLUTIONS "

MARCH 21, 2018

RELEASE ONLY UPON DELIVERY

Good morning Chairman Burgess, Ranking Member Green, and members of the subcommittee. Thank you for the opportunity to be here today to discuss the Food and Drug Administration's (FDA or the Agency) role in combating our nation's ongoing crisis of opioid addiction. This is one of the most profound public health challenges facing our country. We need to work together, and consider more active and creative steps, if we're going to make significant inroads against this tragic epidemic.

The issue of opioid misuse and abuse remains one of my highest priorities. We believe it will take carefully developed, sustained, and coordinated action by everyone involved to adequately address the addiction and death afflicting our communities. At the same time that we take steps to reduce the rate of new addiction and address the medical needs of those currently addicted, we also need to make sure that our regulatory steps maintain appropriate prescribing for patients in medical need. We recognize both the urgency and complexity of this crisis. We are committed to reexamining all of our authorities as FDA considers what further steps the Agency can take.

Steps to Address Abuse and Misuse of Prescription Opioid Analgesics

The scope of the epidemic is much larger than FDA's purview, but we know FDA has a critical role to play. We have asked ourselves how our authorities can be used most effectively to address this unprecedented problem. This is especially true when it comes to helping make sure that fewer people become addicted through the medical use of these drugs. It's true that the epidemic is shifting to street drugs. A growing number of people will have their first exposure to opioids through heroin, illicit fentanyl, or other illegal drugs. But a large percentage of people who will become addicted to opioids will still have their first exposure through a lawful medical prescription. Often that first prescription will be for an immediate release formulation of these drugs. At FDA, we can impact both routes to new addiction. On the one hand, our regulatory oversight of lawfully prescribed drugs gives us some important opportunities to impact prescribing in ways that can reduce the rate of new addiction while making sure patients with medical needs have access to appropriate therapy. FDA also plays an important role in the interdiction of unlawful drugs, in particular, illegal drugs that are shipped through International

Mail Facilities. We want to make sure that across the full scope of our portfolio, we are doing everything we can to vigorously address this public health crisis.

Some percentage of patients who are prescribed opioids will develop an addiction to these drugs. Addiction is characterized by a pronounced craving for the drug, obsessive thinking about the drug, erosion of inhibitory control over efforts to refrain from drug use, and compulsive drug taking. This is very different than physical dependence on opioids. The repeated administration of any opioid almost inevitably results in the development of tolerance and physical dependence. These short-term results of physical dependence from repeated opioid administration require dose tapering. We have taken steps to address both the risk of addiction and physical dependence. We recently announced our intention to expand our risk management plans, known as Risk Evaluation and Mitigation Strategies or REMS, to incorporate, for the first time, all opioid analgesics that are intended for use in the outpatient setting, including the immediate-release formulations. We have revised the associated Blueprint[1] for how providers should be educated about pain management in general, and prescribing opioid analgesics specifically. And we are requiring that this training be extended to all providers likely to come into contact with patients who are prescribed these medicines, including nurses and pharmacists.

FDA also is taking immediate action when needed, as we did with FDA's first-of-its-kind request to remove a marketed opioid pain drug from sale due to the public health consequences associated with the product's abuse. We are also looking closely at certain opioids that may have a higher abuse potential. This includes oxymorphone, an active ingredient in certain opioid drugs. If we were to determine, through a scientific process, that a particular opioid drug was more prone to abuse, and addiction, we would consider taking additional regulatory steps.

We believe one key to reducing the rate of new addiction is to rationalize prescribing, to help make sure that patients are prescribed opioids only when medically indicated. When a prescription is written, it should be for a dose and duration of use that comports closely with the clinical purpose. We are considering several potential strategies to promote proper opioid

[1] *https://www.regulations.gov/contentStreamer?documentId=FDA-2017-D-2497-0683&attachmentNumber=1&contentType=pdf.*

prescribing and dispensing that involve new measures with respect to how opioid products are packaged and labeled, and how providers are educated about their proper prescribing.

In December, FDA hosted a public workshop on the role of packaging, storage, and disposal options within the larger landscape of activities aimed at addressing abuse, misuse, or inappropriate access of prescription opioids. We discussed, among other topics, how new types of packaging, such as unit dose blister packs, could encourage prescribers to opt for shorter durations of use, thereby limiting the number of opioids dispensed to patients. This could reduce overall exposure, and potentially the rate of new addiction. This could also address the problem of excess supply in the U.S., as there would be fewer pills left in medicine cabinets that could be inappropriately accessed by family members, including children. Moreover, provided FDA concluded there was sufficient scientific support for shorter durations of use, this could provide the basis for further regulatory action to drive more appropriate prescribing.

Such measures would have a goal of reducing the number of doses dispensed, and reducing the risk of leftover pills that can be inappropriately diverted. Using our Sentinel database and contracts with external researchers, FDA has assessed opioid analgesic dispensing and refill patterns by medical indication and provider specialty. This analysis is still ongoing, but preliminary results give FDA some important insight into the amount of opioid analgesic that patients appear to need to control acute pain, by medical indication. FDA also reviewed published literature to get additional insights into the number of pills dispensed, used, and left over by patients who are prescribed opioid analgesics for different medical indications. These analyses are important applications of the resources dedicated to our post market safety efforts, including use of the Sentinel database to answer questions to inform regulatory policy. We will aim to make our findings available in future publications, but the operative point is that FDA can pursue analyses to guide policy making. Resources dedicated to more routine analyses of this kind could allow us to more carefully tailor our policy efforts to avoid – although not eliminate – the risk that we create some unintended obstacles for patients who have an appropriate medical purpose for a longer duration of opioid analgesic use; and some unfortunate obstacles for the doctors and pharmacists who need to prescribe and dispense these medications. But we all must

come together and accept that there are no easy options and that properly addressing this crisis is going to require some shared commitments and sacrifice.

We are also considering the feasibility of incorporating new prescribing information in opioid analgesic labeling. If, for example, medical professional societies (the dental association, for example) were to create evidence-based guidelines on appropriate prescribing for different medical needs, and FDA reviewed the scientific support for these guidelines and determined that it was sufficient to support updates to product labeling, we could potentially use our current authority to adjust product labeling. If this type of information were incorporated into product labeling, it could be used as part of a framework for helping to ensure more appropriate prescribing and dispensing. In addition to labeling changes, if FDA determined that packaging opioid analgesics in blister packs in certain quantities was necessary to ensure safe use, FDA could also potentially require manufacturers to implement these packaging changes. We also recently requested that manufacturers of over-the-counter loperamide – an FDA-approved product to help control short-term symptoms of diarrhea – make packaging changes, such as the use of blister packs, in order to address issues related to the abuse and misuse of that product.

FDA is considering other new steps to better confront this crisis. Among other actions under consideration: Earlier this year, FDA held a public hearing to explore ideas for using our REMS authority to impact opioid prescribing practices. One idea under consideration by our Opioid Policy Steering Committee is requiring sponsors to ensure that prescribers provide specific documentation for a prescription above a specified quantity, such as a statement that the quantity prescribed is medically necessary for the patient. The Steering Committee is exploring evidence-based approaches that would encourage electronic prescribing as a mechanism for the prescriber to provide documentation of medical necessity before the drug is dispensed by the pharmacy, as well as how to leverage the current system of prescription drug monitoring plans (PDMPs) to improve safe opioid prescribing.

Steps to Address Illegal Narcotics and Interdiction

On the issue of illegal narcotics, such as illicit fentanyl, that are coming into the U.S. via international mail, FDA has taken action to enhance our operations at international mail facilities (IMFs). FDA plays an important role related to the interdiction work that takes place in the IMFs. When an illegal controlled substance is identified in the IMFs, our partners at Customs and Border Protection (CBP) will immediately seize it, such that products readily and initially identified as controlled substances will not come to the FDA investigators in these facilities. Instead, what FDA is tasked with opening, inspecting, and sometimes testing include products that are perceived to be illegally-imported FDA-regulated drug produets; for example, if they are believed to be counterfeit drugs or unapproved drug products like kratom. But as part of our work to examine what initially are believed to be non-opioid drug products, we still identify a large amount of controlled substances, in some cases because they might be disguised as other kinds of drug products. To give you some statistics on the scope of the risk: From the end of September 2017 through January 2018, of about 5,800 suspicious packages that FDA was tasked with inspecting because they were suspected of containing illegal prescription or counterfeit drugs or dietary supplements, 376 were controlled substances, including opioids, and were referred back to CBP for seizure. In some measure, the FDA investigators are a last line of defense in the IMFs, working closely with CBP. As the sophistication of those trying to penetrate our mail facilities continues to increase, this represents a growing vulnerability.

To address these risks, last year, we tripled the number of import investigators we have in the IMFs, allowing us to nearly quadruple the number of suspicious packages that we're able to open and inspect. This has taken our footprint from 8 to 22 full time employees (FTEs), the maximum capacity that our space in these facilities allows. We took these steps by allocating additional resources to this mission that we were able to redeploy from other parts of our critical enforcement mission as part of our Office of Regulatory Affairs (ORA). As part of this effort, we also doubled the number of our Port of Entry Special Agents, our criminal investigators who cover ports and the IMFs, from 6 to 12.

Our aim is to stop, inspect, and test more packages that contain suspicious drugs.

As part of these efforts, we also increased our CyberCrime Investigative Unit. This unit now consists of 11 criminal investigators. This special team has specialized training in disrupting and dismantling the large online networks that manufacture and sell foreign unapproved and counterfeit drugs, including opioids, to the U.S.

Last spring, FDA's Office of Criminal Investigations announced a major takedown of a drug trafficking organization for involvement in manufacturing fake prescription drugs with fentanyl. FDA's CyberCrime unit assisted with this investigation and plays an integral role in a large percentage of all of FDA's criminal investigations. They are a critical and unique asset that we have already, and will continue to, invest in.

As the committee continues its efforts to address the opioids crisis, FDA looks forward to providing whatever support we can. Thank you again for the opportunity to testify today.

Mr. BURGESS. The chair thanks the gentleman.

The chair recognizes Dr. Schuchat, 5 minutes, for an opening statement please.

STATEMENT OF ANNE SCHUCHAT, M.D.

Dr. SCHUCHAT. Good morning, Chairman Burgess, Ranking Member Green, and members of the Committee. CDC has vast experience tackling epidemics, and I appreciate the chance to talk today about our work fighting the Nation's opioid crisis.

At CDC, we are focused on using data for actions to inform strategies to prevent opioid misuse, abuse, and overdose, and to prevent health-related consequences of opioid use, including the spread of infectious diseases, like HIV and hepatitis, and the impact of opioids on mothers and babies. CDC leads comprehensive prevention efforts by promoting responsible opioid prescribing, tracking trends, and driving community-based prevention activities to reduce opioid overdose deaths and related harms.

America's opioid overdose epidemic affects people from every community. The problem is getting worse. In 2016, more than 63,000 people died of drug overdose, and preliminary data indicate that the trend worsened in 2017. We have seen increases in babies born withdrawing from narcotics. New data suggests one baby is born with signs of neonatal abstinence syndrome every 15 minutes, about 100 babies a day. We have also seen a drop in life expectancy for the first time since 1993. For every one person who dies of an opioid overdose, over 60 more are already addicted to prescription opioids, and almost 400 misuse them.

CDC supports State health departments providing resources and guidance to implement evidence-based prevention interventions so States can rapidly adjust as we learn more about what works best in this very fast-moving epidemic. A nimble Federal and State response is crucial.

CDC now funds 45 States and Washington, D.C., to advance prevention, including by improving prescription drug monitoring programs, or PDMPs, improving prescribing practices, gathering timely high-quality data, and evaluating policies. We hope to expand this funding to 50 States.

States are making progress in working toward more comprehensive and effective monitoring through their PDMPs, which is essential to improve clinical decision-making and use data as a public health surveillance tool. With CDC funds, many are increasing use by providers and pharmacists, enhancing the timeliness of reporting, and integrating with electronic health records.

For example, in North Carolina, they have integrated prescribing data from the PDMP within the clinical workflow of existing health information systems across the State. Improvements like that show how we can make vital data actionable with the goal of saving lives.

CDC is also leading improvements to the public health data needed to understand and respond to the crisis. We improved the timeliness of reporting, updating preliminary data on overdose deaths, on our website every month. Through our funding to States, we are ramping up our efforts to get more comprehensive and timely data from emergency rooms, emergency medical serv-

ices, medical examiners, and coroners. We are tracking nonfatal overdoses. And as you have heard, we recently reported on the 30 percent increase across the country.

We also recently released data using toxicological and death scene evidence from 10 funded States, allowing for a more robust characterization of opioid overdose deaths. That analysis found that fentanyl was involved in more than half of the recent opioid overdose deaths.

CDC continues to educate providers and the public on opioid use through the implementation of our Guideline for Prescribing Opioids for Chronic Pain and the Rx Awareness communication campaign. We are making the guideline more accessible to clinicians through interactive training and a mobile app. The campaign focuses on the risks of prescription opioids, and it features real life accounts of individuals living in recovery and those who have lost someone to this terrible problem.

In addition to our partnership with States, CDC believes this epidemic requires a collaboration across sectors. We have been working side by side with law enforcement, like the DEA, to determine risk factors for illicit opioid overdose and target implementation plans for community specific prevention strategies. We draw on experts from across our agency to address the many facets of the crisis. The comprehensive public health approach is playing a key part in addressing the epidemic. We didn't get into this epidemic overnight, and we are not going to get out of it overnight. We need intensified sustained efforts to reverse the epidemic.

Thank you.

[The prepared statement of Dr. Schuchat follows:]

Energy and Commerce Subcommittee on Health Hearing

March 21, 2018

Testimony of Dr. Anne Schuchat

Acting Director

Centers for Disease Control and Prevention

Good morning Chairman Burgess, Ranking Member Green, and Members of the Subcommittee. Thank you for the opportunity to share information about the efforts underway at the Centers for Disease Control and Prevention (CDC) to reverse the trajectory of our nation's opioid overdose epidemic. This epidemic is complex and requires a multi-sector, multi-pronged response. I am pleased to be here today to discuss the federal government's activities to curtail deaths stemming from opioid misuse, abuse, and overdose. In particular, I will focus on CDC's unique role in prevention, current programs, successes, and future endeavors.

Given the enormity of this national crisis, collaboration across agencies is essential. Each sector of government has a role to play—whether implementing prevention activities, providing treatment to individuals with opioid use disorder, identifying and disrupting the flow of illicit opioids into and across the country, or advancing research to increase our knowledge on strategies that hold promise. As the nation's public health and prevention agency, CDC is applying scientific expertise to understand the epidemic and use that information to create interventions to prevent further harms, including the spread of infectious disease and the impact of opioids on mothers and babies. CDC continues to be committed to the comprehensive priorities outlined in the HHS strategy and to saving the lives of those touched by this epidemic. CDC's work falls into five key strategies to address opioid overdose and other opioid-related harms: 1) conducting surveillance and research; 2) building state,

local, and tribal capacity; 3) supporting providers, health systems, and payers; 4) partnering with public safety; and 5) empowering consumers to make safe choices.

CDC tracks and analyzes data to improve our understanding of this epidemic. Since 1999, more than 632,000 Americans have died from drug overdoses. In 2016, the death toll continued to rise. Over 63,600 deaths resulted from drug overdoses.[1] More than 42,000 of those deaths involved opioids.[2] According to the most recent provisional data, there were 67,344 drug overdose deaths in the 12-month period ending August 2017. This is an increase of nearly 8,000 deaths attributed to drug overdose compared to the 12-month period ending August 2016. CDC's data indicate that these increases were primarily driven by synthetic opioids, including illicitly manufactured fentanyl (IMF). Given the evolving nature of this epidemic, it is essential that we continue to track and analyze data to target prevention efforts.

Data are crucial in driving public health action. Timely, high-quality data can help public health, public safety, and mental health experts better understand the problem, focus resources where they are needed most, and evaluate the success of prevention and response efforts. During the past few years, CDC has invested in strengthening the capacity of states to monitor the opioid overdose epidemic and target their prevention activities.

CDC currently provides funding and scientific support to 45 states and Washington, D.C. to equip states with the tools and technical expertise they need to implement a comprehensive prevention program within their communities. States utilize their funding to enhance Prescription Drug Monitoring

[1] https://www.cdc.gov/mmwr/volumes/67/wr/mm6709e1.htm
[2] https://www.cdc.gov/mmwr/volumes/67/wr/mm6709e1.htm

Programs (PDMPs) and leverage them as public health tools, improve health system and insurer practices for safer opioid prescribing, support community-level response and prevention activities, and evaluate policies that may impact the opioid epidemic (e.g., naloxone distribution and Good Samaritan laws). In addition, CDC funds 32 states and Washington, D.C. to improve the timeliness and comprehensiveness of fatal and non-fatal opioid-involved overdose reporting and to disseminate data to stakeholders.

PDMPs are state-run databases that collect patient-specific prescription information at the point of dispensing. While PDMPs vary from state to state in terms of their operation, components of PDMPs that optimize their utility include universal registration and use, real-time reporting, active management (ensuring there is proactive reporting of PDMP data), and interoperability with electronic health records (EHRs) and PDMPs in other states, particularly neighboring ones. PDMPs are among the most promising state-level interventions to improve opioid prescribing, inform clinical practice, and protect patients at heightened risk of opioid misuse, abuse, and overdose and can help providers identify patients who may be misusing prescription opioids or other prescription drugs. In addition, states can use PDMP data to determine "hot spots" or areas where there is a spike in opioid prescribing to target interventions, such as education for prescribers on best practices ("academic detailing").

Using CDC funds, states are enhancing the utility of their PDMPs in various ways. For example, North Carolina has integrated prescribing data from its PDMP within the clinical workflow of existing health information systems across the state. In Washington, prescription review data from PDMPs are proactively sent to EHRs at emergency departments (EDs) and urgent care sites to inform clinical

decision making within those care venues. To enhance usage of PDMPs among providers, some states have taken steps to make access easier by integrating them into EHR systems, permitting physicians to delegate PDMP access to other health professionals in their office (e.g., physicians assistants and nurse practitioners), and streamlining processes for providers to register for PDMP access. Rhode Island has seen great success in streamlining provider registration by investing in PDMP outreach, education, and enforcement. The Rhode Island Department of Health conducted more than 40 continuing medical education (CME) and educational programs regarding responsible prescribing, PDMP registration, and PDMP use. As a result, PDMP registration in Rhode Island increased from 73 percent in January 2016 to 100 percent in September 2016

After the release of the CDC Guideline for Prescribing Opioids for Chronic Pain in March 2016, CDC began efforts to facilitate its integration in practice by updating clinical decision supports including alerts on morphine milligram equivalent thresholds within EHRs, setting lower defaults on prescribing amounts for the initiation of opioids for chronic pain management, and adding prompts for providers to check the PDMP for informed prescribing on behalf of their patients. Using CDC funds, New Jersey enhanced its PDMP so that it now automatically converts dosages of commonly prescribed opioids of differing potency—such as codeine and oxycodone—into morphine milligram equivalents allowing prescribers to compare the total potency of all opioid medications being used and thus identify individuals who may need closer monitoring, tapering, or other measures to reduce risks.

CDC supports states to improve data collection and the timeliness of reporting fatal and nonfatal opioid overdoses and associated risk factors in order to better inform the public health response within and across states. The program uses ED and emergency medical services (EMS) data, provided to CDC

regularly to track and analyze national patterns of morbidity data. At the state level, the system can detect sharp increases (i.e., potential outbreaks) or decreases (i.e., successful intervention efforts) in nonfatal overdoses which helps states target response and prevention resources to communities most in need or when potential outbreaks are detected.

To improve collection of data for fatal overdoses, funded states leverage CDC's National Violent Death Reporting System (NVDRS) platform to collect data on all unintentional or undetermined overdose deaths. The data includes valuable contextual information from death scene investigations, detailed information on toxicology, the route of administration, and other risk factors associated with a fatal overdose that help states target their interventions to decrease deaths.

CDC's support for enhanced data collection in states has provided a better understanding of the challenges states face in working toward more timely and comprehensive opioid overdose data. CDC identified capacity constraints within medical examiner and coroner offices as a hindrance to timely and quality data. To address this, with an increase in appropriations received in Fiscal Year 2017, CDC gave 32 states supplemental funding to support comprehensive toxicology testing through state medical examiner and coroner offices.

In a relatively short time, CDC-funded states have scaled up their data collection expertise to improve their understanding of the epidemic and enhance response and prevention efforts. For example, Ohio is leveraging more timely data to improve the rapidity of its public health response. When there is an anomalous spike in opioid overdoses detected through syndromic ED data, an alert is sent to the local public health department so that they can respond accordingly, increasing access to naloxone in

affected areas, working with community partners to increase linkage to treatment, and/or collaborating with law enforcement to detect and respond to changes in illicit drug supply. In Kentucky, public health officials are tracking naloxone administration reported to their EMS system and are using those data to detect anomalous spikes in opioid overdoses both at the state and local levels. In Wisconsin, public health officials are working to link ED and EMS data together to better understand non-fatal overdose trends. They are also linking their fatal overdose data with PDMP data to better understand instances where opioids were prescribed to decedents prior to their death. These data linkage initiatives have helped the state to better understand trends, determine areas within their state at particular risk, and identify and address pertinent risk factors to prevent further overdoses.

CDC recently released data using toxicological and death scene evidence from 10 funded states, allowing for a more robust characterization of opioid overdose deaths. Analysis found that fentanyl was involved in more than half of opioid overdose deaths and that more than half of deaths testing positive for fentanyl and fentanyl analogs also tested positive for cocaine, methamphetamine, or heroin. The findings also indicated that illicitly manufactured fentanyl and fentanyl analogs were a major driver of opioid overdose deaths in multiple states. Similarly, ED syndromic and hospital billing data on opioid-involved overdoses were analyzed and show that opioid overdose rates increased an average of 35 percent in 16 states reporting for the selected time period.

CDC has helped strengthen collaboration across sectors to jointly move forward on strategies; and employ programmatic enhancements to their PDMPs, insurance programs, and educational outreach efforts. In Fiscal Year 2019, CDC plans to release new funding announcements for states with a focus

on implementing the strategies that have demonstrated the most promise thus far. In addition, CDC hopes to expand support to all 50 states and Washington, D.C., increase timeliness of data sharing, and gain a truly national picture of the opioid crisis while assisting states with their ability to prevent opioid-related morbidity and mortality.

CDC is also taking the lead in preventing opioid-related harms such as the spread of infectious disease and the impact of opioids on mothers and babies. The recent threefold increase in hepatitis C and the 2015 HIV outbreak in Indiana underscore the urgency of the issue. New hepatitis C infections have increased more than 167 percent in recent years and states like Kentucky, Tennessee, Virginia, and West Virginia reported a 364 percent increase in new hepatitis C infections from 2006 to 2012 in persons under 30. Surveillance for viral hepatitis is limited. Infectious disease surveillance is essential to know the true scale of the epidemic and facilitate more effective state and local responses.

Collaboration at the community level between public health, public safety, healthcare, education, and faith-based stakeholders as well as coordination across multiple levels of the US health care system, and implementation of tailored community-based prevention services are needed to prevent infectious diseases, including HIV, attributed to injection drug use.

CDC also recognizes the serious impact that the opioid epidemic is having on mothers and babies. New data show that one baby is born with signs of neonatal abstinence syndrome (NAS) every 15 minutes in the United States – or nearly 100 infants per day. It is critical that we improve data collection in this

vulnerable population, and use this data to drive public health action to better protect mothers and babies. CDC is leveraging the infrastructure of existing birth defects surveillance systems to improve our ability to monitor the occurrence of NAS.

A comprehensive response to the opioid crisis requires a partnership across sectors. As such, CDC has been working closely with law enforcement agencies, such as the Drug Enforcement Administration (DEA), to determine risk factors for a fentanyl overdose and to implement prevention strategies. In addition, the Heroin Response Strategy (HRS), funded by the Office of National Drug Control Policy (ONDCP) and deployed in 10 High Intensity Drug Trafficking Areas (HIDTAs), links public health and public safety. The HRS covers 22 states, from Georgia to Maine. Under the governance of the HIDTA directors, CDC sharpens strategic directions, ensures proper coordination and training, and improves performance measurement. CDC also supports the training and technical assistance for the 22 public health analysts embedded in the program. As part of the HRS, CDC is launching 13 pilot projects to better understand what communities can do to prevent opioid overdose deaths. There is a shortage of evidence to guide public health-law enforcement integrated community response, and CDC's initiative is designed to build scientific evidence about what works.

CDC recognizes the successes that have been achieved, but also knows that there is much work to be done. Building the capabilities of public health laboratories to contribute to non-fatal overdose surveillance and resulting public health interventions is essential. There is a particular need to fill the gap of testing specimens for tracking morbidity through systematic, routine laboratory testing of drugs

and patient samples to obtain and disseminate public health information to public health officials and laboratories.

As this crisis continues to unfold, it is important that public health response is nimble and flexible to adapt to new threats. This fast-moving and complex epidemic will require sustained focus to sustain prevention and mitigate the consequences of opioid use disorder.

Thank you for the opportunity to testify on this important issue. I would be happy to answer any questions.

Mr. BURGESS. Thank you, Doctor.

Dr. Jones, you are now recognized for 5 minutes for an opening statement, please.

STATEMENT OF CHRISTOPHER M. JONES, PHARMD

Dr. JONES. Thank you. Chairman Burgess, Ranking Member Green, and members of the committee, thank you for the opportunity to discuss the opioid crisis and the Federal Government response.

From the start of his administration, President Trump has made addressing the opioid epidemic a top priority. And at SAMHSA, we share the President's commitment to bringing an end to the crisis. Families and communities across our Nation have been impacted by increasing prescription and illicit opioid abuse addiction and overdose. And the emergence of illicit fentanyl and other potent synthetic opioids has only fueled the crisis in recent years.

As the department's lead agency for behavioral health, SAMHSA has been at the forefront of the response to the opioid crisis. Under the HHS opioid strategy, our work focuses on advancing prevention, treatment, and recovery services and overdose prevention through funding to build State and local capacity, providing education, training, and technical assistance, and data collection analysis and evaluation to track emerging trends, identify what works, and support the integration of evidence into practice.

Today, I want to focus on several recent actions SAMHSA has taken to enhance our response to the opioid crisis. In the area of funding, SAMHSA distributed $485 million to States and territories under our State targeted response to the opioid crisis grants in May 2017. This funding supports State efforts to reduce opioid overdose deaths and provide the full complement of prevention, treatment, and recovery support services.

In November of 2017, SAMHSA announced that it was accepting applications for $1 million in supplemental STR grants to expand and enhance those efforts in States hardest hit by the epidemic. On Monday of this week, SAMHSA awarded supplemental STR grants to New Hampshire, Massachusetts, and West Virginia. SAMHSA also provides critical funding for treatment and recovery services for specific high risk and vulnerable populations, such as those involved in the criminal justice system and pregnant and postpartum women.

In September 2017, SAMHSA awarded nearly $10 million over 3 years for new State pilot grants authorized by CARA that enable outpatient based care for pregnant and postpartum women and nearly $50 million over 5 years in new grants to support residential treatment services for pregnant and postpartum women.

SAMHSA has been a leader in efforts to reduce overdose deaths by increasing access and availability to naloxone to reverse overdose. In September 2017, SAMHSA awarded funding to grantees in 22 States from programs authorized by CARA to provide resources to first responders and treatment providers who work directly with populations at high risk for opioid overdose.

Developing a well-trained workforce and facilitating the integration of evidence-based interventions into practice are key goals of SAMHSA's education, training, and technical assistance efforts. In

January 2017, SAMHSA awarded $12 million to create—I'm sorry, January of 2018, we awarded $12 million to create the Opioid STR Technical Assistance program. This new program is providing direct technical assistance to States and local jurisdictions to support the implementation of evidence-based practices that are tailored to the State-specific context. And last month, SAMHSA released TIP 63, medications for opioid use disorders, which now includes information about all of the FDA-approved medications for the treatment of opioid use disorder as required in CARA.

In addition, SAMHSA's providers clinical support system for medication-assisted treatment, which provides national training and mentoring to support clinicians interested in providing addiction care, has also revised its DATA waiver training to include information on all FDA-approved medications for treatment of opioid use disorder.

Given the importance of providing clinicians and patients with actionable information about opioid addiction and pregnancy, last month, SAMHSA released clinical guidance for treating pregnant and parenting women with opioid use disorder and their infants. This guidance provides clear information on a range of real-world scenarios faced by healthcare providers who are caring for mothers and infants.

And in January 2018, SAMHSA issued a final rule pertaining to substance use disorder treatment records, commonly referred to as Part 2. As required in 21st Century Cures, SAMHSA also held a public meeting in January to obtain feedback from stakeholders on Part 2. The vast majority of those who spoke at the meeting expressed their support for further aligning Part 2 and HIPAA, and acknowledge that congressional action would be needed to achieve many of their goals.

In the area of data analysis and evaluation, SAMHSA is standing up the National Mental Health and Substance Use Policy Laboratory, created under the 21st Century Cures Act. The policy lab, charged by Congress with supporting innovation, evaluating promising approaches, and facilitating the adoption of evidence-based policies is prioritizing its efforts on opioids.

Finally, the President's fiscal year 2019 budget for SAMHSA includes $15 million to reestablish the Drug Abuse Warning Network, or DAWN, a national public health surveillance system that will improve emergency room monitoring of substance use, including opioid misuse.

SAMHSA is committed to combating the opioid crisis and looks forward to working with Congress to advance this important work.

Thank you for inviting me to testify, and I look forward to your questions.

[The prepared statement of Dr. Jones follows:]

House Committee on Energy and Commerce

Subcommittee on Health

Hearing titled, "Combating the Opioid Crisis: Prevention and Public Health Solutions"

March 21, 2018

Written testimony on behalf of

Christopher M. Jones, PharmD., M.P.H.
Director, National Mental Health and Substance Use Policy Laboratory
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services

Chairman Burgess, Ranking Members Green, and Members of the Committee. Thank you for the opportunity to discuss the opioid crisis in the United States and the Federal response. From the start of his Administration, President Trump has made addressing the opioid epidemic a top priority, and at the Substance Abuse and Mental Health Services Administration (SAMHSA) we share the President's commitment to bringing an end to this crisis, which is exacting a heavy toll on individuals, families, and communities across the country.

Over the past 15 years, communities across our Nation have been devastated by increasing prescription and illicit opioid abuse, addiction, and overdose. According SAMHSA's National Survey on Drug Use and Health (NSDUH), in 2016, over 11 million Americans misused prescription opioids, nearly 1 million used heroin, and 2.1 million had an opioid use disorder due to prescription opioids or heroin. Over the past decade, the U.S. has experienced significant increases in rates of neonatal abstinence syndrome (NAS), hepatitis C infections, and opioid-related emergency department visits and hospitalizations. Most alarming are the continued increases in overdose deaths, especially the rapid increase since 2013 in deaths involving illicitly made fentanyl and other highly potent synthetic opioids. Since 2000, more than 300,000 Americans have died of an opioid overdose. Opioids were involved in 42,249 deaths in 2016, and opioid overdose deaths were five times higher in 2016 than 1999.

The opioid epidemic in the United States can be attributed to a variety of factors. For example, there was a significant rise in opioid analgesic prescriptions that began in the mid-to-late 1990s. Not only did the volume of opioids prescribed increase, but also well-intentioned healthcare providers began to prescribe opioids to treat pain in ways that we now know are high-risk and have been associated with opioid abuse, addiction, and overdose, such as prescribing at high doses and for long durations. One additional factor is a lack of health system and healthcare provider capacity to identify and engage individuals with opioid use disorders, and to provide them with high-quality, evidence-based opioid addiction treatment, in particular the full spectrum of medication-assisted treatment (MAT). It is well-documented that the majority of people with opioid addiction in the United States do not receive treatment, and even among those who do, many do not receive evidence-based care. Accounting for these factors is paramount to the development of a successful strategy to combat the opioid crisis. Further, there is a need for more rigorous research to better understand how existing programs or policies might be contributing to or mitigating the opioid epidemic.

In April 2017, HHS outlined its five-point Opioid Strategy, which provides the overarching framework to leverage the expertise and resources of HHS agencies in a strategic and coordinated manner. The comprehensive, evidence-based Opioid Strategy aims to:

- Improve access to prevention, treatment, and recovery support services to prevent the health, social, and economic consequences associated with opioid addiction and to enable individuals to achieve long-term recovery;

- Target the availability and distribution of overdose-reversing medications to ensure the broad provision of these drugs to people likely to experience or respond to an overdose, with a particular focus on targeting high-risk populations;
- Strengthen public health data reporting and collection to improve the timeliness and specificity of data and to inform a real-time public health response as the epidemic evolves;
- Support cutting-edge research that advances our understanding of pain and addiction, leads to the development of new treatments, and identifies effective public health interventions to reduce opioid-related health harms; and
- Advance the practice of pain management to enable access to high-quality, evidence-based pain care that reduces the burden of pain for individuals, families, and society while also reducing the inappropriate use of opioids and opioid-related harms.

As HHS's lead agency for behavioral health, SAMHSA's core mission is to reduce the impact of substance abuse and mental illness on America's communities. SAMHSA supports a portfolio of activities that address all five prongs of HHS's Opioid Strategy.

Improving Access to Prevention, Treatment, and Recovery Support Services

SAMHSA administers the Opioid State Targeted Response (STR) grants, a two-year program authorized by the 21st Century Cures Act (P.L. 114-255). By providing $485 million to states and U.S. territories in fiscal year (FY) 2017, this program allows states to focus on areas of greatest need, including increasing access to treatment, reducing unmet treatment need, and reducing opioid overdose related deaths through the provision of the full range of prevention, treatment and recovery services for opioid use disorder. The President's Budget for SAMHSA in FY 2019 proposes an initial allocation of $1.2 billion to SAMHSA for a variety of new and expanded efforts to fight the opioid crisis. Of that amount, $1 billion is included to expand STR grants, an increase of $503 million above the FY 2018 Continuing Resolution amount for these activities.

In November 2017, SAMHSA announced that it was accepting applications for $1 million in grants for Opioid State Targeted Response (STR) Supplements. The purpose of this program is to expand and enhance prevention, treatment, and recovery support efforts in the states hardest hit by the nation's opioid epidemic. The purpose of the supplemental funding is to bolster efforts already being made through the STR grant program. One Monday, SAMHSA awarded grants to three states that are among those with the highest overdose death rates and rate of increase in death rates. This funding follows the STR grants which SAMHSA distributed to states and territories based on number of overdose deaths and the number of people needing treatment.

Following the nationwide public health emergency declaration on October 26, SAMHSA announced a new Technical Assistance (TA) effort to focus on the specific needs of states and local jurisdictions to address the opioid crisis in their areas. In January, SAMHSA released $12

million in funding to the American Academy of Addiction Psychiatry to begin the effort to utilize local expertise to provide TA and training on scientifically based evidence-based practices to combat the nation's opioid crisis. The Opioid State Targeted Response TA program aims to provide technical assistance on evidence-based practices across the spectrum of prevention, treatment and recovery. The technical assistance and training program will ensure that Americans suffering with opioid use disorders will gain access to the life-saving evidence-based medication-assisted treatment and psychosocial services they need.

SAMHSA also has several initiatives aimed specifically at advancing the utilization of or MAT for opioid use disorder, which is proven effective but is highly underutilized. SAMHSA's Medication Assisted Treatment for Prescription Drug and Opioid Addiction (MAT-PDOA) program expands MAT access by providing grants to states with the highest rates of treatment admissions for opioid addiction. Twenty-two states are currently funded by MAT-PDOA, and in September 2017, SAMHSA awarded $35 million dollars over three years in additional MAT-PDOA grants to six states. The President's Budget for SAMHSA for FY 2019 maintains $56 million for the MAT-PDOA program.

SAMHSA also provides critical funding for MAT for specific high-risk and vulnerable populations, such as those involved with the criminal justice system and pregnant and postpartum women. SAMHSA's criminal justice grantees can use up to 20 percent of their grant awards for the purchase of FDA-approved medications for treatment of opioid and alcohol addiction. Since 2013, SAMHSA has seen a steady increase in the number of drug courts integrating MAT into their programs with 57 percent of active programs currently doing so. The President's Budget for SAMHSA for FY 2019 expands the use of drug courts.

Under SAMHSA's Pregnant and Postpartum Women's (PPW) program, which serves women with opioid or other substance use disorders who are pregnant and/or newly parenting, grantees are encouraged to ensure access to MAT for opioid addiction, which has been shown to improve birth outcomes. Last month SAMHSA awarded $9.8 million over three years for new State Pilot PPW grants authorized by the Comprehensive Addiction and Recovery Act of 2016 (CARA, P.L. 114-198) and $49 million over five years in new PPW service grants to support the recovery of pregnant and postpartum women struggling with substance abuse, including opioid addiction. The President's Budget for SAMHSA for FY 2019 expands these services to pregnant and postpartum women and their children.

Last month, SAMHSA released a new publication "Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants." SAMHSA's Clinical Guidance comes at a time of great need for effective opioid use disorder (OUD) treatment. In 2016, over 20,000 pregnant women reported using heroin or misusing pain relievers in the past month. Newborn babies of mothers who used opioids while pregnant are at risk of neonatal abstinence syndrome--a syndrome of physical and neurobehavioral signs of withdrawal. The Clinical Guidance offers standard approaches to a range of real-world scenarios faced by healthcare

professionals working with mothers and infants. For each scenario, the guidance offers clinical action steps and supporting evidence. The action steps reflect the best available treatment, including medication-assisted treatment for the mother and infant and appropriate types of social supports and follow-up services.

A well-documented challenge to improving access to opioid use disorder treatment is a lack of providers who can provide MAT. SAMHSA supports a number of training initiatives to increase the number of qualified healthcare providers who can provide treatment for opioid addiction. In the last four years, more than 62,000 medical professionals have participated in online or in-person trainings on MAT for opioid addiction through SAMHSA's Provider's Clinical Support System (PCSS)-MAT. This program is a national training and clinical mentoring project that provides the DATA waiver training necessary for physicians, nurse practitioners, and physician assistants to provide office-based treatment of opioid use disorders and provides mentoring of newly trained physicians by experienced specialists, and maintains a library of evidence-based practice materials for continuing education.

SAMHSA regulates opioid treatment programs (OTPs), which dispense methadone and may also dispense and prescribe buprenorphine and administer extended-release naltrexone. In coordination with the Drug Enforcement Administration (DEA) and states, territories, and the District of Columbia, SAMHSA reviews new and renewal applications for OTPs through an accreditation process that ensures programs have sound risk management practices in place and are using evidence-based treatments. SAMHSA also oversees physicians, nurse practitioners (NPs), and physician assistants' (PAs) ability to prescribe buprenorphine in office-based outpatient treatment settings. On July 8, 2016, SAMHSA published a final rule, which allows certain qualified physicians who have obtained a waiver to prescribe buprenorphine for up to 100 patients for at least a year, to request and receive approval to treat up to 275 patients. The regulation provides that these licensed physicians can become eligible for the patient limit of 275 either by being board certified in Addiction Medicine or Addiction Psychiatry or by practicing in a qualified practice setting.

These physicians are required to complete a SAMHSA reporting form each year to ensure that physicians prescribing at the new, higher level are in compliance with the regulatory requirements for the increase in the patient limit. As of March 3, 2018, 3,992 physicians have been provided a waiver to prescribe up to 275 patients. Most recently, SAMHSA began processing waivers to allow NPs and PAs to prescribe buprenorphine in accordance with the requirements of CARA. As of March 3, 2018, 4,863 nurse practitioners and 1,276 physician assistants have received waivers to prescribe buprenorphine. Now that TIP 63: *Medications for Opioid Use Disorders* has been released, SAMHSA will ensure that currently waivered practitioners receive this document which includes information about the appropriate use of all FDA-approved medications for the treatment of opioid use disorders consistent with the requirements of CARA.

SAMHSA also recently released a fact sheet, "Finding Quality Treatment for Substance Use Disorders." This fact sheet provides individuals and families with some of the right questions to ask when looking for quality treatment, including whether the treatment program is licensed or certified by the state, whether the program offers FDA approved medications, whether the program includes family members in the treatment process, and whether the program provides other supports in addition to treatment. The fact sheet is on SAMHSA's website: https://store.samhsa.gov/shin/content//PEP18-TREATMENT-LOC/PEP18-TREATMENT-LOC.pdf.

In January, SAMHSA issued a final rule related to the regulation of substance use disorder treatment records (Part 2) that takes steps to further modernize Part 2 to better address new models of integrated care and the use electronic health records. This rule is one way to strengthen the nation's efforts to ensure safe and effective care of all who seek treatment for opioid addiction. The rule also reflects an effort to better align Part 2 requirements with those of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). As required by the 21st Century Cures Act (section 11002), SAMHSA held a public meeting on January 31, 2018, to obtain input about the impact of Part 2 on "patient care, health outcomes, and patient privacy." The vast majority of those who spoke at the listening session expressed their support for further aligning Part 2 and HIPAA and acknowledged that to achieve many of their goals Congress would need to take action on legislation. While the Administration has not taken a position on any particular bill related to Part 2, I want to assure you that SAMHSA supports further consideration of the benefits of aligning the statute governing Part 2 with HIPAA.

The President's Budget for SAMHSA for FY 2019 proposes additional funds that will help States provide services to reduce injection drug use and related HIV/AIDS and Hepatitis C infection rates related to opioid use.

SAMHSA also promotes recovery through targeted grants, such as last month's award of $4.6 million over three years in Building Communities of Recovery (BCOR) program grants, created by CARA. The purpose of this program is to mobilize resources within and outside of the recovery community to increase the availability and quality of long-term recovery supports for individuals in or seeking recovery from addiction. These grants are intended to support the development, enhancement, expansion, and delivery of recovery support services as well as promotion of and education about recovery. Programs will be principally governed by people in recovery from substance abuse and addiction who reflect the community served. The President's Budget for SAMHSA for FY 2019 maintains funding for the BCOR program.

Targeting Overdose-Reversing Drugs

SAMHSA has been a leader in efforts to reduce overdose deaths by increasing, through funding and technical assistance, the availability and use of naloxone to reverse overdose. SAMHSA's "Opioid Overdose Prevention Toolkit," first released in 2013, is one of SAMHSA's most downloaded resources. The Toolkit provides information on risks for opioid overdose, recognition of overdose, and how to provide emergency care in an overdose situation. The

Toolkit is intended for community members, first responders, prescribers, people who have recovered from an opioid overdose and family members, as well as communities and local governments.

SAMHSA provides a number of funding streams that can be used to expand access to naloxone. States are able to use Opioid STR funds to purchase and distribute naloxone, and some states are also using a portion of their SABG funds for opioid overdose prevention activities. SAMHSA is currently providing $11 million per year in Grants to Prevent Prescription Drug/Opioid Overdose Related Deaths to 12 states. These grants are also being used to train first responders on emergency medical care to be rendered in an overdose situation and how to administer naloxone as well as how to purchase and distribute naloxone. In September 2017, SAMHSA awarded funding for grants authorized by CARA, including almost $46 million over five years to grantees in 22 states to provide resources to first responders and treatment providers who work directly with the populations at highest risk for opioid overdose. The President's Budget for SAMHSA for FY 2019 proposes additional funding to allow communities to purchase the overdose-reversing drug naloxone for first responders.

Strengthening Public Health Data and Reporting

SAMHSA's National Survey on Drug Use and Health (NSDUH) provides key national and state level data on a variety of substance use and mental health topics, including opioid misuse. NSDUH is a vital part of the surveillance effort related to opioids, and the data from NSDUH has been used to track historical and emerging trends in opioid misuse, including geographic and demographic variability.

The President's Budget for SAMHSA for FY 2019 includes $15 million to re-establish the Drug Abuse Warning Network, a national public health surveillance system that will improve emergency room monitoring of mental and substance abuse crises, including those related to opioids. This will be an important tool in tracking substance misuse and related toxicities nationally and will help in addressing these issues as they evolve.

Thank you again for inviting me to testify today. I look forward to answering your questions.

Mr. BURGESS. Thank you, Dr. Jones.

I want to thank all of our witnesses.

We now move to the question portion of the hearing. I am going to recognize myself for 5 minutes.

And, Dr. Jones, let me start at your end of the table. You saw the reports that were printed in the press in the past couple of weeks. About $500 million was set aside in Cures for the purposes of addressing this epidemic, and yet those funds have yet to be directed toward State efforts.

So first off, is that as that was reported? Is that accurate, what we were reading in the papers a couple of weeks ago?

Dr. JONES. So I think it is important to clarify that the money to the States under the STR program was distributed May 1. So the States have the money. The sort of bottleneck for spending down the money is at the State level, largely due to variations in how States go through their procurement process to contract with providers to provide services. So the money is not at SAMHSA. It is actually at the State.

Mr. BURGESS. So let me just ask you, and I am sure the answer will be yes, but will you work with any Member who feels that they are having difficulty getting those funds accessed by folks in their State? That is the whole purpose of putting the money there in the first place, correct?

Dr. JONES. Absolutely. And we have put a process in place to look at the implementation of STR more broadly where we have our grants' management officials who are in regular contact with the States to address questions that come up around can these things be covered under this, as well as meeting regularly and the assistant secretary to really help provide leadership and top-down approach to helping the States advance.

I will also say the $12 million STR Technical Assistance program, which I mentioned in my opening statement, is really intended to support the States to achieve their strategic goals under the STR program. And one of those is specifically looking at how are we providing the services that the funding is intended to provide. So I think the TA in particular will be very helpful to the States in spending that down.

But we are certainly open and happy to talk to any Member or constituent who has raised issues with being able to spend down the money.

Mr. BURGESS. Thank you.

And Dr. Schuchat had mentioned in her testimony about—I think it was 100 neonatal abstinence cases a day that are being now acknowledged. Did I get that correctly, Dr. Schuchat?

So the money that you have put forward in SAMHSA, I appreciate that, but at 100 new cases a day, are we even coming close to scratching the surface there?

Dr. JONES. Well, I think that what is important in looking at neonatal abstinence syndrome is that it really is a comprehensive approach. So some individuals may be prescribed opioids for pain during their pregnancy, which may result in a neonate being born physically dependent on opioids, others may be misusing or using illicit opioids. And at SAMHSA, we certainly have tried to put out

guidance, as I mentioned, the clinical guidance around treating parenting and pregnant women.

Mr. BURGESS. I don't mean to interrupt you, but I am running out of time. And I get that, and I appreciate that. But at 100 neonatal abstinence cases a day that Dr. Schuchat is talking about, I mean, that is a pretty big problem. And from the perspective of for every neonate with a syndrome, there is a mother who also has a problem. And with what we have given you so far, are you able to meet that challenge?

Because many of us do have a concern that some of the changes, the increase in maternal mortality that they reflect around the country may be as a consequence of this opiate activity.

Dr. JONES. So I will say I certainly think that we are trying to put out money as quickly as possible and to help advance evidence-based practices. The magnitude of the issue, as Dr. Schuchat mentioned, continues to grow, and we need to make sure that resources are commiserative with the scale of the problem.

Mr. BURGESS. Well, again, we may communicate more about that, because it is an important topic.

And, Dr. Gottlieb, once again, I want to thank you for including me in your visit to the International Mail Facility. You testified to the fact that one-tenth of 1 percent of packages are actually being inspected. Really, it is hard to imagine the volume of stuff that is coming in that requires you and CBP to inspect and intervene. Can you speak to that just a little bit more about what your needs are?

Dr. GOTTLIEB. Thank you, Congressman. Thanks for joining us on that visit to the JFK International Mail Facility. That facility in particular, there is about a million packages a day going through that facility. We get 2.4 million packages a day going through the combined international mail facilities. And based on estimates that are derived from some analysis we did from 2004, we estimate that about 9 percent of all packages contain some form of drugs, either prescription drugs, counterfeit drugs, or controlled substances. And to your point, we estimate that we are physically inspecting less than probably 0.05 percent of them.

Now, we target packages. And we target certain packages for x-ray, and then we target certain packages for physical inspection. And so intelligence is key here in terms of targeting the right packages. And we do do a good job of that, but getting more information is better. But we know we are missing packages.

And so, the key is getting more personnel into those facilities, being able to operate more quickly and more efficiently with our authorities, and getting better intelligence in terms of targeting our resources more effectively. And we could do more across all three domains.

Mr. BURGESS. And it is just so important. The agent who intercepted a flip-flop, sliced it open, and pulled out a counterfeit passport, I was just astounded, number one, that they picked it up, and, number two, who thought that was a good idea in the first place?

With nothing implied, I would now recognize Mr. Green of Texas, 5 minutes for your questions, please.

Mr. GREEN. Well, I appreciate that intro.

Dr. Gottlieb, I want to thank you for all your efforts and seriously look at how FDA can play a role in combating the opioid crisis facing our country. We must examine how we prescribe and dispense opioid, how we can limit or deter diversion, and how we can treat those that suffer.

In your testimony, you noted the majority of the people who become addicted to opioids are first exposed through the lawful prescription. Many of us on the committee have committed to examining how lawful prescriptions have contributed to this crisis and what steps Congress and Federal agencies can take to reduce the rate of addiction from lawfully obtained opioids.

The FDA took unprecedented action last year when it requested the withdrawal of an opioid treatment due to the concern that the benefits associated with the product were outweighed by the risk of abuse and manipulation. One of the bills noticed today is a discussion draft that offered to allow the FDA to take into consideration the potential risk of abuse and misuse of making approval decisions. Currently, FDA examines a drug for safe and efficacy for their intended use when making approval decisions.

Will you discuss how FDA's approval and assessment of a drug would change if the agency's authority was modified as proposed in the draft?

Dr. GOTTLIEB. Thanks for the question, Congressman. As you mentioned, we recommended the withdrawal of Opana ER earlier this year based on a consideration around a risk that was only manifested when that drug was used illicitly. In this case, it was when the drug was crushed and injected, it created a certain autoimmune phenomenon in particular that wouldn't have been manifested if the drug was taken as intended.

We believe we have the legal authority to look at risks associated purely with illicit use as a component of how we assess risk and benefit both pre- and post-market. We exercised that authority in this case. But I do think that this is an opportunity for Congress to think about how that authority can be tailored specifically against this challenge and particularly with respect to controlled substances.

For drugs outside of controlled substances, if we are trying to address an unlabeled use, a risk associated with an unlabeled use, typically, we would use our REMS authority, and that would be adequate. But in the setting of drugs that have an abuse liability associated with them and are used in an illicit fashion, having carefully constructed authority, I think, could benefit the agency and benefit consumers.

Mr. GREEN. I understand that some stakeholders must be hesitant to make modifications to the FDA's current risk benefit assessment. As we continue to work on the legislation, how would FDA recommend that we target this legislation to ensure that we are appropriately targeting the controlled substances that are fueling this opioid crisis?

Dr. GOTTLIEB. We can certainly tailor this kind of consideration to controlled substances to scheduled products. Congress clearly recognized that there needed to be certain controls and certain special considerations with respect to controlled substances in the formation of the Controlled Substances Act. The Controlled Sub-

stances Act creates a lot of controls on the prescription and prescribing of a narcotic that don't exist for any other drug.

And so we have already crossed the Rubicon, if you will, with respect to trying to create special considerations with respect to controlled substances. I think this would just be, you know, furtherance of that and basically just a clarification of an authority that we not only believe we have but we have exercised. And so it is an opportunity, I think, for Congress to tailor that authority behind the specific challenge that we face.

Mr. GREEN. OK. Thank you. And I am looking forward to working with you and the FDA so we can make sure this legislation is really a benefit and can do it. Thank you. And we must closely examine how we can limit the ability of opioids to be wildly prescribed as also abused and misused, while also balancing the need to ensure accessibility for those who suffer from more chronic pain, and I look forward to continue working with you.

In my last minute, Dr. Jones, I would like to turn to talk to a bill introduced earlier this week by Congressman Guthrie, Luján, and Bucshon, the Comprehensive Recovery Centers Act. That seems like something that would be useful. But to create a pilot program to support opioid treatment centers, or CORCs in the legislation, we always have to have an acronym. Essential requirement of CORCs in our legislation is a must-have, dedicated outreach efforts in the community, including a large public health system, criminal justice system, higher education, and community partners.

Do you agree that this connectivity with the community stakeholders is important?

Dr. JONES. Thank you for the question. I think that providing comprehensive services for individuals who have opioid use disorder is really critical to their success. As a person in long-term recovery from opioid addiction, I am very familiar with navigating the fragmented system. And so providing that as a sort of a one-stop shop I think really sets people up for success. And we need to make sure they have access to evidence-based care like medication assisted treatment, but housing supports, employment, other supports to really make them successful in the long run is very important.

Mr. GREEN. Well, I am out of time. But I also know that we have a network already of federally qualified health centers and that we just need to expand to give them that opportunity to see how they can treat the whole person, including their addiction.

So, Mr. Chairman, I know I am out of time. Thank you.

And I will submit some questions.

Mr. BURGESS. The chair thanks the gentleman.

The chair recognizes the Chairman of the Full Committee, Mr. Walden, 5 minutes for questions.

Mr. WALDEN. Thank you, Mr. Chairman. I really appreciate the work you are doing here and the other members of the committee and our witnesses.

And, Dr. Schuchat, thank you for being back here before the committee. At least two of the three, maybe all three of you have been here on multiple occasions. So we really appreciate your leadership at CDC and the work you have been doing.

As PDMPs have evolved in recent years, incorporating PDMP data into a prescriber or pharmacist clinical workflow seems to be the key to ensuring that the data are used effectively while also increasing efficiency and saving time for providers. So, Dr. Schuchat, what are the barriers currently that prevent more States from incorporating PDMP data in the clinical workflow? And aside from prescription dispensing data, what other information can be collected by PDMPs, and how can this help CDC's surveillance efforts?

So what currently do you find or do you hear from the States create barriers?

Dr. SCHUCHAT. Yes. We are making substantial progress, particularly in selected States that have really integrated the prescription drug monitoring program into the electronic health record. Making it easy for clinicians is the only way to make it work, making it universal so all clinicians are using it, which involves registering them and getting them onboard. But integrating it into the clinical workflow in the office or in the pharmacy will make it a one-stop shop for folks. The technology is not that complicated, but every State is starting from a different place, and each State has different laws that also get incorporated.

But in the past couple years, we have seen an increase in the use of them in many States and an increase in the attributes that they have so that people can get active management. You get alerts when you are overprescribing or when you have interactions with other drugs. That is a feature that is very important. You can also link the data for public health use and find the hot spots: Where are the providers that are at the extreme level of prescribing and where are the counties that have the higher use. So, really, it is about integrating with electronic health record and also integrating with other systems in the State.

There is also the cross-State lookup, the interstate operability, which is—most States have that ability, but not to look up with all other States. They have agreements with neighboring States. So I would say that the barriers are very insurmountable. It is attention, resources, and policies.

Mr. WALDEN. All right. Good. And I know our resident pharmacist, Dr. Carter, and I were talking yesterday—or Congressman Carter—about some of the issues he has encountered. And I am sure he will dig into this deeply with his great experience on this.

Dr. Gottlieb, thanks for the good work you are already doing in this area and interdiction and everything else to give us guidance and what you are doing through the agencies. I think it is important to understand the role you see the FDA playing in the fight against opioids. And I, again, commend you.

Can you speak to the mission of your agency and how it fits in the larger efforts of fighting this opioid crisis?

Dr. GOTTLIEB. I think we have responsibilities across multiple domains. I think we have a responsibility to, and in terms of places we can effect this crisis, I think we have the opportunity to reduce overall prescribing, to rationalize prescribing through things like education or application of the REMS. We recently, as you know, extended our REMS authority to all the IR drugs to try to rationalize prescribing, trying to effect dispensing to make sure that

when prescriptions are written, the amount that is dispensed is appropriate for the clinical circumstances.

We obviously have a role to play in interdiction. I have talked about that here today. And I think we also have a role to play with respect to new technology, trying to bring onto the market abuse-deterrent formulations. We have taken steps to do that, trying to bring onto the market drugs that don't have all the abuse liabilities that are associated with opioids, trying to create innovation for medically assisted treatment.

So we have taken steps to cross all those domains. Those are the large areas where we are working.

Mr. WALDEN. Thank you very much. And we appreciate your input and guidance on these various bills that are before the committee today and tomorrow.

Dr. Jones, you mentioned in your testimony the listening session on the topic of alignment of 42 CFR Part 2 and HIPAA that was required by 21st Century Cures. Can you elaborate upon those discussions at the listening session and explain how the bills were examined, did they either align or conflict with what participants were saying? And also, can you discuss the enforcement authority for Part 2 infractions in comparison to HIPAA enforcement?

Dr. JONES. Thank you. So from the listening session, again, there is passion on this issue across the spectrum. But I think there was a consistent recognition that, from the stakeholders, that Part 2 may in and of itself—the constraints around treating information differently may in and of itself be stigmatizing, sort of reinforcing the idea that people who have addiction or substance use disorders should be treated unfairly.

I think on the side of addressing and making sure that people have parity to healthcare, that people who have substance use disorders should be given the best treatment that they can. And often having all the information about the patient is a really critical part of that. I think those were sort of the common themes that were shared.

And from our standpoint, and we certainly are encouraged that Congress is looking at better alignment of Part 2 and HIPAA. And as I said in my opening statement, we do think, and certainly from the listening session, it was fairly clear that many of the folks felt that congressional action would be needed. We have taken a lot of flexibilities that we can take under our administrative rulemaking authority. I think it is now at the point where Congress would need to take action.

Mr. WALDEN. I think so too.

Thank you to our panelists. Again, thank you, Mr. Chairman. Thank you for your leadership.

Mr. BURGESS. The gentleman yields back. The chair thanks the gentleman.

The chair recognizes the gentleman from New Jersey, the Ranking Member of the Full Committee, Mr. Pallone, 5 minutes for questions, please.

Mr. PALLONE. Thank you, Mr. Chairman.

I wanted to start with Dr. Gottlieb. I wanted to thank you for appearing before the committee again and for your forward thinking when it comes to the opioid crisis this country is facing.

And I have long been concerned about the number of illicit, unapproved, and often counterfeit drugs that are entering our supply chain through our mail facilities. I work with FDA and my Democratic colleagues to provide the agency with additional authority and FDASIA to help combat this problem, but understand from you that more must be done.

So first question is would you discuss briefly some of the problems related to illicit drugs that FDA is witnessing at our international mail facilities? I know the chairman asked a similar question, but maybe be a little more specific about the drug packages. You said in your testimony that they are often unlabeled or shipped with bulk and disguise. You want to talk a little bit more about that more specifically?

Dr. GOTTLIEB. That's right, Congressman. One of the keys to our ability to destroy packages or seize them is the ability for us to establish intended use. And so when people who are shipping drugs into the country engage in label stripping, where they strip away the information from the package itself or from the drug product, we often can't establish intended use. And so we have to just return the package to the sender, effectively, because we can't destroy it. We can't go through a destruction proceeding because we can't establish it is a drug.

And our concern around this is that it is not a good deterrent. And we often see the same packages coming back a second and third time. In fact, sometimes, we will see packages that will be sent back, and then they will come back in with the same investigator's writing on it through the same mail facility.

The other thing we are seeing is more and more small packages. And so the shippers know that we have to initiate an individual proceeding against each package. And so if you send in sort of a bulk package with thousands of small boxes in it, we would have to initiate a proceeding against each individual box to establish that it is a drug, what the intended use is. And this is often prohibitively difficult for us. So, again, we are in a position of holding these packages in the international mail facilities while we go through a notification process to the consignee and then just returning them to the sender, because we can do that based on an appearance standard. We can't get to the ability to destroy these packages because it is a higher standard, and we would have to establish intended use. And so they are purposely shipping these in in a way to evade our authorities. They know what our gaps are, if you will.

Mr. PALLONE. All right. Well, as I understand it, hundreds of millions of packages go through international mail facilities each year. But as you said—well, FDA only has the resources to examine about 40,000 of these packages per day. So that is why I introduced the bill I mentioned, H.R. 5228, or the SCREEN Act, which would provide FDA with additional authority and resources to combat this problem.

Mr. Chairman, I would ask unanimous consent to submit the text of H.R. 5228 for the record for the hearing.

Mr. BURGESS. Without objection, so ordered.

[The information follows:]

AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

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115TH CONGRESS
2D SESSION

H. R. 5228

To strengthen the authorities of the Food and Drug Administration to address counterfeit drugs, illegal and synthetic opioids, and opioid-like substances, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 8, 2018

Mr. PALLONE introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Budget, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To strengthen the authorities of the Food and Drug Administration to address counterfeit drugs, illegal and synthetic opioids, and opioid-like substances, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act" or the "SCREEN Act".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Detention, refusal, and destruction of drugs offered for importation.
Sec. 3. Notification, nondistribution, and recall of adulterated or misbranded drug products.
Sec. 4. Seizure.
Sec. 5. Single source pattern of shipments of adulterated or misbranded drugs.
Sec. 6. Debarring violative individuals or companies.
Sec. 7. Account to strengthen efforts of FDA to combat the opioid and substance use epidemic.

SEC. 2. DETENTION, REFUSAL, AND DESTRUCTION OF DRUGS OFFERED FOR IMPORTATION.

(a) CERTAIN IMPORTED PRODUCTS DEEMED TO BE DRUGS.—Section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)) is amended by adding at the end the following:

"(3) An article being imported or offered for import is deemed to be a drug if it—

"(A) is or contains an active ingredient that is contained within—

"(i) a drug for which an approval is in effect under section 505 of this Act; or

"(ii) biological product for which a license is in effect under section 351 of the Public Health Service Act;

"(B) is or contains an active ingredient that is contained within a drug or biological product for which an investigational use exemption is in effect under section 505(i) of this Act or section 351(a) of

the Public Health Service Act, for which substantial clinical investigations have been instituted, and for which the existence of such investigations has been made public; or

"(C) is a chemical analog of a drug or biological product described in clause (A) or (B).".

(b) ARTICLES OF CONCERN.—

(1) DELIVERY BY TREASURY TO HHS.—The first sentence of section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended by striking "and cosmetics" and inserting "cosmetics, and potential articles of concern (as defined in subsection (t)), and controlled substances described paragraph (6) in the third sentence of this subsection".

(2) REPEAL OF ANTIQUATED REVIEW PROCESS.—

(A) REPEAL.—The second sentence of section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is repealed.

(B) TECHNICAL CHANGE TO KEEP NUMBERING OF SENTENCES THE SAME.—The first sentence of section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended by striking "the owner or consignee,

who may appear" and inserting "the owner or consignee. The owner or consignee may appear".

(3) REFUSED ADMISSION.—

(A) IN GENERAL.—The third sentence of section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended—

(i) by striking "If it appears from the examination" and inserting "Subject to subsection (b), if it appears from the examination"; and

(ii) by striking "then such article shall be refused admission, except as provided in subsection (b) of this section" and inserting "or (5) such article is an article of concern (as defined in subsection (t)), or (6) such article is a controlled substance (as defined in section 102 of the Controlled Substances Act) for which a listing in any schedule is in effect (on a temporary or permanent basis) under section 201 of the Controlled Substances Act, or (7) such article is being imported or offered for import in violation of section 301(cc), then such article may be refused admission, and

if it appears such article may not be imported into the United States pursuant to subsection (d) or it appears that the article is a counterfeit drug, then such article shall be refused admission".

(B) DEFINITION OF ARTICLE OF CONCERN.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by adding at the end the following:

"(t) ARTICLE OF CONCERN DEFINED.—For purposes of subsection (a), the term 'article of concern' means an article that is or contains a drug or other substance—

"(1) for which, during the 24-month period prior to the article being imported or offered for import, the Secretary of Health and Human Services—

"(A) has requested that, based on a determination that the drug or other substance appears to meet the requirements for temporary or permanent scheduling pursuant to section 201 of the Controlled Substances Act, the Attorney General initiate the process to control the drug or other substance in accordance with such Act; or

"(B) has made a determination, following the publication by the Attorney General of a no-

tice in the Federal Register of the intention to issue an order temporarily or permanently scheduling such drug or substance in schedule I of section 202 of the Controlled Substances Act, that such article presents an imminent risk to the public health; and

"(2) with respect to which the Attorney General has not—

"(A) scheduled the drug or other substance under section 201 of such Act; or

"(B) notified the Secretary of Health and Human Services that the Attorney General has made a determination not to schedule the drug or other substance under such section.".

(c) INCREASING THE MAXIMUM DOLLAR AMOUNT OF DRUGS SUBJECT TO DESTRUCTION.—The sixth sentence in section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended by striking "except that the Secretary" and all that follows through the two periods at the end and inserting "except that the Secretary of Health and Human Services may destroy, without the opportunity for export, any drug refused admission under this section, if such drug is valued at an amount that is $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation pursuant to

section 498(a)(1) of the Tariff Act of 1930 or such higher amount as the Commissioner of Food and Drugs may set based on a finding by the Commissioner that the higher amount is in the interest of public health) and was not brought into compliance as described under subsection (b).".

(d) DESTRUCTION OF ARTICLES OF CONCERN.—The sixth sentence of section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)), as amended by subsection (c), is further amended by inserting before the period at the end the following: "; and the Secretary of Health and Human Services may destroy, without the opportunity for export, any article refused admission under clause (6) of the third sentence of this subsection.".

(e) TECHNICAL AMENDMENTS.—The seventh, eighth, and ninth sentences of section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) are amended—

(1) by striking "a drug" each place it appears and inserting "an article"; and

(2) by striking "the drug" each place it appears and inserting "the article".

(f) RULE OF CONSTRUCTION.—The last sentence in section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended to read as follows:

"Clauses (2), (5), and (6) of the third sentence of this subsection shall not be construed to prohibit the admission of narcotic or nonnarcotic drugs or other substances, the importation of which is permitted under the Controlled Substances Import and Export Act.".

SEC. 3. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED DRUG PRODUCTS.

(a) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

"(eee) The failure to comply with any order issued under section 569D.".

(b) NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED DRUGS.—Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

"SEC. 569D. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED DRUGS.

"(a) ORDER TO CEASE DISTRIBUTION.—

"(1) IN GENERAL.—If the Secretary has reason to believe that the use or consumption of, or exposure to, a drug may cause serious adverse health

consequences or death to humans, the Secretary may issue an order requiring any person who distributes such drug to immediately cease distribution of such drug.

"(2) ACTION FOLLOWING ORDER.—Any person who is subject to an order under paragraph (1) shall immediately cease distribution of such drug and provide notification as required by such order, and may appeal to the Secretary within 24 hours of the issuance of such order. Such appeal may include a request for an informal hearing and a description of any efforts to recall such drug undertaken voluntarily by the person, including after a request under subsection (b). Except as provided in subsection (c), an informal hearing shall be held as soon as practicable, but not later than 5 calendar days, or less as determined by the Secretary, after such an appeal is filed, unless the parties jointly agree to an extension. After affording an opportunity for an informal hearing, the Secretary shall determine whether the order should be amended to require a recall of such drug. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

"(b) EMERGENCY RECALL ORDER.—

"(1) IN GENERAL.—If the Secretary has credible evidence or information that a drug subject to an order under subsection (a) presents an imminent threat of serious adverse health consequences or death to humans, the Secretary may issue an order requiring any person who distributes such drug—

"(A) to immediately recall such drug; and

"(B) to provide for notice, including to individuals as appropriate, to persons who may be affected by the recall.

"(2) ACTION FOLLOWING ORDER.—Any person who is subject to an emergency recall order under this subsection shall immediately recall such drug and provide notification as required by such order, and may appeal to the Secretary within 24 hours after issuance of such order. The person subject to an emergency recall order shall conduct the recall notwithstanding the pendency of any such appeal. An informal hearing shall be held as soon as practicable but not later than 5 calendar days, or less as determined by the Secretary, after such an appeal is filed, unless the parties jointly agree to an extension. After affording an opportunity for an informal hearing, the Secretary shall determine whether the order

should be amended pursuant to subsection (d)(1). If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

"(e) NOTICE TO CONSUMERS AND HEALTH OFFICIALS.—The Secretary shall, as the Secretary determines to be necessary, provide notice of a recall order under this section to—

"(1) consumers to whom the drug was, or may have been, distributed; and

"(2) appropriate State and local health officials.

"(d) ORDER TO RECALL.—

"(1) AMENDMENT.—Except as provided under subsection (e), if after providing an opportunity for an informal hearing under subsection (a) or (b), the Secretary determines that an order issued under subsection (a) or (b) should be amended to include a recall of the drug with respect to which the order was issued, the Secretary shall amend the order to require a recall.

"(2) CONTENTS.—An amended order under paragraph (1) shall—

"(A) specify a timetable in which the recall will occur;

"(B) require periodic reports to the Secretary describing the progress of the recall; and

"(C) provide for notice, including to individuals as appropriate, to persons who may be affected by the recall.

"(3) ASSISTANCE ALLOWED.—In providing for notice under paragraph (2)(C), the Secretary may allow for the assistance of health professionals, State or local officials, or other individuals designated by the Secretary.

"(4) NONDELEGATION.—An amended order under this subsection shall be ordered by the Secretary or an official designated by the Secretary. An official may not be so designated under this section unless the official is the director of the district in which the drug involved is located, or is an official senior to such director.

"(e) SAVINGS CLAUSE.—Nothing contained in this section shall be construed as limiting—

"(1) the authority of the Secretary to issue an order to cease distribution of, or to recall, an drug under any other provision of this Act or the Public Health Service Act; or

"(2) the ability of the Secretary to request any person to perform a voluntary activity related to any

drug subject to this Act or the Public Health Service Act.".

(c) DRUGS SUBJECT TO REFUSAL.—The third sentence of subsection (a) of section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381), as amended by section 2(b)(C), is further amended by inserting "or (8) in the case of a drug, such drug is subject to an order under section 568 to cease distribution of or recall the drug," before "then such article shall be refused admission".

(d) APPLICATION.—Sections 301(eee) and 569D of the Federal Food, Drug, and Cosmetic Act, as added by subsections (a) and (b), shall apply with respect to a drug as of such date, not later than 1 year after the date of the enactment of this Act, as the Secretary of Health and Human Services shall specify.

SEC. 4. SEIZURE.

Section 304(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(b)) is amended by striking the first sentence and inserting the following: "The article, equipment, or other thing proceeded against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty rather than the procedure used for civil asset forfeiture proceedings set

forth in section 983 of title 18, United States Code. On demand of either party any issue of fact joined in any such a case brought under this section shall be tried by jury. A seizure brought under this section is not governed by Rule G of the Supplemental Rules of Admiralty or Maritime Claims and Asset Forfeiture Actions. Exigent circumstances shall be deemed to exist for all seizures brought under this section, and in such cases, the summons and arrest warrant shall be issued by the clerk of the court without court review.".

SEC. 5. SINGLE SOURCE PATTERN OF SHIPMENTS OF ADULTERATED OR MISBRANDED DRUGS.

Section 801 of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end the following:

"(u) SINGLE SOURCE PATTERN OF SHIPMENTS OF ADULTERATED OR MISBRANDED DRUGS.—If the Secretary identifies a pattern of adulterated or misbranded drugs being offered for import from the same manufacturer, distributor, or importer, the Secretary may by order choose to treat all drugs being offered for import from such manufacturer, distributor, or importer as adulterated or misbranded unless otherwise demonstrated.".

SEC. 6. DEBARRING VIOLATIVE INDIVIDUALS OR COMPANIES.

(a) PROHIBITED ACT.—Section 301(cc) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(cc)) is amended to read as follows:

"(cc) The importing or offering for import into the United States of an article by, with the assistance of, or at the direction of, a person debarred from such activity under section 306(b)(3).".

(b) DEBARMENT.—Section 306(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(b)) is amended—

(1) in paragraph (1)—

(A) in the matter preceding subparagraph (A), by striking "paragraph (2)" and inserting "paragraph (2) or (3)";

(B) in subparagraph (B), by striking "or" at the end;

(C) in subparagraph (C), by striking the period at the end and inserting ", or"; and

(D) by adding at the end the following:

"(D) a person from importing or offering to import into the United States—

"(i) a controlled substance as defined in section 102(6) of the Controlled Substances Act; or

"(ii) any article that is regulated by the Food and Drug Administration that is valued at $2500 or less (or such higher amount as the Secretary of the Treasury may set by regulation pursuant to section 498(a)(1) of the Tariff Act of 1930)."; and

(2) by striking paragraph (3) and inserting the following:

"(3) PERSONS SUBJECT TO PERMISSIVE DEBARMENT; IMPORTATION.—

"(A) FOOD.—A person is subject to debarment under paragraph (1)(C) if—

"(i) the person has been convicted of a felony for conduct relating to the importation into the United States of any food; or

"(ii) the person has engaged in a pattern of importing or offering for import adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

"(B) IMPORTATION OF DRUGS.—A person is subject to debarment under paragraph (1)(D) if—

"(i) the person has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance (as defined in section 102 of the Controlled Substances Act); or

"(ii) the person has engaged in a pattern of importing or offering for import drugs that are—

"(I) adulterated, misbranded, or in violation of section 505; or

"(II) controlled substances whose importation is prohibited pursuant to section 401(m) of the Tariff Act of 1930.".

SEC. 7. ACCOUNT TO STRENGTHEN EFFORTS OF FDA TO COMBAT THE OPIOID AND SUBSTANCE USE EPIDEMIC.

(a) IN GENERAL.—The Commissioner of Food and Drugs (referred to in this section as the "Commissioner") shall use any funds appropriated pursuant to the authorization of appropriations under subsection (c) to carry out the programs and activities described in subsection (d) to strengthen and facilitate the Food and Drug Administration's efforts to address the opioid and substance use epi-

demic. Such funds shall be in addition to any funds which are otherwise available to carry out such programs and activities.

(b) FDA OPIOID AND SUBSTANCE USE EPIDEMIC RESPONSE FUND.—

(1) ESTABLISHMENT OF FUND.—There is established in the Treasury an account, to be known as the FDA Opioid and Substance Use Epidemic Response Fund (referred to in this subsection as the "Fund"), for purposes of funding the programs and activities described in subsection (d).

(2) TRANSFER.—For the period of fiscal years 2019 through 2023, $110,000,000 shall be transferred to the Fund from the general fund of the Treasury.

(3) AMOUNTS DEPOSITED.—Any amounts transferred under paragraph (2) shall remain unavailable in the Fund until such amounts are appropriated pursuant to subsection (c).

(c) APPROPRIATIONS.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the period of fiscal years 2019 through 2023, there is authorized to be appropriated from the Account to the Food and Drug Administration, for the purpose of carrying out the programs and activities described

in subsection (d), an amount not to exceed the total amount transferred to the Account under subsection (b)(2). Notwithstanding subsection (g), such funds shall remain available until expended.

(2) OFFSETTING FUTURE APPROPRIATIONS.—For any of fiscal years 2019 through 2023, for any discretionary appropriation out of the Account to the Food and Drug Administration pursuant to the authorization of appropriations under paragraph (1) for the purpose of carrying out the programs and activities described in subsection (d), the total amount of such appropriations for the applicable fiscal year (not to exceed the total amount remaining in the Account) shall be subtracted from the estimate of discretionary budget authority and the resulting outlays for any estimate under the Congressional Budget and Impoundment Control Act of 1974 or the Balanced Budget and Emergency Deficit Control Act of 1985, and the amount transferred to the Account shall be reduced by the same amount.

(d) FOOD AND DRUG ADMINISTRATION.—The entirety of the funds made available pursuant to subsection (c)(1) shall be for the Commissioner of Food and Drugs, pursuant to applicable authorities in the Public Health

Service Act (42 U.S.C. 201 et seq.) or the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and other applicable law, to support widespread innovation in non-opioid and non-addictive medical products for pain treatment, access to opioid addiction treatments, appropriate use of approved opioids, and efforts to reduce illicit importation of opioids. Such support may include the following programs and activities:

(1) Obligating contract funds beginning in fiscal year 2019 for an educational campaign that will—

(A) educate patients and their families to differentiate opioid medications;

(B) raise awareness about preferred storage and disposal methods; and

(C) inform patients, families, and communities about medication-assisted treatment options.

(2) Building the Food and Drug Administration's presence in international mail facilities, including through—

(A) improvements in equipment and information technology enhancements to identify unapproved, counterfeit, or other unlawful pharmaceuticals for destruction;

(B) increased and improved surveillance;

(C) renovations at international mail facility locations; and

(D) the purchase of laboratory equipment.

(3) Enhancing the identification and targeting of firms and products being offered for import into the United States through review and analysis of websites, imports data, and other sources of intelligence thereby making best use of the Food and Drug Administration's inspectional and analytical resources.

(4) Increasing the number of staff to increase the number of packages being examined, ensuring the safety of the staff undertaking this work, and ensuring that packages identified as illegal, counterfeit, misbranded, or adulterated are removed from commerce through available authorities, including administrative destruction.

(5) Enhancing criminal investigations resources (including full-time equivalent employees and equipment), imports surveillance, and international work.

(6) Obtaining equipment and full-time equivalent employees needed to efficiently screen and analyze products offered for import, including by building data libraries of new substances and analogues

to facilitate identification and evaluation of pharmaceutical-based agents and by purchasing screening technologies for use at international mail facilities.

(7) Operating the Food and Drug Administration's forensic laboratory facility to ensure adequate laboratory space and functionality for additional work and full-time equivalent employees.

(c) ACCOUNTABILITY AND OVERSIGHT.—

(1) WORK PLAN.—

(A) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Commissioner of Food and Drugs shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a work plan including the proposed allocation of funds appropriated pursuant to the authorization of appropriations under subsection (c) for each of fiscal years 2019 through 2023 and the contents described in subparagraph (B).

(B) CONTENTS.—The work plan submitted under subparagraph (A) shall include—

(i) the amount of money to be obligated or expended out of the Account in

each fiscal year for each program and activity described in subsection (d); and

(ii) a description and justification of each such program and activity.

(2) REPORTS.—

(A) ANNUAL REPORTS.—Not later than October 1 of each of fiscal years 2020 through 2024, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report including—

(i) the amount of money obligated or expended out of the Account in the prior fiscal year for each program and activity described in subsection (d);

(ii) a description of all programs and activities using funds provided pursuant to the authorization of appropriations under subsection (c); and

(iii) how the programs and activities are advancing public health.

(B) ADDITIONAL REPORTS.—At the request of the Committee on Health, Education,

Labor, and Pensions of the Senate, or the Committee on Energy and Commerce of the House of Representatives, the Commissioner shall provide an update in the form of testimony and any additional reports to the respective congressional committee regarding the allocation of funding under this section or the description of the programs and activities undertaken with such funding.

(f) LIMITATIONS.—Notwithstanding any transfer authority authorized by this Act or any appropriations Act, any funds made available pursuant to the authorization of appropriations under subsection (e) may not be used for any purpose other than the programs and activities described in subsection (d) strengthen and facilitate the Food and Drug Administration's efforts to address the opioid and substance use epidemic.

(g) SUNSET.—This section shall expire on September 30, 2022, except that—

(1) this subsection does not apply to reporting under subsection (e)(2); and

(2) this section shall remain in effect until such time, and to such extent, as may be necessary for

the funds transferred by subsection (b)(2) to be fully expended.

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Mr. PALLONE. Thank you.

Dr. Gottlieb, in examining this issue, will you please outline for me what key authorities or actions Congress could take? I know you talked a little bit about it. But if you get more specific about key authorities or actions Congress could take to help you address the problem that you are witnessing at our international mail facilities.

Dr. GOTTLIEB. Well, one authority would be to be able to establish that product as a drug based on its chemical composition, whether it has similar chemical composition to an already approved FDA drug or is an analog of an FDA-approved drug. If we were able to establish that a drug is a drug based on chemical composition, then we could establish that as misbranded under 505 just by looking at the labeling associated with the product. And this would allow us to be more efficient in making the determinations as to violative product and we can then enter into a destruction proceeding.

Another efficiency that we can gain is changes to our seizure authority. Right now seizure authority allows the FDA to bring a lawsuit to seize a violative product. But a judge must first make a finding of probable cause, if probable cause exists. And I have been personally engaged in situations since I have been back at the agency where we have gone through a multi-week process to try to get a proceeding before a judge to affect a seizure of a product that we had concerns around and wanted to take off the market quickly. So we could go back to the way FDA used to operate with respect to seizure authority prior to 2006 and the agency operated this way for decades and decades and allow us to affect a seizure based on an imminent public health hazard standard, so we can go before a clerk in the court and get an order to seize a product, and then have the hearing before the judge after that. That would allow us if there is an imminent public health hazard and we want to take a product off the market in advance of the due process proceeding, which obviously has to occur, it would allow us to intervene more quickly.

FDA, there was a change in some law in 2006 that unfortunately swept FDA in, I think inadvertently. I will leave it to Congress to determine the legislative history. But if we can revert back to how we used to exercise our seizure authority, that would be helpful.

Finally, I would just highlight the ability to bundle products coming in and treat a light shipment as one shipment, if you will, for purposes of bringing a proceeding against it rather than having to look at the individual boxes or packages, because that is a gap that people who are intent on trying to slip drugs into the U.S. are unfortunately exploiting.

And all of this is about getting to your point about how many packages we look at each day, one of the keys is getting more resources into those facilities and we have targeted more resources to the IMF for money that we found inside the agency. We are obviously looking to increase our capacity even further. But even as we bring on more resources, we want to make sure those resources are used in an efficient way. So a lot of these authorities are aimed at making our people more efficient. Right now an individual investigator in the IMF can open maybe up to 15 packages a day. We

want to make those individuals more efficient so that they can be opening more packages and we can get that 0.05 percent up to a more representative sample.

Mr. PALLONE. Thank you. Thank you, Mr. Chairman.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentleman from Kentucky, the Vice Chairman of the Subcommittee, Mr. Guthrie for 5 minutes for your questions.

Mr. GUTHRIE. Thank you, Mr. Chairman. Again, thank you for your leadership on this issue and for everybody's focus on this issue, I appreciate it.

I am going to talk about a bill that Congressman Green, Luján, Bucshon, and I have introduced titled the Comprehensive Opioid Recovery Centers Act or CORCs. We proposed a new standard of care for the treatment of opioid use disorders. And I would like to get your views on the importance of required features of the CORCs from Dr. Jones from SAMSHA.

SAMSHA's new publication titled treatment improvement protocol number 63, medications for opioid use disorder repeatedly emphasizes the need for patient centered individualized care in which the medications are prescribed to a patient based on that person's clinical needs. Yet according to a recent analysis of SAMSHA's data, published by Health Affairs, fewer than 3 percent of all licensed substance abuse treatment facilities in the country are able to offer all three.

Most programs offer only one or two types of medications at the most and some offer none at all. Do you agree, Dr. Jones, do you agree that the current opioid addiction treatment system is not offering a full range of medication options?

Dr. JONES. I would say that there are regulatory constraints on how medications can be offered. So methadone under current statute and regulation can only be offered through opioid treatment programs. For buprenorphine you would have to have a waiver so physicians, nurse practitioners, PAs would have to have a waiver after receiving training to prescribe buprenorphine in their limits on the number of patients. Extended release, naltrexone or vivitrol which is the antagonist version of the three medications can be prescribed by anybody within their scope of practice.

So there are constraints in saying that every treatment facility should be able to offer that because it may not be possible for every treatment facility to be an opioid treatment program. I think what is important is that we build the system so that patients have access to the treatment that is most appropriate for them. So it is not that everybody has to be an OTP, but that there is some relationship for if methadone is the best thing for that patient access that they would be able to access that, same with buprenorphoine or naltrexone.

And we have seen opioid treatment programs increasingly start to offer buprenorphine and naltrexone, recognizing that patient preference is a really important part of the long-term trajectory of someone with opioid use disorder.

Mr. GUTHRIE. Those options need to be available if somebody presents to a center that only does one and it is not the best treatment

for them, they are not getting the best treatment. That is what we are trying to look for in our bill. So we appreciate your help on it as well.

Do you see the current fragmented, siloed approach as a problem? I guess that feeds to the answer you just gave.

Dr. JONES. Fragmentation and siloing always works well. No, no.

It clearly is a problem for individuals, because when somebody comes in with opioid addiction, there is a lot going on with that individual. So they may have legal issues, they may have issues with safe and supportive housing, they may have issues with family care. And we are really at SAMSHA with our STR dollars and our other programs trying to build that system which I think is analogous to what you are trying to accomplish that allows that patient to receive those services in a comprehensive manner where they are not trying to show up in different places and say, oh, wait, you have to go here, you have to go there. That there are places that are doing that. And we are seeing States like Rhode Island that are implementing centers of excellence, which are essentially taking that model and putting that into place where people if they are coming from the criminal justice system are connected in to these centers of excellence so they can look at things like insurance coverage, housing, employment, vocational training. And we are seeing success with those areas. I think we need to continue to scale up those types of interventions.

Mr. GUTHRIE. Well, thanks. I just had someone from Louisville come in who said that they have a recovery center that is trying to do the holistic complete person approach. And so you really addressed it, but I just want to specifically pull out one specific of all the comprehensives and that is job training. One of the unique provisions of our bill is a requirement that they provide job training and job placement assistance. A recent analysis published by Brookings Institute found that about one-third of the people who were no longer looking for work had opioids being prescribed to them.

Do you agree that this focus on supporting successful reentry into the workforce should be a valuable addition to establishing long-term recovery? The relationship between work and recovery I would like for you to address.

Dr. JONES. I think certainly people want to have purpose and structure in their day. And so a job provides some purpose and structure for individuals. I think that is an important thing among the array of services an individual would need to be successful.

Mr. GUTHRIE. Thank you. I am about out of time. That completes—I can't really get to the next questions. So, I appreciate you being here. We look forward to working with with my fellow colleagues to move this bill forward. I appreciate it.

Thank you. I yield back.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentlelady from California, Ms. Matsui for 5 minutes for your questions.

Ms. MATSUI. Thank you very much, Mr. Chairman.

Dr. Schuchat, thank you for your testimony today. I have heard concerns about how increasing injection drug use is resulting in in-

creased incidents of HIV and hepatitis C. As you look at solutions to the opioid epidemic, we should also examine how the opioid crisis may have a cascading impact on the rest of the our public health. That is why I am cosponsoring eliminating opioid related infectious diseases act discussion draft with my colleagues on the committee Representatives Lance and Kennedy to support additional public health surveillance activity at CDC on this topic.

Dr. Schuchat, what is a concurrence rate of opioid use in infectious diseases?

Dr. SCHUCHAT. The infectious disease complications of opioid use are really are tragic and they were most dramatically seen in Scott County, Indiana, where over 200 people developed acute infectious disease, acute HIV infection and most had also hepatitis C. We have seen hepatitis C increase 140 percent recently. We have seen particular increases in young people. And we have recently seen multistate outbreaks of hepatitis B and hepatisit A as well. Most recently we have had salmonella associated with the kratom botanical and we have also got a group A strep outbreak that is associated with injection.

So injecting drugs and also other opioid use can lead to these infectious disease complications, sometimes clustered and sometimes throughout the Nation. We think it is really important to improve surveillance and also to assure wraparound services when we are dealing with addiction to make sure there is infectious disease screening as well so that people who do have hepatitis C or HIV can get into appropriate care.

Ms. MATSUI. Thank you.

Dr. Jones, has SAMHSA done any work in this space?

Dr. JONES. Yes. So SAMHSA had funding programs in place for colocation of HIV and hepatitis C services within substance abuse treatment. Again, as Dr. Schuchat said, it is a really important part to address the comprehensive issues of individuals who are coming in. And now that we have curative therapy for hepatitis C, it is really important that we are testing people as they come in. And our funds have been put into place to help build that system.

Ms. MATSUI. Good, good.

Now the solutions to this epidemic will come from a lot of different places and angles and requires to examine all of the different problems that led us to where we are today. One of the main ways that I have heard of are people becoming addicted to opioids whether prescriptions or illegal started with prescription opioids found in the home. Maybe it is left over prescription drugs, a teenager has had their wisdom teeth pulled, they got 30 day's worth of pills, but they only needed one or two. And the bottle is still sitting in the medicine cabinet.

Dr. Gottlieb, do you see potential for technology to play a role in ensuring the efficient return or destruction of unused opioids?

Dr. GOTTLIEB. I do, Congresswoman. I agree with your point the chief risk of the liberal prescribing wasn't so much that the patients would become addicted. Although, we know that that happens, but that the excess meds feed the river of pills that are coursing through our communities. And so we do see an opportunity to try to inspire sponsors and others in the supply chain to provide tools that could allow patients to dispose of those pills. This can be

something that Congress could provide some authorities around, it is something that could be encouraged by the provider community as well, but there are tools to do that. We don't regulate the tools. Many of them they are not medical devices, some of them allow the patient to destroy the pills themselves or render them inert, but they are available.

Ms. MATSUI. OK. Thank you. UC Davis Medical Center in my district of Sacramento houses an entire division devoted to pain management, including a pain management clinic. The doctors and researchers there participate in a program called Project ECHO which allows experts in effective pain management at UC Davis to remotely train less specialized doctors practicing in remote or isolated areas.

Opioids is certainly one method of pain management and one that can be very necessary. For example to improve a patient's quality of life at the end of their life in hospice. However, opioids are not the only option for pain treatment and more should be done to explore both existing and new alternate options.

Pain is not something that people should have to live with but clearly taking the convenient way out by using opioids has led to serious problems. However, there is a middle ground. We shouldn't get rid of opioids completely, but we can better understand when and how to use them.

Dr. Gottlieb, can you comment on any potential for FDA to contribute in this area?

Dr. GOTTLIEB. We have taken a lot of steps in recent months to try to use our tools, particularly our REMS authority to increase provider education. I think it is a point well taken that part of what got us here is a change in prescribing patterns that led to more liberal prescribing. Many people who became medically addicted, their first exposure was through a lawful prescription, often that was for an immediate release formulation of the drugs.

So we have take steps to expand our REMS authority that asks sponsors to provide education to physicians to the immediate release formulations of the drugs, which represents about 90 percent of all the pills. We are looking at other things that we can do, for example packaging, if we can get more of IR drugs into blister packs that might encourage more rational prescribing. Physicians might opt for a blister pack that maybe had a 3 or 5 day unit of dose in it as opposed to a 30 day bottle. So we are continuing to look at other tools that we could adopt and practices that we could pursue to try to affect physician behavior here.

Ms. MATSUI. OK. Thank you very much. And I yield back.

Mr. BURGESS. The chair thanks the gentlelady. The gentlelady yields back.

The chair recognizes the gentleman from Michigan, Mr. Upton, former chairman of the committee to ask your questions.

Mr. UPTON. Well, thank you, Mr. Chairman. And I appreciate this hearing, and appreciate the good work by our distinguished panel. I know we all have tremendous concerns about this. And it is something that has grilled down to all of our constituents.

I hosted a meeting in Kalamazoo at the WMed School, a place where Dr. Burgess came for a hearing on 21st Century Cures a few years ago. The governor's office, to our State mental health folks,

to our law enforcement people, treatment folks, it is an issue that people really do care about. In fact, the local sheriff, a good guy said that they knew that as we look at these staggering statistics of people that have died because of the overdoses that they had personally knew of at least 150 folks just in that county that they saved because of Narcan. By having that available to their officers. And I have talked to a number of—all of my Sheriffs in my six counties that I represent. It is a standard procedure, sadly.

And one of the things that a number of us have discussed is maybe somehow being able to reduce the cost of these lifesaving drugs because it is a real financial burden, particularly in rural areas where perhaps they don't have the resources to be able to have that available as it reaches out.

A couple of things that I would like to ask this morning. First of all, I want to commend our chairman, Greg Walden, this is a huge issue. I have a list of just 20 some different bills that are all bipartisan as far as I know that we intend to move through this committee. He has reached out to our leadership. We have time, I believe, that is reserved a little bit later this spring to get the bills to the floor and hopefully provide the time to get the Senate to be able to endorse and embrace these and get them to the President.

I know a number of us on both sides of the aisle have had personal discussions with the President about it. He cares deeply about this issue and something where we could work on together.

And a couple questions that I have, Dr. Gottlieb in your written testimony for our hearing back in October you said that the FDA strongly supports a transition from the current market dominated by conventional opioids to one in which the majority of opioids have meaningful abuse deterrent properties. Can you update us on the FDA's efforts on the abuse deterrent formulations in terms of where we are?

Dr. GOTTLIEB. We continue to take steps to try to help transition this market including through the approval of some additional drugs, we have abuse-deterrent features associated with them. We have approved 10 in all. We also recently issued guidance that lays out the pathway for how you can genericize these abuse-deterrent formulations because you don't want to create a monopoly market where there is no potential for generic entry to compete with abuse-deterrent formulations out there after the IP has lapsed on these drugs.

We are also taking efforts to reevaluate the nomenclature in terms of how we refer to these to make sure that we are not convening to prescribers something that isn't intended, that there is not a perception somehow because these are an abuse deterrent they can't be abused and people can't get addicted to them. They are resistant to manipulation, that is the feature that they have and we want to make sure we adequately conveying that.

But ultimately to get to the essence of your question, Congressman, we need to maybe a policy decision as to whether or not we can make a determination that the advent of abuse deterrent formulation lowers the rate of addiction over a population, that if you converted the market to abuse deterrent formulations, would you bring down the rate of overall addiction. And we continue to collect data to make that determination.

That is a determination we want to make as a matter of policy and not have to do it in the context of each individual occupation. We have some data forthcoming soon that will help inform that question where we have looked at the conversion rates to heroin addiction from prescription opioid use and looked at whether or not areas where there was a higher use of abuse-deterrent formulations had a lower conversion to the abuse of street drugs. That kind of data is going to help us, help inform our view and get closer to being able to make that threshold determination.

Mr. UPTON. So like Chairman Burgess and Ranking Member Pallone indicated, the difficulty of identifying these packages that are coming in, whether it is FedEx, UPS, Postal Service—I sat down with my local law enforcement folks a number of months ago, actually almost a year ago, and they described to me the situation of west Michigan. There is literally one postal inspector for all the packages that come into Grand Rapids, which is the distribution point for the whole west side of the State.

And they indicated one postal inspector is certainly an issue. But as we look at fentanyl coming in, what type of capabilities have you been able to provide for our local law enforcement to identify fentanyl as you look at these tens of thousands of packages that inundate all of these facilities literally every single day.

Dr. GOTTLIEB. Well, Congressman, Customs and Border Protection has primary responsibility in the international mail facilities where we are for the controlled substances when they are identified. But we do identify an increasing number of packages that aren't perceived a controlled substance on first blush. Either they get through a screen or through a dog that is sniffing packages. And we are only X-raying in those facilities 1 percent of the priority mail packages. I don't want to get too detailed into the statistics of what we do in there to reveal our weaknesses. But we are not looking at everything, we are targeting what we do to packages that we believe are more likely to contain controlled substances.

But with respect to fentanyl in particular, we have scientific expertise and tools that allow us to identify fentanyl analogs and we assist CBP in that effort in trying to inform that process and inform the tools that they use in those facilities to identify those drugs. But it is a challenge, I will tell you that. And the vulnerability that I worry about the most is this bad actor who dresses up an opioid as an ordinary pharmaceutical product or an OTC product because that is an area of vulnerability right now if you are looking to evade detection.

Mr. UPTON. I know my time has expired. Thank you.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentlelady from Florida, Ms. Castor for 5 minutes for your questions please.

Ms. CASTOR. Thank you, Mr. Chairman. And thank you to all of you for work on this public health crisis.

Dr. Jones, I want to continue on the line of questioning by my colleague Mr. Guthrie from Kentucky on treatment. A 2015 study published in the Journal of the American Medical Association found that 80 percent of Americans with opioid addiction do not receive treatment. In your testimony you identified the lack of treat-

ment as one of the primary factors in the growing opioid epidemic. You say, the lack of a health system and healthcare provider capacity to identify and engage individuals with opioid use disorders and to provide them with high quality evidence based opioid addiction treatment, in particular the full spectrum of medication assisted treatment. It is well documented that the majority of people with the opioid addiction in the United States do not receive treatment. And even among those who do, many do not receive evidence-based care.

In the last Health subcommittee meeting we had I asked Dr. Colony from Brandeis University about this, he heads an opioid research center, the head of the physicians for responsible prescribing. In answer to my question he said, I think the only way we are going to get there is a massive Federal investment in the billions. We have to create a treatment system that doesn't really exist yet. The majority of the State drug and alcohol license programs don't offer buprenorphine, many don't even have enough physician time. Many people often have to pay from their own pocket for medication. If we really want to see deaths start to come down, it has it to be easier to get treatment than it is to get a bag of dope.

When someone who is opioid addicted wakes up, they are going to need to use. They often have something by their bedside. They will feel very sick when they start to wake up. If they have got $20 and they know where to go get heroin even with Fentanyl in it, that is what they are going to do. If finding a doctor is more expensive and difficult we are not going to see the overdose deaths start to come down. We really have to build a system that doesn't exist yet. And I don't see any other way than investing billions of dollars to create it.

And this is informed by a constituent back home in Tampa I have been working with. A middle class family, this father has come to Members of Congress because he doesn't know anywhere else to turn. He has a 22-year old son who has been addicted to opioids since he was 15 years old. They have good insurance. He stated though even with good insurance he has personally invested over $100,000 trying to help his son. He learned that the cost to combat his son's addiction could be limitless.

As healthcare carriers are unwilling to fund addiction healthcare beyond the point of immediate physiological safety. His son as of December 2017 celebrated 4 months of good health before relapsing again. And he has gone through so many different treatment methods. Clearly there has to be a paradigm shift here. I know there are some important bills. I like Mr. Guthrie's bill with others on the recovery centers. The workforce is a significant issue, Ms. Clark of Massachusetts has a bill. But what do we have to do? It has to be something much more extensive than we are even thinking about now.

If you could redesign a system now and really we are spending so much on lost productivity and healthcare dollars that don't really get to the heart of the problem. How would you design the system now? What do we need to do for this paradigm shift?

Dr. JONES. Thank you for the question. I think that you raise a number of really important issues. And I think they are the exact

conversations that we are having at SAMHSA in thinking about how are we being good stewards of the dollars that Congress has given us as we are investing $1 billion over the last 2 years, the President's budget up to $1 billion for STR funds? How are we building that system? Because the system is fragmented and too many times individuals are paying a lot of money for ineffective care.

And so part of that is to actually look at the innovations and how services are provided. And as I mentioned earlier thinking about centers of excellence, or hub and spoke models, or nurse care management models. Those are things that have been studied in different States that have shown increased retention, reduced drug use, improved outcomes. And that is how we are trying to frame our dollars in how we are requiring those dollars to be spent by States——

Ms. CASTOR. Is that just building on the current system or is there something you needed like almost a VA type of system for this healthcare emergency.

Dr. JONES. It is sort of enhancing the system that doesn't exist so that the services are collocated and that the evidence-based treatments, i.e., medications are being provided. So moving away from a siloed fragmented system where it may be an abstinence based approach that medications are not even considered, to a system where medications are a central component of what is being offered to patients, but that it is also taking advantage of treatment on demand.

So when somebody comes in, that is again connection of the emergency departments, where somebody experiences an overdose or somebody has an infectious disease complication, using that touch point in the health system to connect that individual into treatment. That is the system that we are trying to build.

I will use Rhode Island as an example, they had a nice study that came out in JAMA psychiatry recently where they expanded medication assisted treatment within their incarcerated population in Rhode Island within the Department of Corrections. They offered all three medications, they were able to do that within their regulatory schemes and they found that there was a 60 percent decline in overdose deaths in the first 6 months of 2017 compared to the first 6 months of 2016. So Rhode Island is certainly a State that has been hard hid by fentanyl and other illicit fentanyl analogs and they are seeing that progress because they built the system. And as people are coming out of incarceration they are connected into these centers of excellence so they can continue to get those supportive services.

And while certainly we put a lot of money towards treatment, I don't think I can underscore enough the importance of recovery support services. So we want patients to get on medications, we want them to do well. But we also need them to be successful in the long run in providing those supports whether they be peer supports, recovery coaches, employment, housing, legal services, those types of things, they are all critical pieces to having that individual success in the long run. There is a lot of structure that needs to be provided and support that needs to be provided and I think we

are building the system but make sure the resources are there to really amplify that system.

Ms. CASTOR. Thank you very much, Dr. Jones.

Mr. BURGESS. The gentlelady's time has expired.

The chair recognizes the gentleman from Illinois, Mr. Shimkus for 5 minutes for your questions please.

Mr. SHIMKUS. Thank you, Mr. Chairman. I will try to ask quick questions, and get quick responses, and help my colleagues and you all survive this long period of questions and answers.

Dr. Gottlieb, in your testimony you talk about the difference between addiction and physical dependence and part of that is how long can physical dependence develop? In your medical——

Dr. GOTTLIEB. I would defer to Dr. Jones. But it could develop fairly quickly. Anyone who is prescribed opioids for any sustained period of time is going to become physically dependent on the drug, that is very different than being addicted to the drug. Addiction is a state where you have more than just a physical dependence on a drug, you have a psychological dependence on a drug and you are engaging in behavior that is not constructive in your life to get access to the drug so there is a very specific——

Mr. SHIMKUS. In my experience when someone has addiction they would tell me that their brain has been changed, this is part of the debate, discussion with this individual was that just said his brain—in essence he used the term pickled in that he not only has this physical dependence, but his—can someone comment about that and how quickly can that occur?

Dr. JONES. Individuals are very different and so they will respond to medication or substance of abuse in very different ways. I do think very have a robust set of research studies that look at changes that do happen in the brain. And for some individuals that change may occur very quickly, for others it may take a longer period of time for changes in the brain to occur.If we look at functional MRI studies it shows that brains of people who are currently addicted light up in different ways than people who are not exposed to substances. Even those effects carry on many years even after they have——

Mr. SHIMKUS. Our challenge is to stop people from being hooked and then deal with those who are addicted. That is why there are a multitude of bills being presented to try to address a lot of these different concerns. I also believe there is a practice of pharmacy, there is a practice of medicine I am sure you all would agree with that. I am also concerned in a rush to judgment on some of the proposed positions because I really want to ensure that those who have chronic pain do not get thrown under the bus or are collateral damage in a response on prescription because those with chronic pain in their lives would be significantly changed if they can't have access or a long set through a prescription through a doctor.

And so some of these short-term, get a new prescription after 3 days, I am actually concerned about that from the patient aspect of—and I want just to throw that on the table.

Dr. Schuchat, on the prescription drug monitoring debate, I live in Illinois, three different States border my congressional district, some have it some don't. How do we fix this whole system so that we know and there can be identification?

Dr. SCHUCHAT. Right. We need interstate interoperability so a clinician can easily essentially automatically have the information about any place that a person has received a prescription. We also need those systems to automatically calculate what is the total dose that the person has gotten to make sure you are not going too high. CDC's been funding 45 States to strengthen these prescription drug monitoring programs, as well as hubs that will help with the——

Mr. SHIMKUS. We have done this under the meth debate and it was somewhat successful when we allow and get the States act together and we can get our act together, to be able to identify this stuff.

Dr. SCHUCHAT. Right. And most States are doing data sharing. It is just we basically need to speed it up and we need to make it very easy.

Mr. SHIMKUS. You need to help us figure out how we can do that because I think——

Dr. SCHUCHAT. I think the resources we have been getting have helped but additional resources that are proposed will help tremendously——

Mr. SHIMKUS. And let me finish on this one. I am sorry to be so short. Fred Upton went down this rabbit hole on the long-term aspects of different drugs that aren't addictive. And I am going to go to Dr. Gottlieb, I think we talked about this personally to about the CMS funding dilemma as far as how do you get that on the actuary so these things get paid? Anyone want to mention that?

Dr. GOTTLIEB. I can't speak specifically to the policies related to CMS. I will tell you that there are a multitude of products available that treat pain and you do want to see the alternatives available as well.

Mr. SHIMKUS. And paid for and on an actuary.

Dr. GOTTLIEB. Yes. One of the challenges right now is that the IR formulations of opioids are very cheap. Vicodin, percocet are generic drugs and they are very cheap.

Mr. SHIMKUS. I yield back the balance of my time.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentleman from Massachusetts, Mr. Kennedy for 5 minutes for your questions please.

Mr. KENNEDY. Thank you, Mr. Chairman. I want to thank you and the Ranking Member Green and all of our witnesses for being here convening an important hearing during another historic snowstorm in Washington. Took me a whole 30 seconds to wipe off my car, but the government is shut down so grateful that you all are here. Thank you.

The wind. Yes, the wind.

The heart of today's hearing is a simple question I believe that is facing our government. Are we doing enough to combat an opioid epidemic that is tearing families apart every single day? I think that despite best efforts of many across government legislative branch and others the answer is an emphatic no. It is an answer that ends up being scrawled across the headlines of our local papers far too often because recently a headline in my own district

read that Attleboro quote, "Attleboro sees 200 percent increase in opioid deaths."

And it was illustrated by every father, brother and sister, son and daughter who will never again laugh or cry with a loved one they couldn't reach help, get them the help they needed in time. An answer written by police officers, fire fighters whose resumes now include a line about being addiction counselors and lifesavers in their own communities.

And as many of us are painfully and personally aware of because we have watched friends and family struggle to overcome this disease. And we know then that we have not done enough. Because it isn't enough to offer local governments a one time funding boost on one hand and then just turn around and cut Medicaid, the single largest payer of behavioral health services in the country by $800 billion with the other.

Is it enough to provide law enforcement with more Narcan only to erode essential health benefits that would guarantee treatment after a life has been saved? Is it enough to call for more treatment beds only to oppose Medicaid lifetime caps and work requirements that will create barriers to care for those battling substance use disorder?

Hearings like this one are a positive step forward, but we know that they are not enough and we know that there are conflicting messages coming out of this administration. So until our colleagues end an assault on Medicaid, an assault on those that are seeking to make themselves and families heal and better, again the largest payer of behavioral health services in this country. The answer to that question is not going to change.

So with that as an umbrella, I wanted to follow up a little bit on what our colleague Chairman Burgess had commented about earlier in his comments about neonatal abstinence syndrome, which has been an issue that many of us have been focused on. One of my colleagues from Massachusetts, Katherine Clark, made a priority of her work in Congress.

Dr. Jones, you had I believe mentioned it a little bit about the influence and the importance of parity when it comes to some of these issues. Neonatal abstinence syndrome is an issue that obviously affects as it impacts on newborns because of addictions in pregnant women. We have a bill that is bipartisan, that is bicameral and believe it or not has a CBO score of zero that seeks to ensure that pregnant women are able to get and newborns are able to get access to the mental and baby health services that they need, including addiction services. And I was wondering if you could expand a little bit on, in your eyes, the importance of access to those services and the importance of parity?

Dr. JONES. Certainly parity is a really critical component to addressing the opioid issue, but more broadly mental health and substance abuse issues. Through requirements set forth in the 21st Century Cures Act, HHS, SAMHSA being a part of that as well as Departments of Labor and Treasury have been working through issuing different pieces of information that can provide facts around parity violations, tools for health plans and other to see if they are in compliance with parity. We have been trying to put the tools in place to address parity more broadly.

Mr. KENNEDY. Do you believe there is sufficient enforcement of those violations?

Dr. JONES. I would say I would defer that to colleagues who are charged with the enforcement side, but we have been trying to put out information on what are the expectations to frequently asked questions around treatment limitations not quantitative treatment limitations, step therapies or other payment and reimbursement strategies, and then providing examples of what are violations. But as far as the enforcement actions, I would defer to those who are actually charged with that.

Mr. KENNEDY. Any additional witnesses want to comment on the enforcement side?

Doctor.

Dr. SCHUCHAT. Just to say that taking a holistic approach as you mentioned is critical and the public health public safety working together is critical, but the same issue making sure the care is there for who need them. And we know that wraparound service, comprehensive services work better than fragmented ones.

Mr. KENNEDY. And so cutting Medicaid by $800 billion, would that strengthen or hinder those services?

Dr. SCHUCHAT. It wouldn't be the best to comment on that.

Mr. KENNEDY. Mr. Gottlieb.

Dr. GOTTLIEB. I used to work in Medicare 15—10 years ago so I am not up to speed and can't comment on it.

Mr. KENNEDY. Appreciate that.

Eight hundred billion dollars less than Medicaid though you were there a little while ago. Eight hundred billion dollars cut to Medicaid, will it strengthen or hinder the program?

Dr. GOTTLIEB. You can certainly do more with more in any program. There is no question about that. If we are properly using our resources we can always do more with more. So I think it is an undebatable proposition.

Mr. KENNEDY. Thank you.

I yield my 30 second overtime back.

Mr. BURGESS. The gentleman's time has expired.

The chair recognizes the gentlelady from Tennessee 5 minutes for your questions, please.

Mrs. BLACKBURN. Thank you, Mr. Chairman.

And Dr. Gottlieb I want to come to you. The hearing we had back in October, I went right down the dais with you all, NIH, CDC, SAMHSA, DEA and said, "Is there any Federal statute that prohibits you from doing your job?" And you spoke up and talked about the international mail facilities and I thank you for that. And I thank you for the subsequent work you have done with my team, as we have worked to do the discussion draft to address the issues with the international mail facilities.

And I want to talk with you for just a minute about section 2(a) of that draft, which looks at the unlabeled or minimally labeled products that come through these facilities and to include those active ingredients that are in some FDA approved drugs and biologics. So let's talk about what authorities you currently have when you encounter these products in the IMF and how this bill will change that authority?

Dr. GOTTLIEB. Thanks a lot, Congresswoman. Thanks for your support of our work on this and we are happy to work with your office and provide technical assistance as you work through these issues. Right now we have to, if we see a drug that we believe is violative in the IMF, in the International Mail Facility, we open a package or a package is pulled by CBP. It comes to us for physical inspection, we open it and we find drugs in it that we believe are counterfeit or illicit drugs, we have to establish intended use. We have to establish that it is a drug based on its labeling. And what we are seeing more and more are minimally labeled drugs.

Sometimes we are seeing whole boxes of just pills with no labeling whatsoever associated with them. And in that setting, if we can't establish that it is a drug based on its intended use based on its labeling effectively we have to return it. We typically will return it to the sender based on an appearance standard, which is lower bar. But if we wanted to destroy that product or enter into some other kind of proceeding against it, we would have to establish that it is a drug based on the labelling.

And so what we have talked about is being able to establish that as a drug based on chemical composition and then being able to go from there to establishing as violative based on some lapse in the requirements under 505, the labeling requirements under 505 section of our statute which would be a more efficient threshold for us to reach in the IMF. The challenge is also that a lot of times the labeling is online. So what we have is our investigators in these facilities going online and doing a lot of research around these products to try to find some link between the product and its shipper that can establish the labeling. That is why we are only able to physically inspect a small number of packages per investigator. So this could make us far more efficient in those facilities.

Mrs. BLACKBURN. OK. Let's talk just a little bit about the bulk, the shipment because the bill will address that and the needed authority there when you have got that adulterated and mislabeled, misbranded drugs that are identified in this bulk shipment.

So, and you have mentioned a couple of times some of the problems that exist there. And as we change that authority, how will that speed up provide those efficiencies? You have talked a little bit about intel, the need for intel, the need for efficiencies. So when we change this, what would the agency gain through the new authority?

Dr. GOTTLIEB. The agency would gain the ability to bundle like packages so that we are not overwhelmed by the same shipper shipping a lot of small packages in. We can bundle the light packages from the same shipper and take one action against them. We would also gain the ability to destroy more of the packages as opposed to just returning them to sender.

So if we know something is clearly violative, believed to be counterfeit, we can destroy it, which we think would be a stronger deterrent than returning it back to the sender only to see the same package come in again in another IMF through another port of entry, or sometimes the same facility. So this is really about gaining efficiencies in the IMFs and trying to use our limited footprint, but nonetheless a footprint that we are trying to grow to look at

many more packages a day so we can get to what we believe is a representative sample of what is coming in.

We are never going to be able to inspect any significant percentage of all of drug packages coming in. I think the key is to make sure we are targeting our resources effectively. That requires intelligence, but it also requires the ability to work efficiently so that we can use the resources that we have in a better way.

Mrs. BLACKBURN. Thank you. I yield back.

Mr. BURGESS. The chair thanks the gentlelady. The gentlelady yields back.

The chair recognizes the gentlelady from Colorado, Ms. DeGette for 5 minutes for your questions please.

Ms. DEGETTE. Thank you very much, Mr. Chairman. I just want to comment on this questioning and other questioning.

Dr. Gottlieb, I am really happy we are talking about improving our assessments of what is coming in in the mail. This committee had a hearing many years ago which was one of those totally revelatory hearings about the importation of drugs. And I can only imagine that the situation has greatly worsened with the opioid crisis.

We have somewhere in the archives of this committee some pictures of what it looks like at these mail facilities with the overwhelming amount of drugs we have coming in and the tiny number of people we have for enforcement. So I am happy we are working on this and I will work with the majority on making sure this bill works.

I did want to ask you, Dr. Schuchat, about the PDMPs, the prescription drug monitoring programs, because those are really a valuable tool to prevent the misuse and abuse of prescription opioids and of course it is administered by the States. The problem is that these systems can have a lag of a few hours to almost a week before the prescription drug data is available. I am wondering what the CDC is doing to help encourage real-time opportunities for detection in the PDMPs?

Dr. SCHUCHAT. Yes the real-time nature is critical so that you get the information current today, not a week old or a month old. The funding that we are providing to 45 States right now helps them get there, but most of them aren't there yet.

Ms. DEGETTE. So what can we do to improve it?

Dr. SCHUCHAT. Yes. The information technology is there, it is getting the upgrades it to the systems that they have.

Ms. DEGETTE. If we can work with you on that let us know.

Dr. SCHUCHAT. Absolutely. Absolutely.

Ms. DEGETTE. The other thing is some of the States, like in my State in Colorado, they are putting together regional PDMPs and that would seem to be something that you can really encourage.

Dr. SCHUCHAT. We think that the States have a good platform, but having a national platform that they can plug into will help with the interstate interoperability and getting really the upgrades to everyone.

Ms. DEGETTE. OK. Dr. Jones, Dr. Burgess asked you about the recent press reports about the SAMHSA funding of $500 million from Congressman Upton's and my 21st Century Cures bill that this whole committee worked so hard on. And we were really proud

that we got $1 billion to help expand States' treatment programs. We have already had $15.7 million in Colorado. It has already helped 22,000 people in Colorado. You said the States are having trouble getting that money out. What can we do to help encourage the States to be more efficient and get that money out? And also, do we really need to give them more money if they can't get the money that we have already given to the treatment and prevention?

Dr. JONES. So I think that some of this is working through the procurement process at the State and there are wide variations and what that looks like at each individual State——

Ms. DEGETTE. I understand you said what the problem was. What can we do to help?

Dr. JONES. Right. So I think one that can be done is to share information where you hear that there are bottlenecks in the system. We would like to——

Ms. DEGETTE. With you? Great.

Dr. JONES. Absolutely. We would like to engage on that. And as we implement the technical assistance at the State level I think that is also another place to engage and provide information to SAMHSA.

Ms. DEGETTE. OK. And do you think that we need more money right now or do we need to get this money out?

Dr. JONES. I think that when you look at the magnitude of the problem while there have been challenges in getting the money out, the scale of the epidemic is large and growing.

Ms. DEGETTE. You think it is worth getting more money?

Dr. JONES. It is important and certainly the 2019 budget supports increases in funding for that.

Ms. DEGETTE. OK. Great.

Dr. Gottleib, I just want to finish with you. One of the bills that we are considering would direct the FDA to issue guidance outlining how and when the FDA would provide accelerated approval and breakthrough therapy designation for treatments to treat pain or addiction. Breakthrough therapies, that is another bill that I worked on and it has really worked, but sometimes—and we know that it can benefit patients, but we need to make sure that it is not unduly taking a toll on the FDA's resources.

You know in 21st Century Cures we also paired new pathways with new funds. What has the experience with the agency been with the resources required for accelerated approval pathways and do we have appropriate resources?

Dr. GOTTLIEB. I will just say that pain is an immediate and subjective endpoint. We can establish it fairly quickly with a limited dataset using scales, analog scales that we have like measure your pain from 1 to 6 or the smily face. With respect to accelerated approval, we don't have a good prototype for an objective buyer marker in this context. The issue with respect to the approval of new pain drugs and drugs that might not have all the abuse liabilities associated with opioids, is typically not demonstrating efficacy. We could demonstrate that fairly efficiently, I don't want to say small but in a very reasonably sized clinical trial, dozens of patients not thousands and hundreds of patients. The issue is more on the safety side.

We have not seen a drug in any pain drug for chronic administration that hasn't had some liabilities associated with it, some safety issues associated with it. So this has been when you are administering one of the drugs over a prolonged period of time, whether it is acetaminophen or the unsaid class now gabapentin, certainly the opioids we have seen side effects associated with just about every drug. So that is where we usually require more robust data premarket to try to discharge any safety concerns.

Ms. DEGETTE. Sort of the opposite of what often happens. Thank you, Mr. Chairman.

Mr. BURGESS. The lady yields back.

The chair recognizes the gentleman from Ohio, Mr. Latta, 5 minutes for your questions.

Mr. LATTA. Thank you very much, Mr. Chairman and thank you very much for our panel for being here today because as we all know about every member in this committee represents the district is having a real epidemic on their own.

Unfortunately Ohio, we all know what is happening there. We are behind Florida and Pennsylvania, we saw in 2015, 3,050 people pass away, we saw in 2016 that number went up to 4,050, in the fiscal year ending on June 30 of last year it was 5,232 people. So it is affecting lives across this country and it is destroying too many families. And so many babies are being born with complications with addiction issues and losing their parents so it is truly an epidemic in this country.

With my legislation the INFO Act, that I have introduced it is important, in my belief, is because one of things that I have run across in my district and talked with professionals out there, law enforcement, it is very difficult for individuals out there to find especially from smaller areas that I represent they doesn't have grant writers that can go out and get help. So what we want to be able to do is have a dashboard out there for these individuals to go to and not only find help but also to find what really takes finding the money.

Dr. Schuchat if I could start with my questions to you, in your testimony you stated that data are crucial and driving public health action, timely high quality data can help public health, public safety, and mental health excerpts under the problem focus resources where they are needed most and evaluate the success or prevention and response efforts. And I couldn't agree more.

Making that data publicly available is a large component of my bill the INFO Act because again I believe this crisis is going to get worse and we need to fight it. Would you speak in depth to how the data derives public health action results?

Dr. SCHUCHAT. This has been a fast moving epidemic and we have seen changes in the principle factors that are driving it so the more timely our data are, the more rapidly we can target interventions. In some States having timely, complete data helps them identify hot spots with increased drug supply or increased overdose occurrences and helps target the resources that can be built there. Whether it is the wraparound services or strengthening the Narcan distribution so we can resuscitate people.

At the clinical level, it can be very important to know what happened to your patient. And so one of the innovative approaches

being used right now in some States is after there is a fatal overdose alerting anybody who gave a prescription to the individual who overdosed in a period before the fatality so that the clinician actually gets that reinforcing behavior that sometimes prescriptions can be contributing to unintended consequences.

We know from medical practice that feedback on how you are doing helps you improve and most of us think we are doing better than we are, so getting feedback into how you are prescribing and the outcomes for your patients.

The other point of data is to know what works and how we can scale that up, and so with all of the expansion, we hope, of the medically-assisted treatment we need to really understand more in a more timely way which approaches work best for which kinds of patients. We are working with SAMHSA right now to evaluate different courses of medically assisted treatment and multiple outcomes for patients.

Mr. LATTA. Dr. Jones, you also mentioned strengthening public health data and reporting. Do you have anything to add about how data can serve to combat this epidemic that we are in?

Dr. JONES. I will just add that I think it is important the more timely data we have the better we can help States as they are thinking about how are they spending down dollars and where are the needs, rural versus urban, different populations. The more granular we can get and the more timely we can get we can be more efficient and targeted with our resources.

Mr. LATTA. Thank you.

And also Dr. Jones, the common thing and again as I mentioned I hear in my district, is finding that grant opportunities or other funding streams, which is very difficult. And that is again why I introduced my legislation this dashboard. How is SAMHSA currently putting out information on their targeted grant programs to support prevention treatment and recovery?

Dr. JONES. So we use a variety of different means to get information out about grants. So we have a specific grant web page on the SAMHSA website that is right at the top where you can find information what are the application processes, we also post on grants.gov so as a more centralized hub for funding. And then we put out press releases or different announcements to stakeholders who would likely be the potential grantees so that they know that today SAMHSA announced X amount of funding for this and then articulate who is eligible for that.

After we make announcements of funding opportunities we often hold webinars or calls with potential grantees to walk through what is the intent, what are the deadlines, what do you need to put in your application and to answer questions to really help people be successful in their grant application.

Mr. LATTA. OK. Thank you very much. Mr. Chairman, I yield back.

Mr. BURGESS. The gentleman's time has expired.

The chair recognizes the gentleman from New Mexico for 5 minutes for your questions, please.

Mr. LUJÁN. Thank you Mr. Chairman. Quickly, it is my understanding that you had a very good hearing yesterday in O&I specific to West Virginia, Mr. Chairman. And I just want to thank you

for holding that important hearing. I think it would be fruitful to find out what is happening in other States as well. In New Mexico our Attorney General Hector Balderas has——

Mr. BURGESS. If the gentleman will yield. That was actually oversight investigation so that was a gentleman from Mississippi who actually chaired that committee.

Mr. LUJÁN. I apologize, Mr. Chairman. Well, Mr. Chairman, I know that you share the goals of what was conducted in O&I as well. All of these States are trying to get this level of data including New Mexico and our Attorney General Hector Balderas, the automation reports and consolidated order system, ARCOS. The data is invaluable. And I think all Members and States would benefit from seeing this data. I think that it is important that the committee work together to make sure we are able to being access that information.

Dr. Schuchat, I know that the opioid crisis put a major issue that your agency has been dealing with over the past decade or more correct?

Yes? I see a nod yes.

I also know the CDC has been concerned about the opioid prescribing rates for quite some time as well. Is that correct?

Dr. SCHUCHAT. Increased concern since 2010.

Mr. LUJÁN. Increased concern since 2010, not since before 2010?

Dr. SCHUCHAT. No. There has been concern, but I would say there has been accelerated concern as we saw some of the data.

Mr. LUJÁN. I appreciate the clarification. In fact, isn't it true that you issued prescribing guidelines to providers last year because of the concern that an over supply of these drugs has contributed to the opioid epidemic.

Dr. SCHUCHAT. Yes, in 2016 we issued guidelines for chronic pain.

Mr. LUJÁN. As you know, this committee has been trying to investigate some of the distribution trends regarding opioids in certain communities. We have tried to understand where increases have occurred and whether those increases represent over distribution. So I would like to share with you a chart showing some of the opioid trends in my district.

I think that there should be a hardcopy in front of you as well. This chart is based on DEA's public ARCOS data. It showed the total amount of hydrocodone and oxycodone a distributor sent to the zip codes in my district from 2000 to 2016. As you can see, the amount of oxycodone increased dramatically by over 400 percent between 2000 and 2012. So the question that I have actually in my district population actually fell during this time period. So what I am interested in understanding is which of these numbers reflects true medical need of opioids in my district?

Dr. SCHUCHAT. There is excess opioid prescribing throughout the country and what we have right now is a sixfold variation from the highest prescribing counties to the lower prescribing counties. We think we can decrease opioid prescribing substantially with best practices about treatment both for chronic pain and for other conditions because too many people get started on opioids who don't need them and some people are continued on opioids after the time where they are necessary.

Our prescribing guidelines from 2016 began a process to improve prescriber practices, the upgrades to the prescription drug monitoring programs and the consumer facing awareness campaign, that we are running, should reinforce improving practices. We have done this before with prescribing for antibiotics in pediatrics where we did start to see decreases, and we think we can do this again.

So I would not say that one of these numbers is the right one. Currently in the United States we have threefold the prescribing of opioids that they have in Europe but we do not have threefold the pain that they have there.

Mr. LUJÁN. So, well you may not be able to identify now or suggest that any of these numbers are correct, would you agree that this trend is alarming and concerning?

Dr. SCHUCHAT. Absolutely, it is terrible.

Mr. LUJÁN. And so does the CDC use this information to identify trends in States so that they can alert us when there is a problem?

Dr. SCHUCHAT. That is right. And we issued a report last summer of the county level opioid prescribing and shared the data, the more granular data with the counties and States so that they could take action at their hotter spot localities, but we also think working with the healthcare professional groups, the licensing groups, the education of our trainees will help us get prescribing into better order.

Mr. LUJÁN. Mr. Chairman, as we can see, these trends in New Mexico there is another slide that we have, we don't have it up for the big screen today, it is consistent with the national trends across the country and what is concerning to me is it is only because of the attention that has been brought by one of our colleagues on the Committee from West Virginia about a small community and what is happening with distributors out there, that now we have staff majority and minority that are looking into this issue.

And which of the Federal agencies is supposed to be doing this work? That is my concern. I don't know that they are doing it because these problems are continuing to grow, get out of control. And so we will continue to submit questions, take a deeper dive and I want to thank the majority and minority staff for the work that they are doing. These oversight hearings are critically important and us making sure that we can do everything that we can to get to the bottom of this. So Mr. Chairman, thank you for the indulgence and to the staff I appreciate the work on the issue.

Mr. BURGESS. The chair thanks the gentleman. The chair likewise appreciates the work of the staff on this.

I recognize Mr. Lance of New Jersey, 5 minutes for questions, please.

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

And before I ask questions, I would like to submit for the record letters from various groups in support of legislation, which I am working, eliminating opiate-related infectious diseases, a letter from the National Association of County and City Health Officials, a letter from the National Alliance of State and Territorial AIDS Directors, a letter from the National Viral Hepatitis Roundtable, a letter from the American Liver Foundation, and a letter from the AIDS Institute.

Mr. BURGESS. Without objection, so ordered.

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

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

Dr. Schuchat, I note that in your testimony you mentioned opiate-related harms of infectious disease and how surveillance for viral hepatitis is limited. I commend you for that because my questions are on this topic.

Why is understanding the scope of infectious disease important with regard to the opiate's Federal response and how does the work of the CDC dovetail into the broader strategy?

Dr. SCHUCHAT. Yes. Many of the infectious disease complications of opioid use or injecting drug use can have lifelong consequences, not just for the individual, but also for those they are in contact with. Clearly, hepatitis C can lead to long-term complications, including liver failure and cancer, and hepatitis B can be passed from mother to baby and lead to chronic infection in the child as well. Of course, HIV is treatable but at terrible consequences, injecting drug use. While we have seen decreases in HIV in injecting drug use, we are starting to see that pattern change right now with our recent opioid problem. So improving surveillance for the infectious disease complications of opioid use is very important in order to better target resources and get screening and care to those who need it.

Mr. LANCE. Thank you. I hope you will review legislation I just introduced with my colleague, Congressman Kennedy, on the other side of the aisle on this committee, completely bipartisan in nature.

My understanding is that currently CDC is running a hepatitis C surveillance program in 14 States, including the State I represent, New Jersey, at a cost of $3.2 million. The current program is passive surveillance, but I have been told by CDC that, with additional resources, the agency could plus up to active surveillance.

Doctor, Could you please speak to the types of tools and resources that the CDC could activate with additional funding?

Dr. SCHUCHAT. Yes. The hepatitis C surveillance isn't wide enough spread. And, in fact, broader surveillance for viral hepatitis, the other types as well, could help, because we are seeing consequences of hepatitis A outbreaks in addition to the hepatitis C and B problem.

The problem with hepatitis C is that a single lab test doesn't necessarily tell you if it is a new infection or an old infection, and so the active surveillance approach, collecting more data, could be very helpful in broadening from the 14 States.

Mr. LANCE. Thank you. Congressman Luján mentioned the incidence of opiate abuse across the country, and I believe you indicated in your response that it may vary, I guess this would be county by county, up to a sixfold. Is that right?

Dr. SCHUCHAT. It is the prescribing that varies sixfold, but the overdose rates vary substantially as well.

Mr. LANCE. Are those figures readily available county by county?

Dr. SCHUCHAT. Yes. We posted the figure last July, and it is available from our website, for the county level data.

Mr. LANCE. Thank you. I would be interested. I have not reviewed that. I would be interested to know where the counties I represent might stand in that. Thank you for that information.

Dr. Gottlieb, you have spoken extensively to the challenges the agency is facing when it comes to intercepting illegal drugs at international mail facilities, and we have had a discussion about that this morning. Can you give us any idea of the sheer volume of unlabeled drugs that come into this country?

Dr. GOTTLIEB. Well, if I may, Congressman, I brought some pictures from our visit to the IMF at JFK, if we can just walk through them.

Mr. LANCE. Thank you.

Dr. GOTTLIEB. So this is the JFK International Mail Facility. This just shows you the package volume coming into the facility.

If we can go to the next slide. These are parcels that were refused and subject to destruction under 708, the FDASIA authority that was mentioned here today. And this is 318 parcels shown in the background, this photo.

Mr. LANCE. This photo was taken recently?

Dr. GOTTLIEB. Recently. This is from the visit that Chairman Burgess and I did to this facility.

These are about a million counterfeit and misprinted drugs scheduled to be destroyed early this spring.

The next slide.

[Slide shown.]

These are, again, packages that were flagged for refusal. We are going to send them back. And you see the red stickers on them.

Next slide.

[Slide shown.]

I had mentioned that we see packages with unmarked tablets. This is one such box that we saw that day of a box of purple pills. I am not sure what they are. I wouldn't suggest trying one.

Mr. LANCE. I will not.

Dr. GOTTLIEB. Next slide.

[Slide shown.]

This is another shipment of unknown green pills that came in from Hong Kong. This was shipped as cosmetics. These haven't been tested. We are not sure what they are right now.

Next slide.

[Slide shown.]

This is another box containing loose blister packs, again, with no labeling, so it is unable to determine what they are based on labeling.

Next slide.

[Slide shown.]

This particular photo was taken at our Secaucus mail facility. We have another IMF in Secaucus.

Mr. LANCE. To the Nation, Secaucus is in New Jersey. And the Kennedy Airport is owned by the Port Authority of New York and New Jersey, a bi-State facility.

Dr. GOTTLIEB. I know it well. I grew up nearby.

This, again, is unmarked pills. And so this is typically what we see when I am talking about the difficulty in establishing labeling.

Next slide.

[Slide shown.]

When I talked about multiple shipments of boxes or small boxes, this gives you a good indication. These are 10,000 separate boxes from one shipper.

Next slide.

[Slide shown.]

Just some more photos of those individual small boxes from one shipper. This came into the Miami IMF, actually.

Next slide.

[Slide shown.]

This shows you what we are increasingly seeing, which is small packages with a lot of different drug contents in them. And since we take a risk-based approach in the IMFs, typically we might not be opening for inspection the very small packages where it looks like it might be for personal use.

The next slide.

[Slide shown.]

This, again, shows you an individual package, again, with a pot-pourri of different drugs in it, including opioids. The drugs on the far right with the green labeling are actually narcotics.

Next slide.

[Slide shown.]

These are two individuals watching——

Mr. LANCE. Who is the person on the left there?

Dr. GOTTLIEB. Well, we were bravely watching this package being opened while the CBP official was masked. We braved it. It is a fair point that the CBP officers, and our own, but particularly CBP, which is the first line of defense looking at the narcotics, do gown up and mask themselves because they don't know what they are going to be cutting into.

This was a big box of different drugs that we opened right off the line. So it had been x-rayed right when we were standing there, and we opened it up and found a lot of different kinds of drugs, including OTC products, which is unusual to find and raises some suspicions.

Next slide.

[Slide shown.]

This is a teddy bear. We didn't set out to seize the teddy bear, but—next slide.

[Slide shown.]

This is what we found inside the teddy bear. Again, unlabeled drug products. This is actually counterfeit Viagra.

And then final slide, if we can go to it.

[Slide shown.]

This is our laboratory facility in the IMF. So when we talk about trying to increase our footprint and improve the physical resources that we have there, this would be something that we would be looking to augment. And we have put some additional resources into this recently, but this is the lab that we use to do the testing in the JFK IMF facility.

Mr. LANCE. Well, thank you. My time has elapsed. But I point out how dramatic this is. And on a bipartisan basis, this committee intends to get to the bottom of it and to rectify the situation.

Thank you, Mr. Chairman.

Mr. BURGESS. The chair thanks the gentleman.

The chair recognizes the gentlelady from Illinois, Ms. Schakowsky, 5 minutes for questions, please.

Ms. SCHAKOWSKY. All right. Dr. Gottlieb, where were those packages going? There were addresses on there.

Dr. GOTTLIEB. I don't know the consignees offhand. All different places in the United States. I would just make one more observation that these are volumes that are clearly intended for secondary distribution. We are not typically seizing, unless a package comes in and we have some targeted information around it that would lead us to believe that it is a violative package, it might contain illicit substances, we wouldn't be looking at the small volumes. We are typically opening up the big packages or the packages that come from known locales or from shippers that we know to be shipping dangerous products into the U.S.

Ms. SCHAKOWSKY. They are going to pharmacies?

Dr. GOTTLIEB. Pharmacies, overseas pharmacies?

Ms. SCHAKOWSKY. No. Directed to pharmacies.

Dr. GOTTLIEB. It wouldn't be commercial pharmacies. These are typically going to illegal routes of distribution in the U.S. Again, we are looking at volumes that are intended for secondary distribution. That big box of purple pills isn't going to an individual.

Ms. SCHAKOWSKY. Is there follow-up to the receiver of these pills?

Dr. GOTTLIEB. Depending on what we find, sometimes we refer hundreds of cases for investigation, and sometimes criminal investigation, depending on what we find. And sometimes when we hold up a package, we will then give a notification that it is coming through and maybe do a dummy drop, if you will, to try to find who is going to pick it up. A lot of times these are going to drop shipment points. They are not going to an individual's home or a business. So we will do investigations off of what we are finding in the IMF, depending on what it is and what our level of concern is. But we refer hundreds of cases away from these.

Ms. SCHAKOWSKY. Thank you.

On the opioid issue, Advocate hospital system in the Chicago area, I went to visit the Advocate Lutheran General opioid unit, actually a substance abuse unit. And they provide detox in their medically managed withdrawal unit. And it is an inpatient process. They only have 12 beds. It is 4 to 7 days. And many of the patients have mental health issues as well as substance abuse, including depression, anxiety, an undiagnosed mental health problem. But when the detox is over, there are not enough programs available to provide essential ongoing follow-up treatment. And so we talked about that.

So, Dr. Jones, I wanted to ask you, there is only a certain number of substance abuse beds available in facilities there, and there is a really long wait. Mental health resources for people have been steadily declining in Illinois and around the country. They were telling me that sometimes it takes 6 to 9 months to place somebody. So they do the detox. They say this is not treatment. This is just getting them stable. And then I said, and then what? In some cases, if a person is homeless, they are just out on the street again.

So I am just concerned about, and we have heard the President talk a lot about mental health, and we all talk a lot about mental

health, behavioral health. And so how do we really address this problem once we find people in need and get them sober?

Dr. JONES. I think it is a really important point that we move away from the idea that we need more beds. The vast majority of people who have an opioid use disorder can be treated very effectively in the outpatient setting, whether that be in an intensive outpatient treatment in combination with medications or in an office-based setting with the use or buprenorphine or naltrexone or methadone in an opioid treatment program.

So we certainly want to make sure that beds are available for those people who have, say, opioid use disorder with a co-occurring serious mental illness, and they need that acute care to stabilize before they are then moved into an outpatient setting or some sort of community-based setting.

Ms. SCHAKOWSKY. I think it is real obvious what we need to do. But my real question is what are SAMHSA or other HHS agencies actually doing to address this problem. It is not really mysterious on what we need more beds for detox, we need more behavioral health outpatient. What——

Dr. JONES. So the STR dollars, which are the opioid specific dollars that have gone out to States, are trying to build the capacity to provide that treatment on demand and moving away, again, from an inpatient treatment perspective to the outpatient setting.

I think it is also important to clarify that detox is not treatment. And if someone is detoxed, they absolutely should be connected to ongoing care. In particular, you could take advantage of the fact that they have been detoxed to induct them into Vivitrol or extended release naltrexone, because people need to be detoxed before they can be on that.

So we are putting dollars into States to build this system of care that can provide care for people with opioid use disorders. We are also making investments in workforce, because we could have all the money in the world for——

Ms. SCHAKOWSKY. Exactly.

Dr. JONES [continuing]. Capacity, but if we don't have people who can provide the care, we are not going to move the needle. So part of our work on the workforce side is, again, through our technical assistance that we are providing to the States, money within that TA program can actually be used to create teams that can train people to get a waiver to prescribe buprenorphine that can address other workforce-related issues. We have our providers clinical support system, which provides that mentoring and training network.

We often hear from primary care doctors that they are hesitant to engage with patients who have opioid use disorder because they don't feel supported. They are not sure that they can manage these patients, so we have a mentoring network that can be used to help shore that up.

And then we are also looking at things like Project ECHO, Centers of Excellence hub-and-spoke models that can handle, really, the acute phase, get somebody stabilized, and then pass them off to a primary care doctor who can manage them holistically moving forward.

So those are the things that we are using our dollars to invest in with the States. And through the TA, we are really trying to

support the rapid scale-up of those innovations, because people are at such high risk of dying if they are coming out of detox and they are not connected to treatment or if they are on a waiting list. And human life is too great to lose, and we should be building those systems that when somebody is ready, they can get the treatment that they need.

Ms. SCHAKOWSKY. Exactly. Thank you so much.

Mr. BURGESS. The chair recognizes the gentleman from Virginia, 5 minutes for questions, please.

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

Dr. Gottlieb, you all are not the only ones who are looking at some of these things. Am I correct in that? And the reason I raise that issue is you have said several times you all don't look at when the international mail facilities and so forth—and I guess I am trying to figure it out, because we recently had one of those drop sting operations in my district, but it was for a small amount of fentanyl to what would appear to be personal use for somebody who was just ordering it over the internet and coming in. They said in the newspaper article that was Customs. Would that have been you all as well?

Dr. GOTTLIEB. Customs has primary responsibility in the IMF for things identified as controlled substances. We will oftentimes work with them. We have criminal investigators that will sometimes work with them. We provide certain expertise.

Mr. GRIFFITH. But you focus on the big shipments. Is that correct?

Dr. GOTTLIEB. So what Customs will do, they will x-ray all the packages, and they will also do some detection, including with dogs, to try to pull out the ones that they believe have controlled substances. They will pull a certain number of packages that they identify with pills that they believe are for secondary distribution, based on either volume or where it is coming from. They will pull them for physical inspection for FDA in those facilities. They will only pull the number of packages on a given day that they think we can physically inspect inside each facility.

Mr. GRIFFITH. All right. Let's talk about that. The Blackburn bill is very interesting, and we heard comments from Mr. Lance, and you showed us all those slides. So what I am asking you is should we put into the Blackburn bill authority for you all to say a shipment has to have this specific labeling and give you the authority if that labeling does not exist for all those pictures we saw of the boxes and boxes of drugs that were unlabeled? You just automatically get to destroy those. Wouldn't that be helpful if we added that in?

Dr. GOTTLIEB. Well——

Mr. GRIFFITH. Yes or no, because I am running out of time.

Dr. GOTTLIEB. It would make us more efficient. The Blackburn bill does provide for that, because it allows us to make a determination that it is a drug based on chemical composition, if I am remembering the bill correctly.

And then we go to the secondary question of whether or not it is labeled appropriately. Most of these products wouldn't be. They would be misbranded.

Mr. GRIFFITH. And what I am indicating to you is if it is not labeled at all, before you even get to try to test it, if it comes in and it is not labeled——

Dr. GOTTLIEB. Information targeting, yes.

Mr. GRIFFITH [continuing]. Destroy it.

Dr. GOTTLIEB. You are speaking about the information with the manifest date and the information we have about the package or the labeling on——

Mr. GRIFFITH. Yes. You showed us pictures of all these unlabeled items coming in. You didn't know what they were. The purple pills, you weren't sure what they were. We know what they are supposed to be, and so forth. Wouldn't you all like the authority just to be able to say if it is not labeled in accordance with what you have set forth in your standards, it is coming from some foreign country, let's just destroy it? Wouldn't that free up a lot of time for going after the folks who might be shipping something in that is labeled but labeled improperly?

Dr. GOTTLIEB. If it is not established that it is drug at all——

Mr. GRIFFITH. Yes. Not labeled, destroy it.

Dr. GOTTLIEB. I haven't contemplated it. There would be dietary supplements——

Mr. GRIFFITH. Think about it and get back to me.

Dr. GOTTLIEB. Thank you.

Mr. GRIFFITH. I appreciate that.

Dr. GOTTLIEB. Thanks, Congressman.

Mr. GRIFFITH. Dr. Schuchat, we have got a discussion draft being considered to help the CDC and, in turn, the States build upon it and improve the State PDMPs, the prescription drug monitoring programs, to achieve maximum effectiveness. How would that discussion draft help CDC?

Dr. SCHUCHAT. Yes. We think that improving the State-specific PDMPs and access to a national platform, that would help them share data across States and have everybody benefit from the upgrades that individual States have done would be helpful. We need to make sure that we reflect the State-specific laws and policies and that they need access to their data to be able to use it and improve it, and we don't really want the lowest common denominator State to be what a new interoperable system would be. But greater attention to the prescription drug monitoring programs and the flexibility to improve them rapidly is important.

Mr. GRIFFITH. All right. Now, I know this is going to sound controversial, but you said something earlier that triggered my brain to work on something.

Dr. SCHUCHAT. OK.

Mr. GRIFFITH. You said that some of these programs will alert the healthcare provider if they are overprescribing an opioid. Is that correct?

Dr. SCHUCHAT. About high dose. If you have many different types of opioids, you can't, in your head, calculate what is the morphine milligram equivalent. In our guideline, we alert people that, over a certain level, special attention is needed, because the border between safely taking those medicines and unintentionally overdosing is small. So we want clinicians to recognize when the cumulative

opioid level is very high so that they can look into it and assess whether it is needed or not.

Mr. GRIFFITH. All right. Yesterday on O&I, we were talking with DEA and all the problems we are having there with pharmacies and some doctors. Would it be helpful or would it create problems if we shared that information when a doctor consistently, or a healthcare provider, consistently is giving too high doses out? Would it be helpful to share that information with the DEA so that we can maybe identify more quickly where we might have a problem? Try to educate first, if it is not criminal, but then look at it if it is.

Dr. SCHUCHAT. In most States, the medical boards would be looking at this high-level prescribing. I think we do think sharing information across systems is really helpful to alert for whatever the issue is. But in terms of what the prescription drug monitoring programs are doing is they are looking at prescribing to the patient, not the pharmacy level data. And Dr. Jones might have something to add there.

Mr. GRIFFITH. Dr. Jones, you want to add to that?

Dr. JONES. I will just say the States are—because PDMPs sort of fall under the rubric of practice of medicine, practice of the health professions, they have different variations in their State statutes. But many of them do have proactive reporting. So it is looking at, you know, outlier prescribers and either sending that, in some cases, to the medical board, in some cases to law enforcement.

Mr. GRIFFITH. OK. One of the issues yesterday was getting the information to show that a healthcare provider, whether it be a pharmacist or a doctor, was not following standard medical procedures in order to get a show-cause order. Now, I was more concerned with the ISOs, because I think they are not using those effectively and should be more aggressive on that. But in the show cause, this is information that could be very helpful. And I would hope we could figure it out. I know it is a little dicey.

And I appreciate your time and yield back.

Mr. BURGESS. The gentleman yields back. The chair thanks the gentleman.

The chair recognizes the gentleman from North Carolina, Mr. Butterfield, 5 minutes for questions.

Mr. BUTTERFIELD. Thank you, Mr. Chairman.

I too would like to thank you, Dr. Jones, for your testimony today, and all of you, as that goes.

Dr. Jones, I appreciate the many counter programs that you highlighted in your testimony earlier. This committee worked diligently on a bipartisan basis on 21st Century Cures and on CARA. One of those programs, the Minority Fellowship Program, is not mentioned at all in your testimony. I believe it to be appropriate to fully fund this bipartisan effort that we passed in the first iteration of CARA.

Dr. Jones, through research, has HHS come to the conclusion that there are significant behavioral health disparities in diverse communities across the country?

Dr. JONES. We certainly know that health disparities and social determinants of health play an important role in the overall health

as well as behavioral health for individuals. And creating culturally appropriate interventions that are evidence based are really important. Again, as I mentioned, we have the State TA program for STR dollars focusing on opioids, because we recognize that there are State-specific contexts in which interventions are going to be implemented.

So I think that is certainly an important area, and it is part of our overall rubric for how we think about dissemination and adoption of evidence-based practices.

Mr. BUTTERFIELD. So this research is ongoing and continues to be on your radar?

Dr. JONES. Absolutely. We continue to put out data and analyses from our National Survey on Drug Use and Health around different disparities that exist around behavioral health issues, whether they be substance use or mental health, among different racial ethnic groups, among different age groups, among people with lower socioeconomic status in a variety of different ways to really get a more comprehensive and holistic picture of how different individuals in our country are being impacted by these issues.

Mr. BUTTERFIELD. Very important.

This committee, Dr. Jones, unanimously approved the reauthorization of the minority fellowship program and an increase in its authorization. There is no other program that will focus on preparing behavioral health practitioners to more effectively treat and serve people of different cultural and economic backgrounds. We have heard that at SAMHSA's Center for Mental Health Services National Advisory Council meeting recently, the newly appointed assistant secretary for Mental Health and Substance Abuse expressed her support for this program.

Why did HHS propose elimination of this program in the 2019 budget?

Dr. JONES. I will just say, some of the specifics of our budget are still working through and, we have a budget and brief that is out, but the other specifics are still in process. We are committed to workforce development that is a priority for the assistant secretary in making sure that workforce development incorporates different racial ethnic groups who may have different impacts and differential impacts of substance use and mental health.

Mr. BUTTERFIELD. Well, considering the strong congressional and bipartisan support for this program, I would ask that you really take a serious look at reauthorizing and funding this program.

Chairman Burgess, I would like to submit for the record a bipartisan letter to appropriators in support of full funding for the Minority Fellowship Program, if I can find it. Here it is.

May I include it in the record?

Mr. BURGESS. Without objection, so ordered.

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

Mr. BUTTERFIELD. Thank you.

Dr. Gottlieb, a number of your colleagues have highlighted the tragedy of neonatal abstinence syndrome that occurs when a mother takes prescription or illicit opiates during her pregnancy, and her baby is born with a physiological dependence to that drug. Far too many babies are born into a life that begin with opioid depend-

ency because their mothers used or at least abused these drugs while she was pregnant.

Would you agree or disagree that there should be special treatments for these newborns?

Dr. GOTTLIEB. Congressman, I would welcome the opportunity to try to help any sponsor that is trying to develop treatment that could specifically address this tragic condition.

Mr. BUTTERFIELD. Well, it is my understanding that there are few options for treating opioid withdrawals in infants. If that is not correct, I would like to know it. But it is my understanding that there are few options for treating opiate withdrawal in infants. And existing options for these babies in the first month of life are not streamlined or standardized and none of the currently used therapeutics are FDA approved for the population.

Would you be willing to work with companies—you said you would work with us, of course. But would you be willing to work with companies and other stakeholders to help identify incentives to accelerate research into this area?

Dr. GOTTLIEB. We would be delighted to work with sponsors in this regard, Congressman. And I would be delighted to work with Congress to see what additional incentives we can try to craft to incentivize, you know, development for what is a very small population but a critical medical need.

Mr. BUTTERFIELD. Let me address in closing the testimony about the types of packaging and excess opiate disposal. Mr. Hudson and I are working on legislation to help assist with the FDA's efforts. Can you describe whether additional authority could be helpful in those efforts to limit the number of opiates dispensed to patients and to make it easier for patients to dispose of leftover opiates?

Dr. GOTTLIEB. Well, we are actively contemplating what we can do under our existing authorities to try to create pathways to blister pack some of the immediate release formulations of drugs. We have a working group that we stood up in the agency looking at this question. This might be something that is hard to reach under our current authorities to either mandate that or to require to be offered as an option that, then, the healthcare system could try to incentivize use of.

But we do believe, at a policy level, that if the IR drugs were in blister pack formulations that were—the number of pills that were appropriate for 3 days, 5 days, 7 days, I think you would see more default prescribing for those shorter duration uses. More physicians would opt for that. We see, in other areas of clinical medicine where there is convenience packaging, physicians will opt for that.

This is an opportunity, I think, for Congress to address this. Congress could conceivably direct it to be done, particularly for the IR drugs. But we will continue to work within the scope of our authorities to see whether this makes sense from a public health standpoint; if it does, how we reach it based under our current authorities.

With respect to disposal, we think that there are a lot of opportunities to provide for avenues to dispose of these drugs for consumers. I think it would very clearly take more pills out of circulation that didn't go on to be diverted. Because we have developed

data that shows a lot of pills are left over on an average prescription.

Mr. BUTTERFIELD. Thank you. I yield back.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back.

The gentleman from Texas.

Mr. GREEN. Mr. Chairman, I ask unanimous consent to place into the record a letter from EVERFI and also a statement by Congressman Hakeem Jeffries on H.R. 449.

Mr. BURGESS. Without objection, so ordered.

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

Mr. BURGESS. The chair recognizes the gentleman from Florida, Mr. Bilirakis, 5 minutes.

Mr. BILIRAKIS. Thank you, Mr. Chairman. I appreciate it.

Dr. Schuchat, the CDC released new prescribing guidelines for opioid back in March 2016, yet a recently released report by the agency indicates that, despite this change, ER admissions due to opioid overdoses have since increased by 30 percent nationwide, the Midwest by 70 percent, and by 54 percent in large cities in 16 States.

What is CDC currently doing to address this issue?

Dr. SCHUCHAT. Yes. We are funding 45 States and the District of Columbia to strengthen their community-based prevention work. We are particularly focused on the prescription drug monitoring programs so that we can improve prescribing and not have people start down the path toward addiction to begin with. But we are also doing work in part of the heroin response strategy on community level projects that explore innovative approaches like having recovery coaches in the emergency room to help people navigate into care from the emergency room.

So this is a big problem. It is getting worse. But we are supporting States, working with the medical community, trying to have system changes, and also doing consumer outreach as well.

Mr. BILIRAKIS. Why did we not see any type of an improvement with these new prescribing guidelines?

Dr. SCHUCHAT. We have actually started to see a decline in prescriptions of opioids. The recent increase in emergency department visits is likely related to the illegally manufactured fentanyl that we have been hearing about through the international mail facilities. While the prescribing is starting to come down, it is actually still too high. So there is a lot more room for improvement, and we are trying to scale up the uptake of our guidelines through medical care, through technology improvements, through academic detailing.

Mr. BILIRAKIS. What do you suggest we do as legislators?

Dr. SCHUCHAT. Well, I think the focus on this is critical, and the resources that have been coming in, are being proposed, are also very important. There are some authorities that could help speed things up. As you hear about the workforce gaps in the medication-assisted treatment world, there are similar workforce gaps in public health information specialists and so forth. So there are some things like direct hiring authority or loan repayment for certain kinds of these special needs that really need to increase for us to turn the epidemic around.

Mr. BILIRAKIS. Thank you.

And I appreciate you holding this hearing, Mr. Chairman.

Dr. Gottlieb, in your testimony, you mentioned that FDA's regulatory oversight over lawfully prescribed drugs gives your agency some important opportunities to impact prescribing in ways that can reduce the rate of new addiction, while making sure patients with medical needs have access to appropriate therapy, and that is all very important. We need a balance there.

Would you discuss these opportunities, sir.

Dr. GOTTLIEB. Thank you, Congressman. I just want to echo your closing statement about patients who have medical need. We have to remember that there are a lot of patients with chronic pain conditions, including patients with metastatic cancer pain who require long-term use of opioids. In some cases, opioids are the only drug that is going to work for certain patients, particularly patients with metastatic cancer pain. So we need to remember that in terms of what we do and how we titrate our policies, that we don't lock those patients out of critical drugs.

But we have taken steps with respect to the use of our authorities, particularly under the risk management plans that we promulgate, in conjunction with the prescribing of drugs, to try to put in place certain measures that will try rationalized prescribing and try to steer the provider towards more appropriate prescribing.

So earlier this year, we updated our REMS to include all the immediate release formulations of drugs. Previously, it was just applied to the long-acting formulations, the higher dose formulations of the drugs. But we know that most of the prescribing and most of the new addiction is through immediately released formulations of drugs. At least that will be the first medications that patients use.

We also expand that to include, not just physician prescribers, but anyone who comes into contact with the patients. So, for example, nurses and pharmacists. So we updated the education. And we also expanded it to include education around alternatives. So instead of just educating providers around the abuse liability associated with opioids and the proper prescribing of opioids, we are now requiring education to include alternative treatments for pain so that they have a full complement, a full picture, of what the scope of prescribing could be.

We are looking at other ways to try to steer prescribing in a better direction. Packaging, I have talked about trying to make potentially the education mandatory or make it mandatory if you want to prescribe higher volume, longer duration drugs. We are talking about maybe requiring sponsors to impose requirements where physicians have to document if they are prescribing certain patterns of use that we know comport with a higher rate of addiction, potential addiction, from the use of prescription products. So there is a range of things we can do.

I will say in response to the question you asked earlier on what can we do to get at this problem, it is very clear there is not a magic bullet here. There is no one solution. It is going to be a complement of many steps that we all take working together to try to effect a crisis of this magnitude.

Mr. BILIRAKIS. Thank you very much.

And I know my time has expired, Mr. Chairman, so I will yield back. Thank you.

Mr. BURGESS. Correct. The gentlemen's time has expired.

The chair recognizes the gentleman from New York, Mr. Engel, 5 minutes for your questions, please.

Mr. ENGEL. Thank you, Mr. Chairman.

I am pleased to be the Democratic lead on two of the bipartisan bills we are considering during this hearing: The Poison Center Network Enhancement Act and the RESULTS Act. And during this panel, I would like to focus on the RESULTS Act, which is a bill I have introduced with Congressman Stivers in a bipartisan way.

The goal of the RESULTS Act is to ensure that Federal grants intended to treat mental health and substance abuse disorders fund activities that are backed by sound evidence so it will help build the evidence-based innovative interventions. And while the concept is obviously straightforward, I want to be sure that it is executed carefully.

As we work to end the opioid crisis, we need to ensure that results drive decision making and that we always keep the door open to new and innovative approaches that could be game changers. And I hope that this discussion will help us strike the right balance.

One of the objectives of the RESULTS Act is to ensure that there are tools available for stakeholders looking to emulate activities and intervention that have shown results and may work in their communities. It is my understanding that SAMHSA intends to use the National Mental Health and Substance Use Policy Laboratory, or policy lab, created by the 21st Century Cures Act, which we are all proud about here, to make information about evidence-based mental health and substance use disorder interventions available to the public.

So in light of the suspension of the National Registry of Evidence-Based Programs and Practices, I am anxious to learn more about what the plans are for the policy lab. So, Dr. Jones, would you explain exactly what types of tools and information will be made available to the public for the policy lab? And when would you expect that policy lab to be fully operational?

Dr. JONES. Thank you the for question. I think it is really important that we are good stewards of our Federal dollars and that we are helping support, whether it be community programs or practitioners implement evidence-based practices. And that is really the frame that we are using as we are setting up a new resource center within SAMHSA, helmed by the policy lab, to accomplish that goal.

So what we are doing now is we are actually going through resources that already exist at SAMHSA that are broader than just sort of a program-by-program listing, which is largely what NREPP was, that can actually help facilitate communities and practitioners to understand what the context in which they want to implement an intervention based on that information, sort of a needs assessment, what are the right interventions that fit our needs, and then how do we actually implement that?

And so SAMHSA has spent quite a lot of time and resource in creating different types of evidence-based toolkits around a sort of community treatment or other mental health treatment approaches

or medication-assisted treatment or community-based substance use prevention, where those resources are somewhat buried on the website at SAMHSA. And we want to bring those to the forefront, because they really do provide the roadmap for how a community or a practitioner would implement evidence-based practices.

So we have been culling through that information. We have reached out to our colleagues across HHS who also have that type of information that could be useful. And we are synthesizing that in creating a website that we believe is quite useful across the spectrum so people from the public who are interested in these issues who are not expert in different topics would be able to point and click into the specific areas. So if they want to learn about youth substance use prevention, they would be able to quickly identify what are the fact sheets that might exist for that versus a community implementation guide, which might not be the most appropriate thing for them.

And similarly, we are doing that for clinicians. There are a number of clinical guidance documents that SAMHSA has put out. As I mentioned earlier, TIP 63 around medications. We have the CDC opioid prescribing guideline. And putting that into sort of a one-stop shop where individuals can get to that. We are absolutely committed to advancing the adoption of evidence-based practices. That is what has been asked of us by Congress for the policy lab, and the assistant secretary as well is committed to that.

Mr. ENGEL. Well, I am glad to hear it. Let me ask you one more question. How will the policy lab help expand access to evidence-based treatment and promote results-driven activities? And the second part to that is how can we in Congress help SAMHSA achieve those goals?

Dr. JONES. So certainly the charge that was given to the policy lab is a tremendous step forward in helping us to do that, to identify what is working and to help disseminate that information. So one thing that we are doing specific to medication-assisted treatment, with our STR opioid dollars, there are quite a lot of natural experiments that are happening in the States. Sort of a natural laboratory of people looking at how do we initiate buprenorphine in the emergency department and connect people to care? How do we scale up medication-assisted treatment in the correctional population? How do we look at these different systems of care?

And so what we are doing now is engaging with States to actually evaluate those innovations and interventions. And the plan would be to very quickly, once we identify what is working, to then disseminate that information out. But also to infuse it into our funding announcements so that we are actually helping to drive evidence into practice through our funding streams and not continuing to support non-evidence-based practices to the money that we are putting out.

Mr. ENGEL. Thank you very much.

Thank you, Mr. Chairman.

Mr. BURGESS. The gentleman's time is expired.

The chair recognizes the gentleman from Missouri, Mr. Long, 5 minutes for questions, please.

Mr. LONG. Thank you, Mr. Chairman. Thank you for having the hearing. And I thank the witnesses for being here today.

In Missouri, from 2012 to 2016, we experienced a 78 percent increase in opioid overdose deaths. I experienced three of those myself, people, friends of mine, lost children in their 20s in those same years, 2012, 2016. They were children from Columbia, Missouri, University of Missouri; Springfield, Missouri, 160,000 population; Kansas City, Missouri. So these were not rural areas.

However, in that study that the Missouri Hospital Association did that showed a 78 percent increase from 2012 to 2016, the biggest spike was in the rural areas. I do a farm tour every year, an agricultural tour, where we tour through our district. I have a lot of rural areas in my district. And we were driving along on the bus one day, riding along in the bus, and looking out. It was just picturesque. It was just gorgeous. It looked like you could have a farmland ad on their, pop on TV, even with the green fields and everything. And the fellow leading the tour said that their number one problem in that area was heroin addiction of the high school kids.

And so my question is this, for Dr. Schuchat, with that sharp increase in the rural areas, how do we ensure that rural areas are getting the resources they need to combat opioid abuse? And what else do you think needs to be done to make sure the rural areas can adequately address abuse?

Dr. SCHUCHAT. Yes. Thank you for that question. It is a terrible problem in some of the rural areas. One of the things we have been doing is working with SAMHSA on evaluating the distribution of naloxone to help wake people up who have overdosed. And there are some gaps in rural areas in a lot of States. So trying to make sure there is the naloxone distribution, but also ability to link to care and the recognition that, perhaps, you know, telemedicine may be helpful for some of the treatments where there are low access areas.

I think it is a big problem that is going to take a lot of time, but the way that CDC is helping is by providing resources to the State health departments and letting them improve their data so they know where the hot spots are so they can improve prevention, treatment, and recovery in the hot spot areas, which in many places are rural.

Mr. LONG. Dr. Jones, you care to elaborate on that?

Dr. JONES. Sure. I would just add that we have actually worked collaboratively with CDC. We did a paper last year looking specifically at drug overdose and drug use disorders or substance use disorders in rural areas to highlight this important issue.

With our STR dollars, again, looking at the system's innovations is a way to help address some of the capacity issues in rural areas. I will use Project ECHO as an example, which started in New Mexico, which has historically had very high rates of opioid addiction and overdose in very rural communities that have very little infrastructure for healthcare. And Project ECHO is at the University of New Mexico. And they actually worked with the rural providers to train them, to provide them with resources that really help support them to provide addiction care in the community so that the individual from the rural area didn't have to travel to the academic medical center 2 hours away in order to get care.

So with our opioid State-targeted response grants, a number of States are looking at that Project ECHO model, looking at other innovative models that you can build that capacity in those areas to address those issues. And I think, again, underscoring the importance of the data to understand where do we need to be targeting those resources is really critical, and working with the States to analyze that data to say, you thought you had a problem in city X, but it is actually city Y, and we need to make sure that we are deploying resources to that area.

Mr. LONG. There is a fellow that sits behind you all occasionally in here, comes in here, quite a few times. He has a son that, I think when he was 19 or 20 years old a few years ago, got out of rehab for his third time. They had, I believe, Christmas, whatever dinner, and opened packages. And the son went upstairs, and they found him on the floor in the bathroom. And they thought he was dead. They got him to the hospital. The EMTs revived him, got him to the hospital.

And he looked at his dad the next day in the hospital, and he said, Dad, I knew when I got out of rehab that I couldn't do the same amount of heroin that I used to do. But I can hardly get it to melt on a spoon, and it about killed him. So they got him on whatever drug it is, the high-price injection thing. I say high price, $1,000 a month. YAnd he has done really, really well since then.

Is it money? If you had all the money in the world, can we attack this problem or not? If you had said, Dr. Gottlieb or Schuchat or Jones, whoever, if you just sit there and write checks all day, is there anything we can do that—what would be the most effective thing we could do if you had an unlimited budget for this problem?

Dr. JONES. Well, certainly, resources are helpful. But as I mentioned earlier, a workforce is equally as important. And we have a lack of sufficient workforce to address the addiction and mental health problems that face our country. So I think——

Mr. LONG. So if you had the money, could you hire the help, or there is just nobody in those fields?

Dr. JONES. We have to think about how resources are used. So part of that is to build that capacity, which is what we are doing with the funding that we have now. So it is building the workforce, it is building the systems, it is building the infrastructure.

So many of the issues that we are talking about today are really the things that we need to be doing to advance that. It is just how do we more quickly scale those things up, and resources are clearly a part of that.

Mr. LONG. OK. I am way past my time.

I yield back. Thank you.

Mr. GUTHRIE [presiding]. I thank the gentleman for yielding back.

And the chair recognizes Dr. Bucshon from Indiana for 5 minutes for questions.

Mr. BUCSHON. Thank you, Mr. Chairman. I was a physician before I was in Congress, so we have kind of seen this coming for quite a while, and I am really pleased that now there is a national attention on this issue.

Dr. Schuchat, I am interested in finding solutions to the opioid epidemic partially by focusing on addressing the underlying causes

of the opioid use disorder and specifically looking at innovative solutions to address acute and chronic pain. Does the CDC collect statistics information about how many Americans suffer from chronic pain or information related to access to treatment?

Dr. SCHUCHAT. That is not a core part of our surveillance systems right now. We don't think that pain itself has increased over the past few decades, but we have changed how we were prescribing for pain with the availability of the longer acting opioids.

Mr. BUCSHON. Is there a need for more information, you think, in that space?

Dr. SCHUCHAT. There has certainly been an increase in people with chronic diseases that we are tracking, and so I think better understanding of pain and the different factors contributing to it will be important, as well as access to alternative approaches for pain management, which are safer and perhaps more effective.

Mr. BUCSHON. OK. Yes. Because pain is very subjective, and it is sometimes difficult to put your finger on it. I can tell you just doing the surgery that I did, the variance in the amount of postoperative discomfort that people would claim to have, that did have, but the severity of that is across an entire spectrum. So that is difficult.

So information on people that truly have chronic pain syndromes that may require long-term opioid treatment might be important, because I think that is one of the concerns that I think patient advocacy groups in that space are concerned about, and information on the actual number and how we deal with that might be helpful.

Dr. SCHUCHAT. Yes. I think it could be helpful, but also knowing what are the best approaches for that. Recently there was a randomized control trial that compared opioids with nonsteroidal anti-inflammatories for back pain and some other things. And at a year out, people who were on the nonsteroidals actually were doing better.

Mr. BUCSHON. I know. I know that. I just read that.

Dr. SCHUCHAT. Yes. So I think we have been taught that we were undertreating pain, and people thought the way to treat pain was with the opioids, and probably there are better ways to treat many kinds of pain. But, of course, not all. And our guidelines were not to take pain medicine away from people with palliative care, metastatic cancer, and end of life, and so forth. But there is a lot of overprescribing.

Mr. BUCSHON. The treatment of pain itself, people become tachyphylactic to the treatment, right? They get resistance so they need more and more. And it may ultimately allow these patients, like you pointed out, the pain actually initiated the therapy in the first place is not the reason why they are continuing to take the medication.

Dr. Gottlieb, successfully tackling the opioid crisis requires, in part, ensuring that patients have access to alternative effective treatments for chronic pain. I would like to note the recent FDA education blueprint for healthcare providers involved in the treatment of monitoring patients with pain highlights the importance of provider awareness regarding the range of therapeutic options for managing pain, including nonpharmacological approaches and pharmacological nonopioid therapies. And further, that non-

pharmacological approaches include the use of approved, cleared medical devices for pain management.

And I know there are a number of existing medical technologies on the market today, including spinal cord stimulation, implantable drug pumps for nonopioid medications, radiofrequency ablation, among a variety of other things.

Could you speak to your perspective on the role of medical technology such as these and others in advancing the treatment of pain and alleviating, partially helping with the opioid crisis?

Dr. GOTTLIEB. Well, I think it plays a critical role. We have over 200 approved medical devices for different pain indications. About 10 of those are very novel technologies. And I think that there is a lot of opportunity for medical devices for a lot of different pain syndromes, particularly where you have regional pain, where you might be taking a systemic drug for what is a regional condition, a regional musculoskeletal pain, in particular, where you might be able to address it with a medical device that is delivering localized anesthesia. So there is a big opportunity.

We are looking at what we can do through our policy tools to try to incentivize development there. We are looking at particularly some challenge programs and trying to get out better guidance on the development of devices that could address pain as a way to try to incentivize more development of those kinds of products.

Mr. BUCSHON. Do you think you have the tools that you need in your toolbox to get some of these innovative products to the consumer or are there barriers that are legislative that might be necessary to help you along in that process?

Dr. GOTTLIEB. I would be happy to give that some thought, Congressman. I can't say right now that there are limitations in our review authorities where we don't have adequate flexibility to make some accommodations here or think in innovative ways. We do have flexibility under the medical device statute, which allows us to titrate the regulatory touch to the sort of complexity of the product and the risk inherent in the product. We do have flexibility on the medical device side of our house to address unique situations where we might want to foster more innovation. So I can come back to you. I will take it back to my folks. I have asked the question internally, and we have come up with things that we think we can do under our existing authorities.

Mr. BUCSHON. OK. I appreciate that. Yes. The actual barrier could be over at CMS at the end of the day, sometimes. I think I found that to be true since I have been in Congress. So we are trying to address that side of it also. Thank you.

I yield back.

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

And the chair recognizes Mrs. Brooks from Indiana, 5 minutes for questions.

Mrs. BROOKS. Thank you, Mr. Chairman.

Some time ago, in about 2015, Indiana, Scott County in particular, experienced a horrific HIV outbreak. And I know the CDC, a lot of different agencies, were very involved in helping us curb that outbreak. And now most recently, we are seeing, and papers are reporting, a massive increase in hep C cases throughout our

State, and in some of my counties I represent specifically, and them being directly connected in many ways to opioid abuse.

And so we know that the majority of these infectious diseases are attributable to injection drug use, and we know public health officials are focusing hard on these problems and on solutions. But I guess I am curious, I want to come back to the CDC. I believe we have talked about this in the past having to do with the HIV outbreaks.

But can you talk to us about, Dr. Schuchat, what you are doing to continue to monitor the infectious disease outbreaks, particularly as we are not turning the tide on the opioid use, and what kind of levels are we seeing nationally, and what tools are available to States to help them react or to try to get ahead of it maybe faster than we are right now? Because I think we are losing another battle, in addition to the opioid battle, but they are, I think, very related.

Dr. SCHUCHAT. Yes. The Indiana outbreak in Scott County was a wake-up call, and we did modeling to identify over 200 vulnerable counties around the country that could be just like Scott County, in terms of outbreaks of HIV or hep C in the context of the opioid use. We distributed that information to the State and local health departments, but much more is needed in terms of improving the surveillance for those infectious disease complications of opioid use disorder. And also the screening treatment and longer term care. The hepatitis C is increasing in many areas, but we don't have as good surveillance for it as we would like.

Mrs. BROOKS. Can you talk to us, though, about surveillance tools that either you use or do you need any additional authorities? How are you surveilling for these outbreaks?

Dr. SCHUCHAT. Yes. The surveillance is usually laboratory based, that the labs do the testing, but there is often a need for active followup to determine is it a new infection? Has it already been reported somewhere else? So it is really strengthening that public health front line infrastructure in the labs and the health departments to be able to improve the quality of surveillance and see the information back more rapidly.

Mrs. BROOKS. So that collaboration that you have with the State and county labs in many ways and State health departments, is there additional funding that as we are hopefully getting ready to in this next budget provide a lot more funding to State and locals who are on the front lines of this, is this something that we need to make sure or that SAMHSA and the grants they put out, that you all can make sure there is more funding for this type of surveillance?

Dr. SCHUCHAT. Yes. This type of surveillance does need to be better supported. We are tracking some of the infectious complications, but not all of them. And we are not doing it quickly enough. We think that better data on prescribing, better data on overdoses, and better data on infectious complications will all help us turn the epidemic around.

Mrs. BROOKS. Are there any other infectious diseases specifically that we ought to be looking for, monitoring for, and raising the level of awareness with our State and local health officials?

Dr. SCHUCHAT. Yes. I would like to signal the need for a nimble and flexible public health response. We wouldn't have expected hepatitis A to increase and associated with injecting drug use, but it has. And we have had large outbreaks in Michigan, in multiple States, California, many States around the country, of hepatitis A. So we think that the broader infectious disease complications of injecting drug use or of the opioid epidemic would be helpful.

Right now, we have a group A strep, the flesh-eating bacteria outbreak that is associated with the injection of drugs. So I think——

Mrs. BROOKS. Would you repeat that?

Dr. SCHUCHAT. The group A strep, which people have heard of as the flesh-eating bacteria, we are having an outbreak of that that has been traced back to injecting drugs. It can come in through the skin.

So I think just as we started this wave of overdoses with prescriptions complicated later by heroin and most recently fentanyl, in terms of infectious diseases, we have to have our eyes wide open. I was talking to a colleague earlier about an outbreak in Scotland of cutaneous anthrax that was associated with injection drugs there. So we need to really look broadly. And certainly, the viral hepatitis infections are the leading ones that we have to be worried about.

Mrs. BROOKS. Thank you. My time is up. And thank you all for your work.

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

The chair recognizes Mr. Carter from Georgia for 5 minutes.

Mr. CARTER. Thank you, Mr. Chairman. And I thank all of you for being here.

Dr. Gottlieb, I will start with you. And I wanted to ask you about something that former Chairman Upton asked you about, and that is the abuse deterrent formulations. I know that in your 2018 action plan, your plan states: Among our science-based efforts, we will assist in the conversion of the market toward wider use of opioid drugs with improved formulations that are harder to manipulate and abuse.

I just wanted you to comment on that and what you see as the role of these particular formulations in the future.

Dr. GOTTLIEB. We do think that there is an opportunity for these drugs to potentially reduce the rate of overall abuse and addiction in the market, and do see a potential opportunity from converting more of the market to abuse-deterrent formulations that are harder to manipulate in ways that allow people who are trying to misuse them to get a dose dump, if you will.

Mr. CARTER. Right. One of the problems is getting coverage for them. How can we assist you in that? I know that insurance companies don't want to cover them because they are more expensive and they are not on formularies. And if they are, they are not on a top tier, and that causes the access to them to be decreased.

Dr. GOTTLIEB. Yes. It is a fair point, and it is one that we observe as well. Obviously, we don't have a direct line into the coverage environment. I think where we could potentially be helpful in the overall scope of that challenge is in trying to facilitate ave-

nues for claims that are more seductive to people who are paying for these drugs.

And so that is why we are trying to move in the direction of accumulating data that can allow us to make a determination that when these drugs are used over a population, they do, in fact, reduce the rate of addiction and abuse. And we are continuing to collect that data.

I made the point before: We are going to have a make a policy decision at some point whether or not, as a policy matter, we think the totality of the data demonstrates that, as you convert the market to abuse-deterrent formulations, you cut down on abuse.

Mr. CARTER. OK. Let me ask you about unit-dose packaging. Some years back, you put Halcion under unit-dose packaging, and it worked very well. And I am just wondering what the holdup is. What will you base that decision on if you decided to go that route with opioids? Is there something you have to base it on?

Dr. GOTTLIEB. We would want empirical data, public health data to demonstrate that, as you move toward blister packs, you, in fact, are going to cut down on the rate of addiction and abuse.

Mr. CARTER. Hasn't that been proven with Halcion?

Dr. GOTTLIEB. Well, we would want to prove it in this context, but you would also want those to be evidence-based insofar as you would want to be blister packing drugs in unit of doses that comport with what common prescribing is.

Mr. CARTER. Right.

Dr. GOTTLIEB. And we are in the process of developing that data. We now have very good data from our Sentinel database that we will be making public at some point in the near future.

Mr. CARTER. OK. All right. Thank you very much, Doctor. I am sorry. I have just got so much time.

Dr. Jones, always good to see you. Thank you for being here. Let me ask you something. I know that health professional education is going to be extremely important, particularly as it relates to doctors and to pharmacists. I remind you that pharmacists are not law enforcement officers. It is unfair to ask us to profile and say that this patient does not need this pain medication.

I have often said that the only thing worse, as a pharmacist, for me, than to fill a prescription that is going to be diverted or used in an unwarranted way is to not fill a prescription for a patient who truly does need it. So I just give you that warning.

But I want to thank you and compliment you on your points that you have made today about comprehensive complete rehabilitation. I have often said that we have got two problems here, two distinct problems. One is tangible. One is, how do we get this under control? How do we limit the number of prescriptions? How do we educate patients and healthcare professionals about the danger of these drugs?

But the other is, what do we do with those people who are addicted? And that is a big, big challenge. Addiction is a lifelong challenge. And I appreciate the emphasis that you are putting on complete rehabilitation and comprehensive rehabilitation. That is so very important, and I want to thank you for that.

Dr. Schuchat, I wanted to ask you, how many States right now require doctors to look at PDMP before they write a prescription for an opioid? I know that Georgia is starting that July 1st.

Dr. SCHUCHAT. Yes. I may need to get back to you on that. I was going to say it might be 36, but let me double check.

Mr. CARTER. OK. That will be fine.

All right. I have got one last question. As was mentioned numerous times during this hearing—we had a hearing yesterday in Oversight and Investigations with the DEA. And, Dr. Gottlieb, you will be glad to know that they have made the top of my list and replaced you now. So I am on them, OK.

But I just want to ask you: I realize you are not under oath, and I realize it is a very uncomfortable situation to talk about other agencies, but how do you interact with them? Because I just don't think they are doing their job.

When you have pharmacists who are not filling prescriptions for doctors, who have a legitimate license and they haven't been for years, yet the DEA does nothing about them, can you imagine how frustrating that is to us?

I can tell you that there are doctors in my community now that the pharmacists won't fill their prescriptions because they are out of control, yet they still have a valid DEA license. They have a valid license. That is unconscionable that that happens.

And I put that blame, yes, on the composite medical boards, but also I put it on the DEA, because I am convinced that they can do something about that. So I just wanted to ask you very quickly, how is your interaction with that agency?

Dr. GOTTLIEB. Who is it for? Is it for me?

Mr. CARTER. Anybody. All three of you. And if you could be quick, because I have got one last thing. All of you.

Dr. SCHUCHAT. Yes. We actually did an exchange with DEA and are trying to strengthen the interactions, but I think you just speak to the system needs improvement.

Mr. CARTER. Oh, it does, so bad.

Dr. GOTTLIEB. I will just comment, Congressman, it is actually very good right now. Historically, there have been challenges if you go back 15 years, but right now we have a good working relationship with them at a staff level and at a leadership level.

And I have met with Mr. Patterson a number of times and talked to him about things we could be doing together to further expand our footprint together.

Mr. CARTER. OK. Dr. Jones.

Mr. GUTHRIE [presiding]. We have got to run over time on this. We need to move on because we have got another panel we are going to bring forward. I appreciate the gentleman's questions. And I now yield 5 minutes to the gentleman from Oklahoma, Mr. Mullin, for questions.

Mr. MULLIN. Thank you, Mr. Chairman.

And, buddy, if you want to, if I get time, I may ask your questions.

Mr. CARTER. Thank you very much.

Mr. MULLIN. You are very passionate about this, and I like that.

Mr. CARTER. I am.

Mr. MULLIN. But he is a guy that does 500 pushups and 500 situps every day. At his age, that is impressive. I had to get there. Sorry.

Dr. Jones, I am going to be speaking to you most of the time. I thank you for being here. I would like to thank the whole panel for being here. My colleague Representative Blumenauer and myself sent a letter to SAMHSA asking the Assistant Secretary's thoughts on legislation, H.R. 3545, the Overdose Prevention and Patient Safety Act.

Yesterday, I received this response from the Assistant Secretary stating that SAMHSA is encouraged to see that Congress examines the benefits of aligning part 2 with HIPAA. I take this to mean that they are supportive of the committee's efforts to align part 2 with HIPAA. Am I correct in saying that?

Dr. JONES. Right. We do favor achieving greater alignment between part 2 and HIPAA.

Mr. MULLIN. I know the chairman had already mentioned this to Chairman Walden, but I want to—and this letter that I want to submit for the record, when—I found one part of it extremely interesting, and I will quote from the letter.

It says: The practice of requiring substance-use disorder information to be more private than information regarding other chronic illnesses, such as cancer or heart disease, in itself can be stigmatizing.

I know you already answered that, but would you like to elaborate a little bit more on what you meant by that?

Dr. JONES. Well, I think it is just the issue of marginalization. So, these protections were put in place to try to reduce stigma, to make sure that people would be able to go forward and receive treatment without concerns that they might lose their job or people wouldn't provide care for them.

Mr. MULLIN. Right.

Dr. JONES. I think we are in a different time in that there is a movement among the recovery community to be more open about being in recovery. As I shared today, I am in recovery.

And so the idea that we are somehow different or what it might do in meaning that your healthcare providers might not have all the information that would be relevant to providing you with high-quality care just further stigmatizes the idea that we are different in some way. And I think that was really the point that she was trying to raise in the letter.

Mr. MULLIN. I literally couldn't agree more with that. We have placed a stigma, and unlike with other diseases, be it through addiction or mental illness, it does seem to carry some type of stigma with it, but it can be overcome. And the more we talk about it and the more we try to allow everybody to see what is happening with the patient, the better that patient can be treated, because that is what it is all about.

I am going to do my good friend and colleague, Buddy Carter, a favor and yield him the remainder of my time to you.

Mr. CARTER. Thank you.

Dr. Gottlieb, I know that you talked about international mail and what is coming through there. Can you speak about domestic mail, particularly about mail-order pharmacies who are sending 90-day

supplies of many medications with the intention of—they encourage patients to get a 90-day supply for a lower copayment and they don't have to get it as often. Is that not a concern as well that they are getting so much of these medications through the domestic mail as well?

Dr. GOTTLIEB. Congressman, that question relates to just the overall prescribing, I think, rather than the issue of the illicit flow. I think you are talking about legal prescribing. I am not sure that would be shipped through the domestic mail.

I think it would have to be picked up at the pharmacy under the CSA, right? Yes. So, if it is prescription opioids that are shipped domestically from a pharmacy to a patient, I think it wouldn't be shipped through a domestic mail facility. They can receive them? OK. They can receive them in the mail. The prescription would be controlling the size in that circumstance.

Mr. CARTER. Right. Right. OK. Well, I just want you to be aware that that is a problem too. You would be shocked at the number of opioids that are going through our mail right now that are coming from mail-order pharmacies, coming through the VA, and many others like that. And that is something we need to look at as well.

And I do appreciate the gentleman yielding his time.

The one last thing I want to say to all of you—and this may be somewhat anticlimactic, but it is very important—Representative Shimkus mentioned this earlier. Please be very careful not to swing this pendulum too far.

I was a hospice consultant for many years. There are people out there who have long-term pain. Hospice patients need these medications. Let's, please, don't go so far that we hinder and block access for those patients who truly do need it.

Thank you, Mr. Chairman. I yield back.

Mr. GUTHRIE. Thank you. I thank the gentleman from Oklahoma for yielding back his time.

And I recognize the gentleman from North Carolina, Mr. Hudson, 5 minutes for questions.

Mr. HUDSON. Thank you, Mr. Chairman.

Thank you to the panel for your time today.

This is such an important issue. As has been said by many of my colleagues, it affects all of our districts. It affects people all across every demographic around this country, and so I appreciate your great work and the time you have devoted today to this hearing.

Dr. Gottlieb, in your testimony, you note, the FDA, through its Sentinel database, is using data to assess prescribing and usage patterns by medical indication and provider specialty. You note this analysis is still ongoing. But can you talk more about the Sentinel database and any preliminary findings FDA has on potential overprescribing?

Dr. GOTTLIEB. What we have been able to do is use our Sentinel database to look at prescribing by indication and look at how many pills are being prescribed based on an indication. We have looked across about 15 different common indications and then look at how many pills are left over after the patient completes the prescription.

And so we have been able to derive where we see excess prescribing. We actually found a couple of indications where we see

patients seeking another prescription. But in the majority, in the vast majority of the indications, there is excess supply, and sometimes there is significant excess supply, which leads to the problems that we have been discussing here today.

We are going to find a venue to make this information public at some point in the future. It is proprietary information, but we will be finding a way to publish this. This is a very important tool for us, because this clearly informs the policy decisions that we are making.

Mr. HUDSON. I appreciate that.

You also mentioned FDA's reviewed published literature on pills dispensed, used, and leftover by patients who were prescribed opioids. Can you give me any specifics on the number of pills leftover, or if not, have you been able to determine how often pills are leftover?

Dr. GOTTLIEB. If I remember the data correctly, and I would be happy to follow up with your office to get you a more precise answer, we looked across about 15 indications, and in all but two, there was leftover. And in most, there was a significant percentage of the pills that were prescribed were leftover. So it is a common phenomenon.

Mr. HUDSON. Appreciate that, if you would help us get that information.

But do you believe then that if consumers had easier access to convenient disposal methods that would help mitigate this oversupply of opioids?

Dr. GOTTLIEB. We do. We think that could help.

Mr. HUDSON. Great. Well, we look forward to working with you on that.

And if my colleague, Buddy Carter, would like some of my time, I would be happy to yield.

Mr. CARTER. Thank you. I thank the gentleman for yielding.

Just very quickly, Dr. Gottlieb, I wanted to also follow up on what I believe one of the other Members on the other side of the aisle had mentioned about when the drugs come through the international mail system in there.

That seems to me like that is a perfect opportunity for a sting operation. Follow it to the end, and do you ever do that? I mean, find out where it is going. Yes, we need to attack the supplier, but we need to attack the users as well. Are we doing that?

Dr. GOTTLIEB. Yes, we are.

Mr. CARTER. OK. Well, thank you. I appreciate that, because that is so vitally important.

Dr. Jones, I wanted to ask you also, and I believe Dr. Gottlieb mentioned it about the use of the opioids, the immediate release, which are cheaper and used more frequently. How do you educate physicians on the proper use of these medications, and is there anything available for them to understand exactly what should be used and when it should be used?

Dr. JONES. So we do have educational programs, as I mentioned earlier, the providers' clinical export system, which focuses on medication-assisted treatment but also on opioid analgesic prescribing for pain. So, really, it is essentially a roster of experts who

can provide training on the appropriate use of medications, whether they be for treatment or pain.

We also, in our opioid STR grant program, allow States to use funding around education on CDC's guidelines specifically. So we are trying to work across agencies to make sure that we are not putting out conflicting messages but that the CDC guideline, the 12 recommendations are really the blueprint for moving that forward and States can use those STR dollars to educate clinicians.

We are, again, trying to do this holistically. We are trying to look at the pain side but also on the addiction side, so that providers, if they are facing that issue, whether it be on pain or addiction or co-occurring pain with someone who has addiction, they are equipped to have that interaction with the patient.

Mr. CARTER. Right. Thank you very much.

One last thing, Dr. Schuchat, I just wanted to ask you, do you monitor prescribing rates in different regions or different areas?

Dr. SCHUCHAT. Yes. We have been using some proprietary databases in order to do that, and we issued a report last summer on county-specific levels of prescribing.

Mr. CARTER. Right. When you see that, do you give that to the DEA or to any other agency and say, "Look, there is a spike here, will you please check it out?"

Dr. SCHUCHAT. We actually gave it to the public as well as to the health departments and other partners. So it is in the media. So it was very well publicized. But it was somewhat delayed, so we were talking, it was 2015 data that we reported last year.

Mr. CARTER. Right. Thank you very much. And I yield back.

Mr. GUTHRIE. The gentleman's time is expired.

Mr. Walberg, from Michigan, is recognized for 5 minutes.

Mr. WALBERG. Thank you, Mr. Chairman.

And my colleague from Georgia, are you out of questions?

Mr. CARTER. That is all I have got.

Mr. WALBERG. I want you to know, I would be willing so that I get some support in the future myself too. I appreciate that—without having to do 500 pushups.

In my townhalls in my district, I am constantly hearing from families who have been impacted by this issue aggressively, and it touched their lives. So I appreciate, Mr. Chairman, not only the opportunity—since I don't sit on this august subcommittee but have deep interest in it—to be able to sit here today and thank you for putting this hearing together.

Earlier this Congress, I introduced Jessie's Law, with Congresswoman Debbie Dingell. It is named in memory of a Michigan resident, Jessie Grubb, who tragically died of an opioid overdose in 2016.

Jessie's parents informed the hospital that she was a recovering addict. And despite informing the hospital of her history with this addiction, the information never made it to her discharging physician, and that made all the difference in the world. Jessie was unknowingly discharged from the hospital with a prescription of oxycodone, which ultimately led to her death the following day.

It is a heartbreaking and entirely preventable story, I think. And it is why we need to pass Jessie's Law, so medical professionals are

equipped to safely treat their patients, prevent overdose tragedies, and ultimately save lives.

Dr. Jones—and I would open it up to the other two panelists as well, if you would care to comment, Jessie's Law aims to help healthcare providers more easily identify patients who have substance abuse disorder.

The bill is focused on patients who have already consented—and that is the key. They have consented to share this information with healthcare providers. This is critical to ensure that mistakes such as what tragically happened to Jessie never happen again and we avoid medical errors that lead to any unnecessary deaths.

Now, this, to me, as uninitiated interested party in this whole situation, seems to be pretty straightforward. And I am surprised that it isn't currently happening.

Could you describe what this information currently looks like in the patient's medical records and what the barriers might be for healthcare providers to see the information quickly, efficiently, and deal with it?

Dr. JONES. I think, certainly, as I have mentioned throughout the conversation today around part 2, equipping healthcare providers with information to understand what is going on with their patients is really important. And often people in recovery have to be their own advocates to self-disclose that they have an addiction.

And the population of that information in electronic health records is pretty varied in how that information may be there. And in some cases, it may still be in paper charts depending on the practice setting, and so it may be very difficult for a clinician to have that information.

I think what you are advocating for in the bill complements the work that we are trying to pursue within the department and provides an additional tool for clinicians to have really important information. I think we have to think about how do we do this in complement with equipping providers with the knowledge of what to do when they have that information.

So we want them to have it. We want them to be accessible. But we also want them to be able to make informed decisions based on having that knowledge. And I think that goes hand in hand with our training efforts around understanding what is addiction, understanding what is the role of pain management in people who have opioid addiction in particular so that you are not—even if you are trying to do the right thing, you are not having an unintended consequence of someone dying from an overdose because you didn't understand as a clinician what risk that was putting the patient at.

Mr. WALBERG. But a discharging physician, wouldn't they, if they had the records in front of them, and I guess that is my concern, if they had in front of them, knowing that this person had voluntarily notified that they were a recovering addict, wouldn't they automatically not give the opioid under discharge?

Dr. JONES. I would not assume that. I will speak from my own personal experience. I had a colonoscopy, which I am sure everyone likes to talk about.

Mr. WALBERG. I am trying to forget it.

Dr. JONES. But I had a colonoscopy. I disclosed to the gastrointestinal surgeon who was performing it and an anesthesiologist

who was there, and I said: You know, I am in recovery; I want to do this without medication.

And the anesthesiologist said: Well, it is propofol; it is not addictive.

And I am an educated person. I am a pharmacist. I understand that that was not a good choice for me.

But I had to, in that moment, be my advocate and be very stern to say, "No, this is, I made my decision, this is how I want to proceed," while getting pressure from the anesthesiologist that, "Well, you need this."

Partly I think she was probably interested in getting paid. If she didn't deliver the medication, she wouldn't get paid. But I would not assume that just because the information is there, while critically important, we have to make sure that we are packaging that with education on then what do you do.

So we put out guidance from SAMHSA on how do you manage pain in patients who have co-occurring substance-use disorders and pain conditions to really try to help move that forward for clinicians. I think the CDC guidelines as well have specific callouts around people who have addiction and how do you manage pain in those individuals.

Mr. WALBERG. Any additional comments?

Mr. GUTHRIE. Thank you. The time is expired.

Mr. WALBERG. I appreciate that. Thank you.

Mr. GUTHRIE. Thank you for yielding back.

I now recognize the gentleman from California, Mr. McNerney, 5 minutes for questions.

Mr. MCNERNEY. I thank the majority for allowing me to wave on.

I thank the panel. It has been very informative, and I don't know a whole lot about this subject.

But, Dr. Gottlieb, I am working on a bill that would give the FDA the authority to ask opioid manufacturers to examine long-term efficacy of an opioid drug, and these studies would take place after the manufacturer receives approval for the drug from the FDA. Does the agency currently have this authority?

Dr. GOTTLIEB. We have authority to request post-market studies that aren't mandated as a condition of approval on a basis of safety considerations, not purely on an efficacy consideration, Congressman.

Mr. MCNERNEY. Do you think it would be helpful for the agency to have this authority?

Dr. GOTTLIEB. Well, one of the questions that continues to come up around opioids is the issues associated with their long-term use. A lot of these have not been studied for chronic administration, yet they are chronically administered.

And so there are certain important questions that we could answer by properly studying the chronic administration, looking at the efficacy over time, whether efficacy declines, and what the complications of that is.

Mr. MCNERNEY. Well, how would the agency use the information then it receives from those studies?

Dr. GOTTLIEB. Well, if we had such studies, if they were collected in the same way we do under the authorities we have to look at

to request post-market safety studies, we would seek to make the results public.

We would seek the ability to incorporate it into labeling as well so it can inform the provider and inform the healthcare system. That is typically how we handle post-market safety studies under the authorities we have right now to request post-market studies.

Mr. MCNERNEY. Very good. And you think that will be useful too late in fighting the opioid epidemic?

Dr. GOTTLIEB. We certainly think that having more information around the long-term efficacy of these drugs could be very useful to prescribers, could be very useful to our own regulatory decision-making, yes.

Mr. MCNERNEY. Thank you.

In your opinion, do you think that building a southern border wall and using the death penalty would be useful in fighting the opioid epidemic?

Dr. GOTTLIEB. Congressman, I certainly think that there are things we need to do from the standpoint of deterrence and interdiction. I have talked about what I want to do here today, which is to step up our work in the international mail facilities.

I stick to my knitting, and I stay within the scope of where I can affect this crisis. And for us, interdiction is a key component of trying to address the overall crisis.

Our footprint is in the international mail facilities in that regard and on the dark web, actually. I haven't talked about that today, but we do a lot of investigative work on the dark web to target rings that are bringing in, for example, illicit fentanyl.

Mr. MCNERNEY. Dr. Schuchat, do you have an opinion on that?

Dr. SCHUCHAT. All I will say is that having good data about the factors that are driving the epidemic is important, and the most recent wave of overdose deaths has been associated with the illicit products that are coming in from other countries.

Mr. MCNERNEY. Well, Dr. Schuchat, and you mentioned data several times in your testimony. Can we refer to this as Big Data, and are you considering using tools such as artificial intelligence and data mining?

Dr. SCHUCHAT. The data that we need is complex. We need it locally for rapid response. We need it at the State level to target resources. We need it nationally to understand the trends and to actually understand what strategies are improving things and what strategies are making them worse.

In terms of the automated learning kinds of issues, that can be really important for things like medical examiners and coroners and coding of the death certificates. We are using some systems now to take the natural text and try to extract information in more timely ways so that we can even just figure out for the emergency department visits or the overdose deaths which ones are drug associated and, of the drugs, which drugs were around.

Mr. MCNERNEY. Well, the war on drugs that started in the last century has been not only a tragic failure but very costly and actually counterproductive. There have been lessons learned, but I am afraid there are lessons that haven't been learned or are being ignored.

Can you assure me that we will benefit from the lessons learned from that undertaking?

Dr. SCHUCHAT. My highest priority is rapid quality data so that we don't make mistakes. And if we have unintended consequences like we have experienced with the overprescribing of opioids, we find them rapidly and take action quickly. So I think we need to have good data that provides evidence-based interventions.

Mr. MCNERNEY. So what about putting more people in jail or taking those sorts of hardline actions?

Dr. SCHUCHAT. Well, I guess, I can make a comment that I think I have seen very innovative work in the drug courts in terms of alternative approaches to getting people into care rather than sentencing. So there is a lot of innovative work going on at local levels around the country.

Mr. MCNERNEY. Thank you.

I yield back.

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

The gentlelady from Michigan, Mrs. Dingell, is recognized for 5 minutes for questions.

Mrs. DINGELL. Thank you, Mr. Chair, and thank you for letting all of us wave on.

And I actually had some of the same questions my colleague from Michigan had, so I won't go there. But I think, in Michigan, we are working in a very bipartisan way on a very serious issue.

And as you know, for me—most of you do. I know two of you do—this is a very personal issue. Having a father who was addicted to opioids when I was growing up, long before anybody understood the power of these drugs or what it did to people, but living with a man who is in chronic pain and every doctor says he needs to have serious pain medicine, I see both sides of this.

And I am very active on this issue, as you know. And more and more people are coming to me, the oncologists, and saying: We can't deny people.

I had someone scream at me last week about how we were denying people who needed pain to get by, and they weren't getting it. So what I really do know is that we need to be doing the research.

Dr. Gottlieb, do you agree that developing more nonopioid pain medications is an important part of solving the opioid epidemic?

Dr. GOTTLIEB. It could certainly help, Congresswoman. We are working with sponsors on that.

Mrs. DINGELL. And thank you.

And I think that promoting more research into nonopioid pain medications is one of the most important things we can do to ensure that people that are legitimately suffering from pain still get the relief that they need. We have got to make sure pendulums don't swing that far.

That is why I have introduced H.R. 5002, the ACE Research Act, with my friend and colleague from Michigan, Fred Upton. This legislation provides NIH with new, flexible authorities to conduct innovative research on ways to respond to public health threats, like the opioid epidemic.

I know that NIH isn't here today to discuss this, but it really is essential that we give them the tools they need to support much-needed research into these nonopioid pain medications.

Dr. Gottlieb, can you talk about how FDA works together with NIH on this type of research and how giving NIH more flexible authorities, like those envisioned in the ACE Research Act, will help us find new drugs faster?

Dr. GOTTLIEB. Well, thank you for the question. I think that there is a critical need for more translational research. We do see new classes of drugs, new potential classes of drugs with new mechanisms that might not have all the addictive qualities of opioids but offer some of the same pain relief.

And so it is important—these are in early development. We don't fully understand the issues associated with these mechanisms and potential safety issues. And so having the translational research in place and the scientific foundation to better develop these products is going to be critically important.

We are working closely with NIH on these efforts, and so we have been partnering with them on the things that they are doing to try to foster and facilitate early research into some of these new mechanisms. So they are a very important partner to us.

Mrs. DINGELL. I think it is really critical.

I am just going to make an editorial comment off the books too, that one of the things that I know is really happening is that people with legitimate pain are being stigmatized.

And they go to get their prescriptions filled; they are feeling like they are dirty somehow. We have to have that compassion, but we also have to educate kids at the early age: This is complicated. We are dealing with something really complicated. So I thank all three of you for the work that you are doing. We just have to accelerate it.

One thing I am also concerned about is that we are doing everything we can to treat children who are born with an opioid dependence and how we can stop that situation from happening in the first place. Two thousand women a month report using heroin or misusing painkillers while pregnant, which is a staggering number.

This question is for Mr. Jones of SAMHSA. I blew that pronunciation. Sorry. Your testimony notes that you recently released a new clinical guidance document regarding how to best treat mothers and their infants who are born addicted to opioids.

How do you recommend to best treat a newborn with an opioid addiction, and how are you disseminating that clinical guidance to providers?

Dr. JONES. So, again, I think there are different situations in what is the best treatment. I think we are still also learning what is the best treatment. I think, several years ago, there was a focus on using morphine or methadone or even buprenorphine to withdrawal, that the neonate would be placed in the NICU, so high acute care, high, expensive, longer stays.

And now we are learning that rooming in with the mother in a regular floor in a quiet environment tends to improve outcomes and shorten the duration of treatment. And so, along with NIH and others across HHS, we are working on an action plan around the Protecting Our Infants Act, sort of an implementation plan which gets to some of these issues.

In the clinical guidance, what we really focused on there is that, again, there are a variety of situations that clinicians may come

across. So it is not that there is a one-size-fits-all, but we present different vignettes that allow them to navigate different situations that they may come across.

Mrs. DINGELL. Thank you. I will yield back.

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

Seeing no others here for questions, I will dismiss the first panel. We appreciate you for being here and taking the time to testify before the subcommittee. And we will bring, of course, our second panel as we transition. So thank you very much for being here.

Thank you. The subcommittee will come back to order.

I appreciate the opportunity for all of you to be here and so each of you will be given the opportunity to do an opening statement, and it will be followed by questions from members. And I will introduce each witness, and I will call in for your opening statement.

I will make sure I say this correct, Thau or Thau?

Ms. THAU. It is Thau.

Mr. GUTHRIE. Thau, OK. I am glad I asked. So Ms. Thau, she is a Public Policy Consultant, Community Anti-Drug Coalitions; Ms. Cartier Esham, Executive Vice President, Emerging Companies, Biotechnology Innovation Organization; Mr. Jeffrey Francer, Senior Vice President and General Counsel, Association for Accessible Medicines; and Dr. John Holaday, Chairman and Cofounder DisposeRx. We appreciate you being here today.

And, Ms. Thau, you are now recognized for 5 minutes to give an opening statement.

Ms. THAU. Thank you so much to these——

Mr. GUTHRIE. Your microphone, please. You have to activate your microphone, please. There you go.

STATEMENT OF SUE THAU, PUBLIC POLICY CONSULTANT, COMMUNITY ANTI-DRUG COALITIONS OF AMERICA

Ms. THAU. Thank you so much. My name is Sue Thau. I am the Public Policy Consultant for Community Anti-Drug Coalitions of America, CADCA. CADCA is the national nonprofit organization whose mission is to build and strengthen community coalitions to create safe, healthy, and drug-free communities.

It is on behalf of the more than 5,000 CADCA coalition members that I want to thank you all for the opportunity to testify today on behalf of H.R. 449, the Synthetic Drug Awareness Act. This important legislation would require the Surgeon General to report to Congress on the public health effects caused by synthetic drug use among 12- to 18-year-olds.

We applaud H.R. 449's focus on youth who disproportionately suffer the negative consequences of drug use because of its deleterious effects on the developing brain.

Preventing or delaying substance use is the single most critical tool in stopping the pathway to addiction and overdose. Primary prevention to stop substance use before it starts is the most cost-effective way to deal with the addiction issues facing our Nation.

Research shows that, for every dollar invested in prevention, between $2 and $20 in treatment and other healthcare costs can be saved. Substance-use prevention has historically been underresourced and underutilized in combating drug issues, including the current opioid epidemic, with most of the emphasis on

funding being directed towards downstream approaches that deal with the problem after it has already reached crisis proportions.

This Surgeon General's report will be invaluable in garnering more attention and resources to address the synthetic drug issue. The best example of Surgeon General's reports that have changed the course of a public health crisis were on smoking and health.

These have provided universally accepted scientific findings that increased awareness, changed social norms, and built broad support for tobacco prevention, cessation, and control programs that ultimately resulted in major population level reductions in smoking among Americans, most notably youth.

Given that more potent and deadly synthetics are being designed almost daily to skirt the Controlled Substances Act and that these drugs are increasingly accessible and available in communities across the entire Nation, this report could not be more timely.

To achieve population level reductions in substance use, a data-driven community coalition infrastructure is needed to plan, implement, and evaluate comprehensive strategies throughout multiple community sectors.

Raising awareness through this report would be incredibly useful at the community level, as it would provide critical science-based information needed to help prevent drug use, intervene with those who have started using, and treat those who become dependent on synthetic drugs.

Communities would use the report to not only raise awareness but to plan and implement a mutually reinforcing combination of evidence-based strategies that are laid out in more detail in my written statement.

These include providing information, enhancing skills, enhancing access and reducing barriers to programs and services, changing consequences and incentives, changing the physical design of the environment, and modifying and changing policies and laws.

This type of synergistic action is what resulted in the massive reductions in tobacco use we have witnessed over the past 55 years. This multiple-strategies-across-multiple-sectors approach is currently how the Drug-Free Communities Program housed in the Office of National Drug Control Policy has achieved major population level reductions in reducing 30-day use of alcohol, tobacco, marijuana, and prescription drugs in 12- to 17-year-olds.

Drug-free community coalition grantees working to combat youth synthetic drug use will find this report extremely useful and use it to raise awareness with scale and scope among community sectors such as parents, youth, schools, and healthcare providers.

This report would also further the ability of community coalitions to design a robust set of locally appropriate and evidence-based interventions capable of resulting in population-level reductions in youth use of synthetic drugs.

CADCA and its members are proud to support H.R. 449. Thank you for the opportunity to testify today, and I am happy to answer any questions you may have.

[The statement of Ms. Thau follows:]

Testimony of Sue Thau

Before The Health Subcommittee of the Committee on Energy and Commerce

Combatting the Opioid Crisis: Prevention and Public Health Solutions

Wednesday, March 21, 2018

2123 Rayburn House Office Building

Chairman Burgess, Ranking Member Green and esteemed members of the Subcommittee on Health of the Committee on Energy and Commerce, my name is Sue Thau and I am the Public Policy Consultant for Community Anti-Drug Coalitions of America (CADCA).

CADCA is a national nonprofit organization whose mission is to build and strengthen the capacity of community coalitions to create and maintain safe, healthy and drug-free communities. CADCA and its members have been working over the past 25 years to develop comprehensive community-wide strategies, to prevent and delay the age of first use of prescription and all other addictive drugs, as well as smoking and underage drinking.

It is on behalf of the more than 5,000 CADCA coalition members nationwide that I want to thank you for the opportunity to testify today on behalf H.R. 449, "The Synthetic Drug Awareness Act". This important legislation would require the Surgeon General to report to Congress on the public health effects caused by the increased rate of synthetic drug use among 12-to 18-year olds, since 2010.

We applaud H.R. 449's focus on the effects of synthetic drugs on our nation's most vulnerable population—our youth–who disproportionately suffer the negative consequences of drug use because of its deleterious effects on the

developing brain. Preventing or delaying the use of harmful and addictive substances, including synthetic drugs, is the single most critical tool in stopping the pathway to addiction and overdose, as well as a host of other negative public health outcomes. Primary prevention, to stop substance use before it ever starts, is the most cost-effective way to deal with the addiction issues facing our nation. Research shows that for each dollar invested in prevention, between $2 and $20 in treatment and other health costs can be saved (Swisher, J.D., Scherer, J., and Yin, R.K. The Journal of Primary Prevention. "Cost-Benefit Estimates in Prevention Research." 25:2, October 2004). Substance use prevention has historically been under resourced and underutilized in combatting drug issues, including the current opioid epidemic. Most of the emphasis and funding have been directed towards downstream approaches that try to deal with the problem after it has already reached crisis proportions.

Having a Surgeon General's report on the actual public health effects of synthetic drug use on 12-to 18-year olds will be invaluable. It will bring much needed public attention to the synthetic drug issues facing our nation's youth and be used in communities across the country to put this issue squarely on the radar screen of policy makers and the general public. We need this report to put a spotlight on the facts and information about the actual effects of synthetic drugs on youth so

that more attention and resources will be mobilized to aggressively address this critical public health issue more intentionally and comprehensively. The best example of a Surgeon General's report that changed the course of a public health crises, was the release on January 11, 1964, by Surgeon General Luther L. Terry, of the first report of the Surgeon General's Advisory Committee on Smoking and Health. The release of this report, was a historic breakthrough leading to a major series of comprehensive actions that are still being taken now, over 55 years later, to curtail the effects of tobacco use on the public health of Americans. The continuing series of Surgeon General's reports on smoking, and the effects of second hand smoke on health, have provided universally accepted information and scientific findings that have been widely reported with scale and scope resulting in increased awareness about the dangers associated with smoking nationwide. These series of reports have served to change perceptions and social norms about the harmfulness of smoking. It has also formed the basis of support for tobacco prevention, cessation and control programs and ultimately resulted in major population-level reductions in smoking among all Americans, most notably among youth, who are currently smoking at the lowest levels in the history of the National Institute on Drug Abuse's Monitoring the Future Study.

Given the prevalence and dangers of synthetic drugs, a Surgeon General's report is warranted. A more robust understanding of the full range of detrimental and long-term effects of synthetic drugs on our nation's youth is clearly needed now. A report would be particularly timely as more potent and deadly synthetic drugs are being designed to specifically skirt the Controlled Substances Act. Synthetic drugs are also increasingly making their way into communities across the nation and sold as "legal" products, which reduces the perception of harm associated with them. This report would greatly contribute to the knowledge base related to the public health effects on youth and provide critical information needed to effectively design comprehensive strategies to prevent youth from using them, intervene with those who have started and treat those who become addicted.

We at CADCA know that to achieve population-level reductions in the use of any substance, a data driven community-based coalition infrastructure needs to be organized to plan, implement and evaluate comprehensive strategies throughout multiple community sectors. Raising awareness through a robust Surgeon General's report would be a critical first step in implementing any comprehensive prevention strategy to achieve population level reductions in use.

Communities then need to build on this raised awareness, by implementing a mutually reinforcing combination of all the following seven strategies:

- Providing Information – Educational presentations, workshops or seminars and other presentations of data (e.g., public announcements, brochures, dissemination, billboards, community meetings, forums, web-based communication).

- Enhancing Skills – Workshops, seminars and other activities designed to increase the skills of participants (e.g., training, technical assistance, distance learning, strategic planning retreats, curricula development).

- Providing Support – Creating opportunities to allow people to participate in activities that reduce risk or enhance protection (e.g., providing alternative activities, mentoring, referrals, support groups or clubs).

- Enhancing Access/Reducing Barriers- Improving systems and processes to increase the ease, ability and opportunity to utilize those systems and services (e.g., assuring healthcare, childcare, transportation, housing, justice, education, safety, special needs, cultural and language sensitivity).

- Changing Consequences (Incentives/Disincentives) – Increasing or decreasing the probability of a specific behavior that reduces risk or enhances

protection by altering the consequences for performing that behavior (e.g., increasing public recognition for deserved behavior, individual and business rewards, taxes, citations, fines, revocations/loss of privileges).

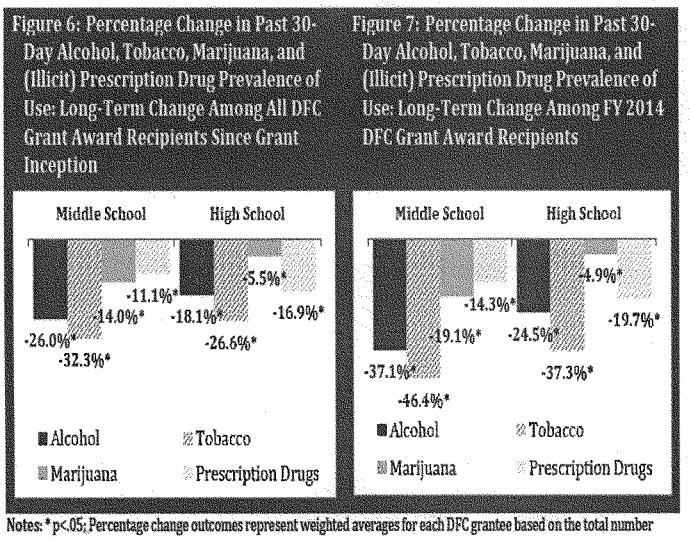
- Changing Physical Design – Altering the physical design or structure of the environment to reduce risk or enhance protection (e.g., parks, landscapes, signage, lighting, outlet density).

- Modifying/Changing Policies – Formal change in written procedures, by-laws, proclamations, rules or laws with written documentation and/or voting procedures (e.g., workplace initiatives, law enforcement procedures and practices, public policy actions, systems change within government, communities and organizations).

This type of expansive, synergistic action resulted in the massive reductions in tobacco use we have witnessed over the past 55 years.

This comprehensive approach for addressing the major youth substance use issues communities are currently facing is how the Drug-Free Communities (DFC) program, housed in the Office of National Drug Control Policy, operates and it has been proven to be effective. The DFC program and its grantees have used their "multiple strategies over multiple sectors" approach to achieve major population-

level outcomes in reducing 30-day use of alcohol, tobacco, marijuana and prescription drugs in 12-to 17-year olds in funded communities.



Drug-Free Community coalition grantees that have used local data to identify synthetic drugs as one of their top local substance use issues facing youth, such as S.A.F.E in Harlem, would welcome this report. It would further their ability to raise awareness and help them design a robust set of locally appropriate interventions, across all of the seven strategies, outlined above, that can ultimately result in population-level reductions in the use of synthetic drugs among youth.

CADCA and its members are proud to support H.R. 449, the Synthetic Drug Awareness Act. We appreciate your leadership on this critically important issue.

Thank you for the opportunity to testify today.

I am happy to answer any questions you may have.

Mr. GUTHRIE. Thank you. I appreciate your testimony.

I will now recognize Ms. Cartier Esham, who doesn't look like she could be the childhood friend of our own Thomas Massie, and a proud Kentuckian. So you are now recognized 5 minutes.

STATEMENT OF CARTIER ESHAM, EXECUTIVE VICE PRESIDENT, EMERGING COMPANIES, BIOTECHNOLOGY INNOVATION ORGANIZATION

Ms. ESHAM. Thank you, Chairman, and thank you, members of the committee. Thank you, and thank you for the opportunity to speak with you today about policy solutions put forward by this committee to address America's opioid crisis.

As mentioned, my name is Cartier Esham, and I work for the Biotechnology Innovation Organization. BIO is the world's largest trade association representing the entire ecosystem of biotechnology companies from the entrepreneurial to the multinational companies.

Our members are dedicated to the development of the next generation of biomedical breakthroughs for the millions of patients suffering from diseases for which there are no effective cures or treatments.

It is this mission focused on innovation that guided the development of BIO's objectives and policy proposals designed to change the paradigm of how we treat pain and addiction in this country and eliminate prescription opioid drug abuse in the future.

They include advancing our scientific understanding of pain and addiction diseases; ensuring that patients have knowledge of and access to the right treatment at the right time with the right support and without stigma; and stimulating R&D for innovative treatments that improve care and prevent abuse.

The current state of innovation for the next generation of pain and addiction therapies holds promise. There are currently 125 clinical development programs looking at novel chemical entities in the pipeline today, 87 percent of which are for nonopioid treatments.

However, less than 4 percent of total venture investment in the biopharmaceutical sector is being directed into companies whose lead product is a novel pain therapy. This is even significantly less for companies working on novel treatments to treat addiction.

By comparison, this is 17 times less than funding we see for the development of oncology drugs. We need to develop and support a more conducive policy environment focused on changing the paradigm of how we treat patients suffering from pain and addiction to realize the full potential innovation could have in creating an America free of prescription opioid addiction.

I would like to highlight three bills today under consideration that, if enacted, would help make these goals a reality. The bill focusing on FDA opioid sparing that would enable FDA and stakeholder collaborations to discuss and develop guidance on ethical and efficient data collection for opioid sparing and availability of that information to patients as part of the label of a product would be extraordinarily helpful.

Enactment of this legislation would provide FDA, biopharmaceutical companies, and investors with an improved understanding

about how data sources can be utilized to support demonstrations that a novel therapy reduces opioid use.

BIO believes the same approach focused on other critical areas, such as improved approaches for evaluating pain, utilization of innovative clinical trial designs would also further improve drug development and review processes for better and safer pain and addiction treatments.

We also support the legislation under consideration that would enable better utilization of accelerated approval and breakthrough therapy pathways. Enactment of this legislation would, again, provide FDA, as well as the biopharmaceutical industry, investors, and other stakeholders with a greater understanding of what is required to meet the criteria to be able to participate in these pathways and ensure that processes intended to expedite approval meet the unique needs of pain and addiction.

These actions would serve as critical signals to not just biopharmaceutical companies but their investors that the development of pain and addiction therapies that are safer, improve quality of care, and reduce the use of opioids is a top priority.

Lastly, we also wanted to highlight the Advancing Cutting-Edge Research Act. This is legislation that would provide NIH with a much needed transactional authority to better enable them to more efficiently distribute funds to conduct or support research required to respond to public health threats such as the current opioid crisis.

In our written statement, we also call for the development of a transparent and focused research strategy to ensure that we continue to advance our understanding of the biology of pain and addiction and develop tools that would improve the diagnosis and treatment of these diseases.

BIO strongly believes that innovation is a key component of efforts to address the opioid crisis. We look forward to working with the committee to put forward policies that will change the paradigm of how we treat pain and addiction, improve patient lives, and advance our ability to achieve our shared goal of eliminating prescription opioid drug abuse in the United States.

Thank you.

[The statement of Ms. Esham follows:]

Testimony of Cartier Esham, Ph.D.
Executive Vice President, Emerging Companies Section
Senior Vice President, Science & Regulatory Affairs
Biotechnology Innovation Organization

United States House
Energy and Commerce Committee
Subcommittee on Health
Hearing on "Combating the Opioid Crisis: Prevention and Public Health Solutions"
March 21, 2018

Chairman Burgess, Ranking Member Green, and Members of the Committee:
BIO appreciates the opportunity to speak with you today about policy solutions put forward by this Committee to address America's opioid crisis.

I am Cartier Esham, Executive Vice President of the Emerging Companies Section and Senior Vice President of Science & Regulatory Affairs at BIO. BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of diseases, and to prevent them in the first place.

BIO's member companies are dedicated to the development of the next generation of biomedical breakthroughs for the millions of patients suffering from diseases for which there are no effective cures or treatments. It is this mission focused on innovation that guided the development of BIO's policy recommendations to change the paradigm of how we treat pain and addiction and eliminate prescription opioid drug addiction in the United States.

The development of innovative therapies for treating pain and addiction is a crucial component of mitigating the current opioid crisis and preventing future opioid addiction. The current state of innovation for next generation pain and addiction therapies holds promise but requires a more conducive policy environment focused on enabling access and incentivizing the investment needed to unleash the full potential innovation to change the paradigm of treatment and improve the lives of patients. Today, less than four percent of total venture investment in the biopharmaceutical sector is being directed into companies whose lead product is a novel pain therapy. Additionally, over the last decade, companies working on novel pain therapies have received 17 times less funding than companies working on oncology drugs, with even less investment for the development of novel therapies

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for addiction. There are currently 220 clinical stage drug programs, with 125 testing novel chemical entities, 87% of which are for non-opioid receptors. While promising, when compared to the 2,617 clinical development programs in oncology it is clear the full potential of innovation in improving care for patients suffering from pain or addiction has not been realized.[1]

BIO's policy recommendations are focused on the following three pillars, which if acted on, would serve to mitigate and work to eliminate prescription opioid drug abuse by encouraging investment into better and safer therapies to treat pain and addiction.

(1) Advancing the understanding of the biology of pain and addiction to enable the development of innovative treatments, and ensuring appropriate and optimal use of existing therapies;
(2) Ensuring that patients suffering from pain or addiction are able to receive the right treatment at the right time with the right support, without stigma; and
(3) Stimulating research and development of innovative treatments that effectively treat pain and opioid addiction and prevent abuse.

BIO would like to discuss three bills under consideration today that if enacted would improve care for people suffering from pain or addiction and help prevent individuals from developing prescription opioid addictions.

BIO supports the discussion draft legislation on FDA Opioid Sparing. This legislation would enable Food and Drug Administration (FDA) and stakeholder collaborations to discuss issues relating to data collection on opioid sparing and inclusion of such information in product labeling to inform development of guidance. Specifically the legislation would direct FDA to develop guidance that would better enable utilization of innovative clinical trial designs to ethically and efficiently collect data on opioid sparing, improve the development and acceptance of endpoints that measure the reduction of chronic pain and opioid use, improve the ability to utilize real world evidence and enable information about opioid sparing data to be included in the label of a product. Enactment and implementation of this legislation would provide FDA, biopharmaceutical companies, medical researchers, and investors with an improved understanding about how data sources can be utilized to support demonstrations that a novel therapy reduces opioid use. In addition to encouraging collaborations and guidance development on opioid sparing, BIO believes the same approach to stakeholder engagement and guidance development on other critical issues such as benefit-risk assessment of novel and safer treatments, improved approval processes for chronic pain indications, modern approaches to non-opioid drug development and review processes, improved mechanisms for evaluating pain, and utilization of innovative clinical trial designs for novel pain and addiction therapies would serve to provide increased understanding and improve drug

[1] Thomas, D., & Wesel, C. (2018) The State of Innovation in Highly Prevalent Chronic Diseases, Volume II: Pain and Addiction Therapeutics.

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development and review processes. These actions would serve as critical signals to biopharmaceutical companies and their investors that there is a well-defined, efficient and effective path forward for developing pain and treatment therapies that are safer, improve quality of care and reduce the use of opioids.

BIO also supports draft discussion legislation that would better enable the utilization of Accelerated Approval and Breakthrough Therapy pathways for innovative and safer treatments of pain and addiction. Enactment and implementation of this legislation would provide FDA and the biopharmaceutical industry with a greater understanding of what is required to meet criteria for these expedited approval pathways and ensure processes intended to expedite development and approval meet the unique needs of pain and addiction medicines. This too would serve as a powerful signal to stakeholders and investors that treatments and therapies that improve and protect the lives of patients suffering from pain and addiction is a top public health priority.

Lastly, BIO supports H.R.5002, the Advancing Cutting Edge Research Act. This draft legislation would provide the National Institutes of Health (NIH) with transactional authority that would enable them to more efficiently distribute funds to conduct or support research required to respond to a public health threat, such as the current opioid crisis. This new authority could also be used to design and implement innovative business models within the government and engage with nontraditional research partners in ways that would otherwise not be feasible. In addition to these new authorities BIO has developed recommendations that call for the development and implementation of a research strategy that is transparent and accountable and focused on advancing our understanding of the biology of pain and addiction, developing tools that would improve diagnosis and treatment of these diseases, and enabling utilization of data to better ensure appropriate and optimal use of existing and future therapies. BIO believes the legislation would be strengthened if these ideas on collaboration and data analytics were added to HR 5002. Making research on the biology of pain and addiction a national priority will further strengthen investor confidence in this area.

BIO strongly believes that innovation is a key component of efforts to address America's opioid crisis. The three bills discussed above and under consideration by this Committee and BIO's complimentary policy proposals described below would serve to advance our scientific understanding of these diseases and enable improved drug development and review processes for the next generation of pain and addiction treatments. These actions would encourage R&D and investment in medicines that will change the paradigm of how we treat pain and addiction, improve patients' lives and help prevent prescription opioid drug abuse in the United States.

Additional Recommendations

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In addition to the excellent work being conducted and discussed by this Committee today, BIO has developed additional complimentary recommendations that would further serve to stimulate investment and advance the development of novel and safer treatment options for pain and addiction and help eliminate opioid prescription drug abuse in the United States.

Stimulating research and development of innovative treatments that effectively treat pain and opioid addiction and prevent abuse: Stimulation of research and development of novel treatments for pain and addiction is critical to ensuring an America free of addiction in the future. BIO recommends that the FDA develop activities to better enable effective and efficient drug development and review for novel and safer treatments for pain and innovative treatments for addiction. In addition to the Opioid Sparing legislation discussed above, BIO recommends that FDA engage stakeholders to discuss and take action to address the following critical issues identified as regulatory barriers for the development of new pain and addiction therapies:

- Benefit-Risk Assessment of Novel and Safer Treatments: Discuss issues and develop recommendations about how to most effectively evaluate the entire benefit-risk profile of a given product. For example, the benefits of abuse deterrent formulations of conventional opioids, non-opioid treatments, and innovative treatments that have, in general, lower or no abuse liability should be considered relative in the context of existing options.

- Approvals for Chronic Pain Indications: Discuss issues and develop recommendations about how to efficiently and effectively obtain approval for a broad chronic pain indication.

- Non-Opioid Alternatives: Discuss modern approaches to the development and review of non-opioid alternatives for pain and develop recommendations.

- Mechanisms for Evaluating Pain: Discuss issues and develop recommendations about how to improve upon current mechanisms for evaluating chronic and acute pain both in the clinic and the clinical trials setting, as well as, how to better enable the utilization of biomarkers and novel endpoints.

- Innovative Clinical Trials: Discuss and develop acceptable mechanisms to streamline clinical trial strategies to expedite the development of novel and safer non-opioid treatments for pain and addiction.

Advancing the understanding of the biology of pain and addiction to enable the development of innovative treatments for pain and addiction and ensure appropriate and optimal use of existing therapies: BIO recommends NIH develop a comprehensive plan that prioritizes and supports

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research at the appropriate institutes and in academia focused on improving our understanding of the biology of pain and addiction, and advancing preclinical modeling and development of better measurements of pain and addiction in the clinical setting. We encourage such a plan to include collaboration with stakeholders and transparency about what activities are planned or completed and how those efforts are advancing the state of scientific understanding of pain and addiction diseases. Specific areas of research that are critical to these advancements include:

- *Developing a more comprehensive understanding of the preclinical pain and addiction environment*
    - Research focused on the following areas would serve to develop a more comprehensive understanding of mechanisms underlying different types of pain as well as biomarkers that allow for the differentiation of pain subsets, and identification of preclinical models that better translate to therapeutic outcomes for people and would help inform the development of novel and safer treatments for pain and addiction.
        - Research investigating potential therapeutic targets with increased receptor/intracellular signaling selectivity
        - Research investigating novel mechanisms for preventing and/or treating opioid addiction and overdose
        - Research on the identification and validation of biomarkers that identify subsets of pain and more accurately predict treatment response for both pain and addiction
        - Research on the identification and utilization of more effective drug screening models and assays that better translate to therapeutic outcomes for patients
        - Research focused on elucidating the underlying biological mechanisms of different types of pain and addiction, as well as differences in pain perception

- *Support a more comprehensive understanding of the clinical pain and addiction environment*
    - Research on and support for developing comprehensive methods for evaluating pain in the patient, tools that allow for better diagnosis of pain, as well as the establishment of clinical trial registries, clinical trial networks, and data sharing and analytics are critical to ensuring patients are able to receive the most appropriate treatment.
        - Research and encourage the development and use, in both the clinic and clinical trial setting, of more comprehensive and objective tools for assessing pain that take into account acute versus chronic pain, the possible neurobiological and psychosocial mechanisms underlying pain, individual differences in pain perception, and distinctions between somatic and psychic pain

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- Research on the development of diagnostic tools that enable the identification of specific causes of pain
- Research on and encouragement of multi-disciplinary approaches to treating pain and addiction by enabling approaches for determining risk or susceptibility for individual patients, and associate outcomes with the basic neurobiology and/or pharmacological alterations
- Support the establishment of clinical trial registries and clinical trial networks for pain and addiction to help develop, validate, refine, and deliver new treatment options to patients
- Support NIH's recommendations to the Drug Enforcement Agency (DEA) regarding research exemption for controlled substances, as this can help advance scientific discoveries in pain and addiction treatment.

- *Improve ability to use data to improve medical decision making*
  - BIO recommends that NIH collaborate with stakeholders, the Food and Drug Administration, and the Centers for Medicare and Medicaid Services and other agencies as appropriate to discuss how to best collect, analyze, and apply data to answer the following critical questions and better inform medical decision making. This collaboration should explore what data is available as well as any data gaps or quality issues that need to be addressed.
    - Which treatment(s) works best for a particular patient and what factors must be considered when making that determination? Is there a certain "type" of patient that typically sees more success with one treatment compared to another?
    - What factors (e.g., training, stigma, reimbursement, faculty size) prevent providers from offering, directly or by referral, all available addiction treatment options?
    - What is the optimal duration of specific treatments?
    - When should a patient's treatment regimen be changed, and how?
    - What gaps or barriers exist which impact the ability to collect, analyze and leverage data to answer the above questions?

Ensuring that patients suffering from pain or addiction are able to receive the right treatment at the right time with the right support, without stigma: BIO recommends that policy makers remove coverage and reimbursement barriers that prevent patient-centered decisions about and access to the most effective treatments for pain and addiction. Additionally, BIO supports successful implementation of laws and regulations enacted to improve patient access to appropriate treatments across pain and addiction.

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Closing Remarks

BIO urges Congress to act swiftly to move legislation on FDA Opioid Sparing, FDA Accelerated Approval and Breakthrough Therapy Status, and H.R. 5002 Advancing Cutting Edge Research forward. We request the Committee consider BIO's additional and complimentary policy proposals outlined in this testimony. Enactment of these policies would change the paradigm of how we treat patients suffering from pain and addiction and achieve our shared goal of eliminating prescription opioid drug abuse in the United States.

Thank you for the opportunity to present our views today. I am happy to answer any questions you may have.

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Mr. GUTHRIE. I thank you for your testimony.

I now recognize Mr. Francer for 5 minutes for an opening statement.

STATEMENT OF JEFFREY FRANCER, SENIOR VICE PRESIDENT AND GENERAL COUNSEL, ASSOCIATION FOR ACCESSIBLE MEDICINES

Mr. FRANCER. Thank you, Mr. Chairman, members of the committee. I am Jeff Francer, Senior Vice President and General Counsel of the Association for Accessible Medicines. AAM's core mission is to improve the lives of patients by advancing timely access to affordable FDA-approved generic and biosimilar medicines.

Generic and biosimilar medicines serve as the backbone of prescription drug savings and now represent greater than 89 percent of all prescriptions in the United States at only 26 percent of total drug expenditures. We, therefore, save patients, payers, and taxpayers nearly $5 billion every week.

AAM commends the subcommittee for its continued efforts to address the public health crisis of opioid prescription drug abuse and this excellent hearing. We are also encouraged by the continued focus of the administration, including FDA Commissioner Scott Gottlieb, on addressing this challenge.

Ensuring patients' safety is of the utmost importance for generic drug and biosimilar manufacturers. Enhanced prescriber training, patient prescription adherence, safe storage, proper disposal, all can help prevent medication abuse and ensure that patients get the full benefit of safe, effective, more affordable generic medicines.

It is critical that we combat the misuse of prescription drugs while also maintaining the legitimate, uninterrupted access to patients who need medical treatment. Generic drug manufacturers play a key role in producing affordable FDA-approved therapies for the treatment of patients.

Importantly, under the Hatch-Waxman amendments that govern the approval of generic medicines, our manufacturers create bioequivalent versions of brand name drugs using the same labeling, and if necessary, the same or equally protective safety programs.

Typically, generic drug manufacturers do not promote drugs to physicians or directly to patients as the brand name manufacturers do. Moreover, once our companies sell generic drugs to the wholesaler, the company does not control the further sale of the medicine to retail pharmacies.

Currently, three large purchasing consortia made up of wholesale distributors and retail pharmacies control the sale and destination of 90 percent of the generic medicines in the United States. AAM believes that a comprehensive approach to the opioid crisis should help ensure responsible drug promotional activities as well as prescribing.

My written statement outlines our recommendations in full, but let me take a moment to summarize. AAM and its members support a range of collaborative strategies and public policies to reduce drug abuse while ensuring appropriate access to medicines for patients who need them.

Specifically, we support expanding and improving prescription drug monitoring programs; enhancing initiatives to assist physi-

cians and other prescribers; and the proper prescribing of prescription drugs, particularly opioids; mandatory ongoing training for providers on best practices in pain management; reducing the potential for divergent and fraudulent prescribing by requiring the use of electronic prescribing for controlled substances; consideration of a 7-day limit on prescriptions of opioids for acute pain; and proper disposal of unused or unwanted prescription drugs through national DEA take-back days.

Lastly, I wanted to share with the subcommittee how AAM and its members are partnering with leading national organizations dedicated to promoting public health and preventing abuse.

Last year, AAM approached EVERFI, a leading provider of electronic training for our Nation's colleges and universities. We asked the organization to develop a module to help students understand the importance of safe use, storage, and disposal of prescription drugs.

With AAM's financial support, EVERFI has developed and made available a prescription drug abuse prevention curriculum free of charge to any college in America in order to help this at-risk demographic make healthy decisions. More than 36,000 students have already taken this course since its launch just last fall.

In addition, AAM and EVERFI have brought together national business leaders and pharmaceutical supply chain partners to fund the rollout of a K through 12 prescription drug program to some of the hardest hit communities in our country.

In conclusion, we look forward to continuing to work with the subcommittee to help address this national opioid crisis and help ensure the proper prescription and use of FDA-approved medicines. I would be happy to answer your questions.

[The statement of Mr. Francer follows:]

Your Generics and Biosimilars Industry

Testimony of

Jeffrey K. Francer
Senior Vice President & General Counsel
Association for Accessible Medicines

Combating the Opioid Crisis: Prevention and Public Health Solutions

U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

March 21, 2018

Your Generics and Biosimilars Industry

Introduction

Chairman Burgess, Ranking Member Green, Chairman Walden, Ranking Member Pallone and members of the Subcommittee, thank you for the opportunity to testify today on solutions to our national opioid crisis and the safe use and disposal of prescription medicines. I am Jeff Francer, Senior Vice President and General Counsel at the Association for Accessible Medicines (AAM).

AAM's core mission is to improve the lives of patients by advancing timely access to affordable FDA-approved generic and biosimilar medications. We are the nation's leading trade association for manufacturers and distributors of generic and biosimilar prescription medicines. Generic and biosimilar medicines serve as the backbone of prescription drug savings and now represent greater than 89% of all prescriptions dispensed in the U.S., but only 26% of total expenditures on prescription drugs, saving patients, payers, and taxpayers nearly $5 billion every week.[1]

AAM commends the Subcommittee for its continued efforts to address the public health crisis of opioid prescription drug abuse. We are also encouraged by the continued focus of the Administration, including FDA Commissioner Gottlieb, on addressing this challenge. According to the National Institute on Drug Abuse, more than 90 Americans die each day after overdosing on opioids.[2] The Centers for Disease Control and Prevention estimates that the total 'economic burden' of prescription opioid misuse alone in the United States is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.[3]

Ensuring patient safety is of the utmost importance for generic drug and biosimilars manufacturers. It is a public health and patient safety imperative that patients take medicines as prescribed and adhere to the instructions of their doctor, pharmacist or other healthcare provider. Enhanced prescriber training, prescription adherence, safe storage and proper disposal all can help prevent medication abuse and ensure that patients get the full benefit of safe, effective and more affordable generic medicines.

It is critical that we combat the misuse of prescription medication while maintaining legitimate, uninterrupted access to medicines to patients in need. Generic drug

[1] AAM 2017 Generic Drug Access & Savings in the U.S., http://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf

[2] National Institute on Drug Abuse.

[3] Schuchat A, Houry D, Guy GP. New Data on Opioid Use and Prescribing in the United States. JAMA. 2017;318(5):425–426.

manufacturers play a key role in producing affordable FDA-approved therapies for the treatment of patients. Importantly, under the Hatch-Waxman amendments that govern the approval of generic medicines, our manufacturers create bioequivalent versions of brand name drugs using the same labeling, and if necessary, the same or an equally protective Risk Evaluation and Mitigation Strategy. Typically, generic drug manufacturers do not promote drugs to physicians or directly to patients, as the brand name manufacturers do. Moreover, once our companies sell generic drugs to a wholesaler, the company does not control the further sale of the medicine to retail pharmacies. Currently, three large purchasing consortiums made up of wholesale distributors and retail pharmacies control 90% of the generic medicines sold in the United States.

AAM Policy Principles

AAM believes that a comprehensive approach to the opioid crisis should help ensure responsible drug promotional activities and prescribing. Recent data reflect the importance of thoughtful and comprehensive public policy in addressing this public health issue. For instance, the total number of prescriptions for Hydrocodone have declined by more than 40% since 2012.[4] During this period, the CDC acted to improve opioid prescribing practices through the CDC Guideline for Prescribing Opioids for Chronic Pain.[5] Yet, at the same time, overdose deaths from heroin and synthetic opioids increased significantly.

Thus, AAM and its members support a range of collaborative strategies and public policies to reduce drug abuse while ensuring appropriate access to medicines for patients who need them, and we recently released a white paper detailing our proposed solutions. This effort will require a multi-faceted and coordinated approach that seeks to:

- Reduce inappropriate prescribing;
- Ensure the safe use of medicines consistent with FDA-approved labeling; and
- Maintain the availability of treatment for individuals struggling with addiction.

As such, AAM supports expanding and improving the use and effectiveness of Prescription Drug Monitoring Programs (PDMP) by increasing interoperability and standardization across the country. Consistent with these principles, AAM supports the "Prescription Drug Monitoring Act of 2017" introduced by Senators Amy Klobuchar (D-MN) and Rob Portman (R-OH) and Representatives Evan Jenkins (R-WV) and Tim

[4] IQVIA, National Prescription Audit, September 2017.
[5] Available at www.cdc.gov

Ryan (D-OH). The bill would require states that receive federal funding for PDMPs to require prescribers to check their state PDMP prior to treatment and to require dispensers to report information into the PDMP. The legislation also would expand efforts to facilitate the sharing of PDMP information among providers across state lines.

AAM also supports initiatives to assist physicians and other prescribers in the proper prescribing of prescription drugs, particularly opioids. This includes the five recommendations of the American Medical Association's Task Force to Reduce Opioid Abuse:[6]

1. Register and use your state prescription drug monitoring program to check your patient's prescription history.
2. Educate yourself on managing pain and promoting safe, responsible opioid prescribing.
3. Support overdose prevention measures, such as increased access to naloxone.
4. Reduce the stigma of substance use disorder and enhance access to treatment.
5. Ensure patients in pain aren't stigmatized and can receive comprehensive treatment

As part of such efforts, AAM supports requiring mandatory, ongoing training for providers on best practices in pain management such as the CDC guidelines for treatment of chronic pain, "doctor shopping" and use of PDMPs, and other issues related to the safe use of opioids.

In addition, AAM supports reducing the potential for diversion and fraudulent prescribing by requiring the use of electronic prescribing for controlled substances. This practice holds the potential to reduce opportunities for diversion and meaningfully contribute to combatting prescription drug misuse. The "Every Prescription Conveyed Securely Act", introduced by Senators Michael Bennet (D-CO) and Dean Heller (R-NV) and Representatives Katherine Clark (D-MA) and Markwayne Mullin (R-IN), would require greater use of electronic prescribing for controlled services in Medicare Part D.

AAM supports consideration of a 7-day limit on prescriptions of opioids for acute pain. Such limits could include appropriate exceptions to balance the need for patients to obtain needed care, including when the prescriber, in their medical judgement, determines that a lengthier prescription is necessary.

[6] American Medical Association, Reversing the Opioid Epidemic, available at https://www.ama-assn.org/delivering-care/reversing-opioid-epidemic.

AAM also supports the continued implementation of the Comprehensive Addiction and Recovery Act. Among other provisions, the legislation allows Medicare Part D plan sponsors to use several utilization management tools that appear to be effective in the commercial sector at reducing abuse of opioids. AAM supports the use of "lock-in" programs, which restrict beneficiaries suspected of inappropriate opioid use to one prescriber, one pharmacy, or both. This solution allows the beneficiary to continue to access opioids as therapeutically appropriate, but requires those prescriptions to be coordinated through a single prescriber or pharmacy. The program as described requires patients and prescribers to be notified before a patient is enrolled, and allows the patient time to appeal the decision and select providers that are most convenient to the patient. Appropriate management of those taking opioids for extended periods of time is one way to combat abuse.

AAM supports proper disposal of unused or unwanted prescription drugs through national U.S. Drug Enforcement Agency Take Back days. We note that just this week Secretary Azar emphasized the importance of the DEA Takeback Program and continuing to improve its results. However, AAM is concerned by the continued growth of state and local proposals to institute mandates on manufacturers to fund such programs. AAM looks forward to working to address this issue in a coordinated way that ensures patient access to affordable generic medicines where medically appropriate.

AAM's Ongoing Efforts to Address Prescription Drug Abuse

AAM and its members support enhanced education for prescribers and providers, and we have partnered with leading national organizations dedicated to promoting public health and preventing abuse. Last year, AAM approached Washington, D.C.-based education-technology company EVERFI—the leading provider of alcohol abuse and sexual assault prevention training for our nation's colleges and universities—and asked the organization to develop a module to help students understand the importance of safe use, storage and disposal of prescription drugs.

Young adults between the ages of 18-25 year old abuse opioids at a higher rate than the rest of the population. According to the 2015 College Prescription Drug Study (CPDS), 10.2% of undergraduates reported using pain medications for non-medical reasons. Opioid-related deaths among Americans age 24 and under almost doubled from 2005 to 2015, when 3,165 were reported, according to the Kaiser Family Foundation, based on data from the Centers for Disease Control and Prevention.

With AAM's financial support, EVERFI has developed and made available a prescription drug abuse prevention curriculum, free of charge, to any college in America in order to help this at-risk demographic make healthy decisions. More than 36,000 students – at schools that include some of the largest land grant colleges in the nation, to the Ivy League to our military academies - have already taken the course since its launch last fall and that number is growing with each successive semester.

The course is producing volumes of data to better understand the challenge of prescription drug misuse in the college community, and to measure the impact of the program. Already, 75 percent of students reported that because of the course they are more confident in their ability to intervene if a friend is misusing prescription drugs, while 73 percent said they now know where to find resources for drug abuse at their institution.

AAM is working to increase student participation in the higher education program nationally and to complement the higher education curriculum with earlier intervention. AAM and EVERFI have brought together national business leaders and pharmaceutical supply chain partners, including chain drug stores, to fund the rollout of a K-12 prescription drug misuse program to some of the hardest-hit communities in our country.

In addition, AAM supports the Community Anti-Drug Coalitions of America (CADCA), the national membership organization representing over 5,000 coalitions and affiliates working to make America's communities safe, healthy and drug-free. AAM is also a member of the National Council on Patient Information and Education (NCPIE) and supports its many prescription drug abuse prevention programs, including:

- Taking Action to Prevent and Address Prescription Drug Abuse: A Resource Kit for College Campuses designed to help inform and mobilize college campuses to raise awareness about and address the misuse and abuse of prescription drugs, and Prescription Drug Abuse Prevention: Resources for Community Action™ guide.

Abuse-Deterrent Formulations of Generic Opioids

Generic drug manufacturers continue to develop medicines, such as opioids for pain management, with abuse deterrent formulations (ADF). Abuse-deterrent technology makes it harder to misuse medicines by crushing tablets for snorting or further dissolving products with intent to inject the contents. However, as the FDA has noted,

this does not mean the product is impossible to abuse or that these properties necessarily prevent addiction, overdose or death. It is important to note that future FDA-approved generic medicines with ADF will be just as abuse deterrent as their brand name counterparts. As FDA continues its efforts, AAM encourages FDA to continue to work with drug makers so that they are better able to bring innovation to the development of ADF prescription opioids. FDA's determination of whether a generic prescription opioid receives ADF labeling should not be based on whether the generic has an identical ADF technology – rather the determination should be based on scientific results. Requiring a specific type of technology could stifle and hamper these much-needed features in generic medicines.

Views on Proposed Legislation

AAM commends the Subcommittee for its continued efforts to enhance our public health response to the opioid crisis. We are presently reviewing the proposed bills, and will follow up with detailed comments. In the interim, we suggest several principles for the Subcommittee to consider in evaluating proposed legislation:

- Legislation should not prevent legitimate and uninterrupted patient access to care.
- Legislation should not limit FDA's discretion to ensure the safety of medicines, and should maintain equal scientific and regulatory standards for brand and generic medicines alike; and
- Legislation should not hinder the ability of manufacturers to collaborate with supply chain partners and federal and local agencies to prevent and treat addiction.

Conclusion

AAM looks forward to continuing to work with the Subcommittee to help address our national opioid crisis and help ensure the proper prescription and use of FDA-approved medicines. I would be happy to answer any questions.

Mr. GUTHRIE. Thank you for your testimony.

And, Dr. Holaday, you are now recognized for 5 minutes for an opening statement.

STATEMENT OF JOHN HOLADAY, PH.D., CHAIRMAN AND COFOUNDER DISPOSERX

Mr. HOLADAY. Thank you, Mr. Chairman, and for the committee for giving me the opportunity to be before you today. My name is Dr. John Holaday. I am the Chairman and CEO of DisposeRx, the country's leading site-of-use medication disposal company. Our president, William Simpson, was unable to attend because of weather problems today.

Our country is in crisis, not only from opioid addictions but from the dangers of prescription drug abuse. Drug overdose, as you know, is the leading cause of accidental death in the United States.

And the failure to properly dispose of unused or expired prescription drugs from our home medicine cabinets, managed-care facilities, hospitals, hospices, and others dramatically contributes to the rapid increase of prescription drug abuse, accidental poisonings, opioid overdoses, and the pollution of our Nation's public drinking water supplies.

National policies have long encouraged improper drug disposal. None of the methods currently recommended for drug disposal are convenient, responsible, secure, and, most importantly, do not prevent diversion of controlled substances. None of these methods incorporate an education component which is directly related to the success of any such program. There is a better way.

DisposeRx is invested in developing a solution that can help eliminate one of the root causes of prescription drug misuse and abuse, which is exposure to unused, unwanted medications in the home.

DisposeRx is the gold standard for at-home drug disposal. We have developed a product that safely, conveniently, and securely allows customers to dispose of their unused medications in their own home when it is convenient to them. This ensures that there is no time lag between dispensing and disposal, eliminating the opportunities for diversion.

Consumers are reaching out for a solution that is simple and safe to use. Data have shown that items returned to drug take-back locations often include such things as nasal sprays, Flintstone vitamins, ointments, and creams.

A survey of the Journal of Drug Abuse revealed that 1.4 percent of consumers returned their unused medications to the pharmacies or take-back kiosks. In fact, 54 percent threw their medications in the trash and more than a third or 35.4 percent disposed of their medications in the sink or the toilet.

And what is more surprising is that fewer than 20 percent of patients reported having received any education as to correct disposal methods. The CDC states that the best way to curb opioid addictions is to stop their diversions from medicine cabinets.

DisposeRx provides patients with an easy solution for drug disposal. Each packet contains a patented blend of nontoxic ingredients that will create a viscous gel when mixed with warm tap water. Simply take your pills, add some water, pour in the contents

of the packet, shake it up, and within 30 seconds to a minute, the drugs are dissolved and permanently sequestered in a gel from which they can't be extracted for abuse and won't leech into landfills.

The components of this sequester the gel so it can't be diverted and it can't be extracted. Our product is the most tested and trusted product in the market today. We have been subjected to rigorous third-party testing for extractability and environmental friendliness.

Extractability testing has shown that, once sequestered, our patented cross-linking polymers, using commonly available household solvents, cannot be extracted or the contents cannot be extracted. So it is nontoxic, and the majority of the components are listed as generally regarded as safe by the FDA. It is not dangerous nor harmful to the environment.

Incorporated into the mission of the DisposeRx team is the commitment to educating the community on the cycle of medication management. This begins in the pharmacy. We realize that successful drug disposal is dependent upon the inclusion of targeted instruction and patient education. Cleaning out the medicine cabinet will become second nature if the mechanism to do so makes it a realistic and obtainable goal for the consumers.

One of the examples is the time that it took between legislation of seatbelt use and the decrease in deaths from automobile accidents. And the same thing occurs with tobacco and other matters that really require legislation in order to jump start the people to start adopting changes in behavior to save their lives.

In closing, we are proud to be bringing patients and families a simple and effective solution for drug disposal. We are honored to be working with a team at Walmart, as they are the leading retail pharmacies that have been the first to supply a consumer site-of-use solution that is both fighting our Nation's opioid epidemic as well as the dangers of prescription drug overdose.

Our mission is to solve the problem of drug disposal. We focus on driving patient education with simple and safe solutions. We fundamentally believe this education of the patients is important in the process, and we remove some of the barriers facing safe disposal and encourage the adoptions of nontoxic site-of-use home solutions.

Thank you very much for your attention.

[The statement of Mr. Holaday follows:]

DisposeRx
Solving the problem of drug disposal

March 21st, 2018

DisposeRx Summary

Thank you Mr. Chairman and members of the Committee for giving me the opportunity to testify before you today. My name is Dr. John Holaday, Chairman and CEO of DisposeRx, Inc, the country's leading site-of-use medication disposal company. Our President, William Simpson, was unable to attend today due to the weather delays.

Our country is in crisis not only from opioid addictions but from the dangers of prescription drug abuse. Drug overdose is the leading cause of accidental death in the U.S. The failure to properly dispose of unused or expired prescription drugs from our home medicine cabinet, managed care facilities, hospitals and hospice centers has dramatically contributed to the rapid increase of prescription drug abuse, accidental poisonings, opioid overdoes and the pollution of our nation's public drinking water supplies.

National policies may have long encouraged improper drug disposal. None of the methods currently recommended for drug disposal are convenient, responsible, secure and most importantly do not prevent diversion of controlled substances. None of these methods incorporate an education component which is directly related to the success of any such program.

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and when it is convenient for them. This ensures that there is no time lag between dispensing and disposal, eliminating the opportunity for diversion.

Consumers are reaching out for a solution that is simple and safe to use. Data has shown that items returned to drug take back locations often times include such things as nasal sprays, ointments and creams. A survey in the Journal of Drug Abuse revealed that 1.4% of consumers returned their unused medications to their pharmacy or take-back kiosk, that in fact, 54% threw their medications in the trash and more than a third, 35.4% disposed of their medications in the sink or toilet. And what is more surprising is that fewer than 20% of patients reported having received any education as to correct disposal methods. DisposeRx provides patients with an easy solution for drug disposal. Each packet contains a patented blend of non-toxic ingredients that will create a viscous gel when mixed with warm tap water. You simply take your pill bottle with the unused medication, add warm tap water and our patented powder, shake for 30 seconds and then simply throw away in the household trash. The components of the gel sequester, (or encapsulate) the drug so that it cannot be diverted for misuse or abuse. It creates a barrier between direct access to the drug(s) and the drug abuser, therefore rendering the drug(s) non-useable.

Our product is the most tested and trusted product on the market today. DisposeRx has been subjected to rigorous third-party testing for both extractability and environmental friendliness. Extractability testing has shown, once sequestered (or encapsulated) by our patented cross-linking polymers, using common household solvents that an addict would have readily available drugs cannot be retrieved from our viscous gel.

DisposeRx is non-toxic and the majority of the components are lists as "generally regarded as safe (GRAS)" by the FDA. Environmental testing has proven that DisposeRx is neither dangerous nor hazardous to the environment. Incorporated into the mission of the DisposeRx team is the commitment to educating the community on the cycle of medication management. We realize that successful drug disposal is dependent on the inclusion of targeted instruction and patient education. Cleaning out the medicine cabinet will become second nature if the mechanism to do so makes it a realistic, obtainable goal for consumers.

In closing, we are proud to be bringing patients and families a simple and effective solution for safe drug disposal. We are honored to be working with the team at Walmart as they are leading all retail pharmacies by being the first to supply a consumer site-of-use solutions that is both fighting our nations opioid epidemic as well as the dangers of prescription drug abuse. Our mission is to solve the problem of drug disposal, we focus on driving patient education with simple and safe disposal solutions. We fundamentally believe is educating patients on the importance of medication disposal and believe together with retailers, federal agencies and physicians we can remove the barriers facing safe disposal and encourage the adoption of non-toxic site-of-use home disposal solutions.

Mr. GUTHRIE. Thank you. I appreciate your testimony.

That concludes all witness testimony. We will now move to member questions. And I will now recognize myself for 5 minutes to begin the questioning period.

Ms. Esham, thank you for being here today. And in your testimony, you mention the importance of ensuring patients suffering from pain or addiction were able to receive the right treatment at the right time with the right support without sigma. I could not agree more, which is why I introduced the Comprehensive Opioid Recovery Centers Act.

Can you please expand on your statement and elaborate on what specific coverage and reimbursement barriers that prevent patient center decisions?

Ms. ESHAM. Certainly. Thank you. And I would like to commend you for the legislation that you are putting forward. As a resident, a person that grew up in Kentucky, having a multifaceted, multidisciplinary approach to treating addiction and making it easier for people to get that help is critically important, so I want to thank you for that work.

In direct response to your question, there are a multitude of proposals and recommendations that we have put forward, but it is our assessment and our recommendation that there are specific barriers and practices that need to be examined and removed and things that are basically precluding access to patients for alternative nonopioid treatments, safer treatments, et cetera.

And that includes looking at or removing barriers that are based on root or administration, so bundling practices that make it difficult to get alternative—nonopioid alternative medicines, step therapy requirements, fail-first requirements. There is a multitude of steps that we think we could take. But, again, there are barriers that exist, and we need to examine them in a holistic way to make sure people are getting the right care.

Mr. GUTHRIE. Thank you. I appreciate your answer.

And, Dr. Holaday, can you please explain—I like the demonstration there—but can you please explain why the cross-polymer technology is such an effective method of sequestration?

Mr. HOLADAY. Certainly. Our product is made up of things which one often derives from corn, generally recognized as safe, so it is actually edible should you choose to do so. But the secret sauce enables these polymers to form rapidly over time after dissolving the drugs that are exposed to them in water.

So, without telling you what the entire product is made of, about five or six different ingredients that, when mixed together, along with one particular key, rapidly forms the gel from which these drugs cannot be extracted for abuse, and they also won't pollute landfills.

Mr. GUTHRIE. That is an effective method there. That is for sure.

So, Mr. Francer, one of the bills being considered today would give FDA additional authority to require modifications to packaging of opioids or that opioids be dispensed in conjunction with the convenient disposal method. I think it makes a lot of sense, but do you have any concerns about these additional measures impeding access?

Mr. FRANCER. So, first and foremost, we support a science-based method of regulation. And I think Dr. Gottlieb indicated before that they want to develop data on how these different features could affect the protectiveness of patients.

We would support such power for the FDA to protect the public health. We would want to make sure that there is equal application across both the brand and the generic. And we would want to make sure that opportunities for gamesmanship and the patents of packaging don't harm access to the generic drugs. But, overall, we would be happy to work with the committee to provide technical assistance to ensure access.

Mr. GUTHRIE. Again, thank you for your answer, and that concludes my questions.

I will recognize Mr. Green for 5 minutes for questions.

Mr. GREEN. Thank you, Mr. Chairman.

We heard from our first panel that—Dr. Gottlieb—the majority of patients who will become addicted to opioids are first exposed to a lawful prescription. I know that all of us here today are exploring creative solutions to addressing the opioid crisis, including addiction abuse and misuse.

I know many of us were pleased to see the FDA take action last year when it requested the withdrawal of an opioid treatment due to the concern that the benefits associated with the product no longer outweigh the risk of abuse and manipulation.

Mr. Francer, one of the bills noticed today is the legislation I am offering. It would allow FDA to take into consideration the potential risk for abuse and misuse in making approval decisions. This seems to be an important and unique decision that the agency should take into account when approving controlled substances.

I understand that some stakeholders may be hesitant to make modifications to the FDA's current risk-based assessment. And as we continue to work on this legislation, how would the AAM recommend that we target this legislation to ensure that we are appropriately targeting the controlled substances that are fueling the opioid epidemic?

Mr. FRANCER. I think it is entirely appropriate to consider the risks of misuse and abuse, and we would be happy to support the development of legislation in that regard.

Mr. GREEN. I think you answered my second question from the chair saying that will you continue to work with us and our colleagues to perfect all the legislation that we are considering today.

Mr. FRANCER. Absolutely.

Mr. GREEN. Thank you.

Mr. Simpson, effective and safe medication disposal is a critical piece of the puzzle in order to reduce access to addictive prescription drugs, including opioids. Mr. Simpson, as you notice in your testimony, easy access and leftover prescription opioids is a dangerous way people become addicted. Improper disposal from our homes, hospitals, managed care facilities, and hospice centers is critical in addressing misuse and diversion. Mr. Simpson, you noted that the drug take-back efforts and the kiosk may not be utilized as often because it requires individuals to identify and visit locations outside their homes, which may be inconvenient, time consuming, and difficult to certain individuals.

Dr. Holaday, I apologize. That was for the previous panel.

Well, that concludes the questions, Mr. Chairman.

Mr. HOLADAY. I must say I am not as young or handsome as Mr. Simpson who was unable to be here today because of weather, but I would be delighted to answer your questions, sir.

Mr. GUTHRIE. I just want to say that this committee has a bill on the floor in the House, so people are going and coming.

Mr. GREEN. That's why we are running back and forth.

Mr. GUTHRIE. So it is an honest mistake.

Mr. HOLADAY. No problem. I will answer Mr. Simpson's question, though.

Mr. GREEN. OK. Well, then I will finish it. I thought we were just messed up.

Mr. HOLADAY. Surprisingly, as you pointed out, people are not inclined to get in their cars and drive to take-back facilities to bring their products to a place where they could be destroyed. They are more likely to do that at home.

We were surprised to find out from some studies of Egan and colleagues that in studying five counties in Kentucky and looking at all the drugs that were dispensed and then looking at all that came back to take-backs and kiosks, less than three-tenths of a percent of the drugs that were dispensed came back. Most of those were Flintstone vitamins and the like. Only 5 percent of those were drugs of abuse.

So take-back facilities are not really very effective. Often they cause liabilities for the facilities, like the pharmacies and others. They also are often diverted from these take-back facilities, as you may know.

We think if one can offer a safe solution that is at home, permanent, and biodegradable, and environmentally friendly, that will stop a lot of the losses and the difficulties of other programs. But I must say we are all for anything that can help stop the cycle of addiction and overdose that begins in the medicine cabinet, including ours and others.

Mr. GREEN. Thank you, Mr. Chairman.

Mr. GUTHRIE. The gentleman yields back.

I now recognize Mr. Shimkus, 5 minutes for questions.

Mr. SHIMKUS. Thank you, Mr. Chairman. Thanks for being here. I know it is a long day. And I know a lot of you are sitting in on the first panel, which I appreciate.

What I have been trying to get my arms wrapped around, I mean, we do have a pharmacist on the panel with this, obviously, the prescriptive authority, and then the legal authority to destroy and who that is, especially in the case—and I know we have a bill that is going to address hospice issues when the prescribee passes. And I think it is a very good debate to have the attending nurse there being able to do this in whatever manner. And I think there is a lot of exciting things going on in that issue.

So it really is a debate on, for me, and this line of questioning, who—is there things that we need to clear up in law as far as who we can designate to do that, who is authorized to do that, who can we educate? Is there an educational aspect of this aspect and is there ambiguity in the law that prohibits this from occurring?

And so I will just go, Ms. Thau and then just down the table, and then I will go to my second question.

Ms. THAU. Yes. I can't speak about ambiguity in the law. I can say that a lot of our coalitions have worked with long-term care facilities. I can give you an example in Fayette County, Ohio, where somebody went to take their loved one's prescriptions. And when they were told they couldn't have them, they said, but this is our inheritance, because they obviously intended to sell them. So it is a gigantic problem, and our people are working piecemeal community by community trying to make sure that those medications are actually withdrawn and are not diverted.

Mr. SHIMKUS. Yes, great.

Anyone else want to weigh in on this? Dr. Holaday?

Mr. HOLADAY. I would say that we were surprised when we began this quest several years ago to find that there is no mandate by the FDA, the DEA, EPA or others to take care of leftover drugs and to encourage their disposal in a safe way. We think that this is an important aspect of managing the entire cycle of drugs from their dispensing to the time that they are gotten rid of. And that if they were properly managed at the end, that could prevent a lot of the divergence. Seventy percent of opioid addicts get started with leftover drugs in medicine cabinets.

Mr. SHIMKUS. Yes. Look at the hospice patient who may be on painkillers and other addictive drugs. And so if there is a million in our country and there is five pills per individual, that is 5 million uncontrolled addictive drugs that could be—and our culture does have a challenge with ownership. You are prescribed nine pills, you use four pills, and by golly, those are your five pills. Right? Paid for by you or your insurance company or whatever. And so that is the educational part that I kind of mentioned in that outline.

So I appreciate that. I think that is something we have to wrestle with some authority by a healthcare professional whose got primary care to be able to have the authority to take and seize and destroy. I think I would support that.

Ms. Thau, obviously, we are pulling out all the stops on the opioid crisis. Earlier, I had mentioned the meth issue. There is still cocaine, there is new synthetic drugs. I don't want them to get lost in this whole debate. So you want to comment on these other aspects, given the time left?

Ms. THAU. Yes, absolutely. Thank you so much. I think what is really important is that we have an addiction crisis in this country. It is it not just an opioid crisis. When coroners look at what is on board when people have overdosed, it is opioids, it is fentanyl, but it is also marijuana, alcohol, Ambien, benzodiazepines; you are absolutely right, meth and cocaine are back.

So what we really need is a permanent infrastructure for prevention, intervention, treatment, and recovery support that is not so drug specific, so that when we sort of fix this opioid problem, we do—and a lot of you were around for the whole Combat Meth Act. You know, oh, well, we dealt with that, and then all the money for that went away. So we really do need permanent infrastructure for the entire continuum of care for this issue for all drugs.

And there is no MAT for stimulants, by the way. So it is fabulously important that there is for opioids, but for cocaine and meth, there is no equivalent for medication-assisted treatments.

Mr. SHIMKUS. Thank you very much.

My time has expired. Thank you, Mr. Chairman. I yield back.

Mr. GUTHRIE. The gentleman yields back.

The gentlelady from California, Ms. Matsui, is recognized for 5 minutes for questions.

Ms. MATSUI. Thank you, Mr. Chairman. And thank you to all the witnesses for being with us today.

We have heard a lot of discussion today about how to address the opioid crisis, how to treat patients with opioid use disorders, and what can be done to ameliorate the impact of the crisis in our communities. However, I also believe that we must be focusing on the roll of primary prevention and what steps we can take to bring awareness to addiction, implications, and how opioid usage and addiction can be prevented in the first place.

I appreciate that Ms. Thau from the Community Anti-Drug Coalitions of America—CADCA, right? —is here testifying and can speak to the importance of prevention efforts and community strategies.

Ms. Thau, what more can be done and should be done to move upstream to prevent opioid misuse in the first place?

Ms. THAU. Thank you so much for the question. Just like there are no simple solutions in general for the opioid problem, when it comes to prevention, it really does take a whole community. So it takes all of the sectors: parents, schools, law enforcement, the healthcare community, youth providing, working together to do everything literally from raising awareness, providing information, building skills in youth, doctors, parents, and getting rid of unused and unwanted medication.

We also have worked in two States to give out 300,000 Deterra packets, which are basically different packets than Dr. Holaday talked about, but that actually render drugs inert. But we have to do everything we can to decrease access and availability and change social norms.

And I just want to give you a great example in Carter County, Kentucky. They, 10 years ago, had a horrible overdose problem, but also the schools came to the coalition and said, listen, we have 23 percent college and career readiness. So they did everything I have talked about across their community. And from 2006 to 2016, their 30-day misuse of prescription drugs for 10th graders went from 12 percent, which is two or three times the national averages, to 1 percent. And that is literally through doing a comprehensive communitywide approach that involved everybody. And they did change social norms.

Chairman Guthrie, you are from Kentucky. So they did this gigantic media campaign called Forget Everything Your Mama Told You About Sharing, and it was done with scale and scope. Because that was one of the problems, people were sharing their meds. So when you do things across—and they did school-based prevention programs, they got a substance use counselor in the schools.

Ms. MATSUI. It was a multisector, everybody.

Ms. THAU. They did everything across all the sectors. And interestingly, not only did their use rates go down exponentially, like for 10th and 12th grade, from 12 percent to 1 percent, but that college and career readiness score went from 23 percent in 2010 to 76.5 percent in 2016, and their graduation rate went from 81 percent to 98.8 percent. So there are major secondary effects when we can reduce the initiation into drug use and stop kids from using in the first place.

Ms. MATSUI. OK. Keeping the same vein, I have a few questions about the roll reports by the Surgeon General play in bringing awareness to public health issues and impact lives of all Americans, how these reports can help prevention efforts in the longterm. Today, we are considering H.R. 449, the Synthetic Drug Awareness Act, which would require the Surgeon General to report to Congress on the public health impacts resulting from the usage of synthetic drugs by adolescents age 12 through 18.

Synthetic drugs are designed to evade the Drug Enforcement Administration's scheduling regime, and drugs like synthetic cannabinoids, such as Spice and K2, are only increasing in prevalence among youth. I think having a report on use access and use of synthetic drugs can bring heightened awareness to this issue, just as other important Surgeon General's reports have, such as the famous 1964 report on smoking and how it has served as a critical tool in acknowledging the deadly health impacts of smoking.

Ms. Thau, can you explain why providing information through reports like this is important to have information collected through this kind of report would be used in the future?

Ms. THAU. Oh, absolutely. People around the country are looking for science-based information that can be paired down into what I will call snackable bites, where people can actually take things out of the report and use them to raise awareness with scale and scope. And I don't think we know enough about the effects of all of these synthetic drugs, how they affect the brain, health. They have some horrible, horrible side effects. They are very addictive. And I think a report like this would do a lot to bring awareness to the issue that people across the country could actually use to educate parents, the healthcare community, youth, schools, and everybody else that comes into contact with youth.

Ms. MATSUI. Thank you very much. I yield back.

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

The gentlelady from Tennessee, Mrs. Blackburn, is recognized for 5 minutes of questions.

Mrs. BLACKBURN. Thank you so much. And we appreciate your patience today and for all of you being here.

We do want to get legislation finished that is going to make resources or provide resources that can help with addressing this on the education prevention, the medically assisted treatment and, of course, the rehab and recovery. And to that end, Ms. Thau and Mr. Francer, I want to talk with you about the education component.

In the mid-1980s, I was chairman of the board for the American Lung Association in Middle Tennessee. And, Ms. Thau, you are need nodding your head. I think you know where I am going. We developed what was called the School Health curriculum. And we raised the money. We paid for teacher in-service training so they

could come take this, and then teach this curriculum in K through 3 on the dangers of smoking and, likewise, the dangers of secondhand smoke. And it was an incredibly successful program.

And over the past couple of months, I have lamented a couple of times that we didn't seem to have that type infrastructure that had a scalable program that we could work through schools and begin to—and it sounds, Mr. Francer, like you are moving this way—look at K through 3, look at elementary, at middle school, at high school and provide the education that is necessary to, first of all, realize addiction is a disease, and then secondly, to be very specific about these Schedule II drugs, the opiates, the psychotropics, what it does, and the effect that it has on your body.

And I would like to hear from the two of you. You are talking about Carter County, Kentucky. Is there something that is scalable? And, Mr. Francer, to you, is there a curriculum? And do you have a way to scale and to get your curriculum into schools and communities?

And, Ms. Thau, we will go with you first.

Ms. THAU. Absolutely. Carter County used something called Generation Rx curriculum, it is a ninth grade curriculum, but they didn't do it in schools. They did it through the Boy Scouts, churches, and youth groups. They also did life skills training, which is a science-based, evidence-based program, in third through ninth grades. So there are the tools.

One of the issues is, unless the schools are part of the larger conversation and the coalition, they don't necessarily want to own this. And I don't know at this point without safe and drug free schools, which we lost the funding for a while ago, unless we can show schools that spending time on this is going to increase educational outcomes, which I think we can do, they are not all that interested in spending the time on doing it. It is a little bit hard to get into the schools at this point. But with this epidemic, I think we have an amazing opportunity to bring them back into the fold as full partners in prevention.

Mrs. BLACKBURN. Sir.

Mr. FRANCER. Well, if there is anything this hearing today has shown is that we need to take an all-hands-on-deck approach to this problem. And I think that one of the keys is early education, as you mentioned.

We have partnered, as I mentioned in my testimony, with a company called EVERFI, which is one of the largest online educational providers. They have developed this curriculum with experts. They started in colleges and universities, and now they are beginning to go younger. And speaking for myself, I remember growing up with drunk driving education early in life and the type of education that you discussed. And so I think that the more, the better, and it is going to take all of us in a comprehensive way to approach this problem.

Mrs. BLACKBURN. Thank you.

Ms. Thau, I have to tell you, I saw the Deterra bag recently, and it is so simple to use. And I thought then for older patients how easy that would be, just to put the unused portion of that prescription, close that top, and throw it away. And then you have elimi-

nated a big part of that problem. So I appreciate that you all are giving those out, making them available.

Ms. THAU. Thank you so much.

Mrs. BLACKBURN. I yield back.

Mr. GUTHRIE. I thank gentlelady for yielding back.

The chair now recognizes Mr. Luján for 5 minutes for questions.

Mr. LUJÁN. Mr. Chairman, thank you very much. And, Ms. Thau, and all our witnesses, thank you so much for being here today. And thank you for working so tirelessly with my team over the last few months, and your expertise has been invaluable.

In your testimony, you state that, "Primary prevention to stop substance use before it ever starts is the most cost effective way to deal with the addiction issues facing our Nation."

You continue to say, "Research shows that for each dollar invested in prevention, between $2 and $20 in treatment and other health costs can be saved."

Substance use prevention has historically been underresourced and underutilized in combating drug issues, including the current opioid epidemic. Most of the emphases in funding have been directed towards downstream approaches that try to deal with the problem after it has already reached crisis proportions.

While I know that we are here to talk about H.R. 449, I was hoping to chat with you a little bit about prevention in general. As you might know, I have had the honor and pleasure of working with my colleagues, of course, Mr. Guthrie, our chair, Mr. Green, Mr. Bucshon, on the Comprehensive Opioid Recovery Centers Act. I am pleased that we can work across the aisle on important issues to better integrate, coordinate, and ensure quality at our substance use disorder programs across the Nation.

As we drill in on prevention, though, in your expert opinion, does a substance use disorder program need to include prevention in order to be comprehensive?

Ms. THAU. Yes. I would say absolutely in general it does. And especially if you are going to do something with comprehensive recovery centers and you want strong linkages with the community, two things: The same community conditions, not a lot of access and availability. Social norms where people don't necessarily think that it is a great thing to use. The same things that keep kids from using are what keep people in recovery in recovery.

So we need to develop, I think, community conditions that are conducive to both preventing use in the first place and keeping people clean and sober when they reenter.

That said, addiction is a family disease. So there is universal prevention, which is aimed at everyone who hasn't used, and then there is selective prevention for very high-risk kids who haven't used yet, like the children of drug abusing parents. So I would say you definitely would want programs involved in these comprehensive opioid recovery centers for the children of people who were getting recovery services at a minimum. And I would also hope that those centers would have strong linkages to the community prevention coalitions that were doing the environmental strategies and the other work in the community to build down the demand for drugs.

Mr. LUJÁN. While I understand the world of prevention efforts is broad, let me attempt to drill in and ask you to help me narrow in in a few areas. So if I were to ask you to narrowly focus prevention efforts in this bill, where would you recommend that we start? How would we be able to narrow this?

Ms. THAU. One, I would probably have linkages to the drug-free communities' coalitions in the same places where these centers were going to be housed so that they could work together. And two, I would figure out how to have selective programming for the kids of parents who were being treated in the centers, both for treatment and recovery support.

Mr. LUJÁN. I would also like to ask your opinion about two other areas, again, as we narrow in on prevention. Do you think it would be reasonable to begin with individuals who are using opioids appropriately for pain management but not addicted, as well as individuals whose family struggle with substance use disorder but who are not addicted themselves, as a narrowing area——

Ms. THAU. No, I definitely think so. So dealing with people who are using opioids and are at high risk for becoming addicted is an indicated approach. So, basically, it is screening, brief intervention, figuring out if somebody does need a referral to treatment. And then, yes, absolutely.

Mr. LUJÁN. And then one last question as my time is about to expire. Do you know of any data suggesting that these would be effective prevention efforts?

Ms. THAU. Yes. There is a lot of data saying that selective interventions, as well as indicated interventions, are very effective.

Mr. LUJÁN. Mr. Chairman, again, I want to acknowledge your leadership and the work that you have done in this space.

And, Ms. Thau, I look forward to working with you on compiling that data so that we can continue to have these conversations with all the staffs involved. And again, thank you for your expertise.

Mr. Chairman, thanks for this important hearing.

Mr. GUTHRIE. Thank you. It has been a pleasure for us to all work together on these issues.

The chair now recognizes Mr. Latta from Ohio, 5 minutes for questions.

Mr. LATTA. Thank you, Mr. Chairman. And thanks very much for our panel for being here today, it is really important, on this issue and lifesaving is what we have to be doing out there.

Ms. Esham, if I could start with you, I strongly support using data to help combat the opioid epidemic, which is why I introduced the INFO Act. Would you elaborate on Bio's recommendation to utilize data to better understand clinical pain and addiction and improve medical decisionmaking?

Ms. ESHAM. I will certainly try. And I have actually been learning a lot myself today. And I think as we have heard from the various panels, there is a lot of data collection being done.

I think our recommendations are not basically designed to say that there is not data or the data is not being collected, as much as to ask the question how can we use data to inform and improve how we treat patients suffering from pain and addiction. And so our recommendation is really calling on NIH perhaps to take the lead and work with other governmental agencies and look at the

data that exists to determine, are we able to use that information to help us determine what treatment works best for a particular patient? Are we treating people in a way that delineates acute pain from chronic pain? Are we able to identify and make sure we are treating people that have psychic pain in the appropriate way? How can we learn about what the optimal duration is for specific treatments? And we have many others that are outlined in my written testimony.

The bottom line is, how can we use data to provide better care today and inform how to provide better care in the future as we have new treatments coming online? And so that is something, I think, that would bear critical information that could really help us examine how we could not only mitigate the opioid epidemic, but just treat patients better.

Mr. LATTA. OK. Thank you.

Dr. Holaday, and thank you for coming in today. The committee is focused on improving prescription drug disposal as an important strategy to help reduce diversion and the resulting misuse or abuse. At the same time, it is important that safe disposal of prescription drugs is not impeded by strength as approaches develop. How should we ensure that the disposal system standards are sufficiently rigorous to providing meaningful improvement and safety?

Mr. HOLADAY. What we have done with our own product was to have it evaluated by a third-party laboratory to ensure that once the drugs were sequestered in this product, that they could not be extracted. Although my Ph.D. Is in pharmacology, the guys on the street that want something out of these are going to be far more creative. And what they will do is they will use vodka or other sources to extract and or inject opioid drugs in others.

I think there needs to be, if you will, a fundamental focus on making sure that the drugs left over in the medicine cabinets are disposed of by some manner that is convenient. We think an at-home solution is the best one. We think we have got an appropriate way of getting rid of them, but that will also prevent diversion for abuse and also prevent pollution of landfills and water supplies.

Mr. LATTA. Let me just follow up on that. Do you think a disposal system review process that would be conducted in a way that is efficient—because again, when things get started, sometimes there is always a question on that review, but should it be efficient—how do we do it without necessarily raising the cost out there?

Mr. HOLADAY. I wouldn't recommend that this be something that is demanded in terms of rigorous for evaluations of products that may remove products, such as assessments of whether something is effective or not. I do think, however, that much in the same way that the 1970 Poison Prevention Act required the childproof closures be put on all drugs, it was legislated; before then it was available, but nobody used it. After legislation, within 2 years, there was a 45 percent reduction of childhood deaths from leftovers or from drugs in medicine cabinets.

And we think that something should be legislated to encourage the use of a system, perhaps at home, we believe, for getting rid of leftover drugs that they wouldn't be available for abuse or diversion.

Mr. LATTA. Well, Thank you very much, Mr. Chairman. I am going to yield back the balance of my time.

Mr. GUTHRIE. I thank the gentleman for yielding.

The chair now recognizes Mr. Pallone from New Jersey, the ranking member of the full committee, 5 minutes for questions.

Mr. PALLONE. Thank you.

I wanted to ask Mr. Francer some questions. The committee has heard concerns from FDA regarding the public health concerns associated with illicit, unapproved, or counterfeit drugs entering our supply chain. And as Commissioner Gottlieb noted on the first panel, these could be products that do not have, or don't contain the right active ingredient, the wrong amount of an active ingredient, or toxic ingredients. And I am obviously concerned about the potential risk this poses to patients, but also about the impact on our supply chain.

I have long been concerned about the number of illicit drugs entering our supply chain and worked with the FDA and many in the generic industry to strengthen FDA's authority in FDASIA, and most recently introduced H.R. 5228, the SCREEN Act, which provides FDA with greater authority and resources.

So, Mr. Francer, obviously you are aware of this issue of illicit or unapproved drugs entering the supply chain through these international mail facilities, but can you describe briefly how this impacts the integrity of the supply chain?

Mr. FRANCER. Sure. And I think like everyone who sat through the first panel, I thought it was extremely concerning to see that deaths from illicit opioids are increasing. Ensuring the safety and integrity of the supply chain is critical. It is one of the features of what keeps drugs safe in our country. And we are supportive of enhancing the FDA's ability to do its job and specifically to try to get at these illicit drugs that are trying to get into our country.

Mr. PALLONE. Well, many of us have talked about how there are millions of these packages that come in through international mail facilities every day, and the FDA only has the resources to inspect a small fraction; I think about 40,000. And the bill I mentioned, my bill would provide FDA with additional authority and resources to combat this problem.

I don't know if you have looked at the bill, but would you support, you know, the types of things that we have in the bill to provide FDA with additional authority and the resources for enforcement in trying to address some of this? I don't know if you want to specifically mention some of the things that we are trying to accomplish.

Mr. FRANCER. Yes. We are looking at the bill. We are supportive of the concept, and I am happy to work with you and your staff.

Mr. PALLONE. What about the resources aspect? We really haven't talked much about that. I know that Commissioner Gottlieb said he did need additional resources. Have you looked to see what all the agencies are always reluctant to say anything more than we need more resources, so if you ask them how much they need, they won't tell you because they probably think they shouldn't. You have any idea what we would be talking about?

Mr. FRANCER. I don't know. I would try to get an answer from the FDA.

Mr. PALLONE. Yes. I know it is hard to get an answer from them on something like that.

All right. Well, then I just would ask that—anybody else want to comment on this, any of the other panelists? I still have 1 1A½ minutes.

All right. Let me ask Ms. Thau. I am interested in your perspective on the importance of prevention and finding prevention services, if you wanted to comment.

Ms. THAU. Yes. I would love to. So I think one of the problems here is because of the tremendous death toll and the horrific way this is presenting in our society, everybody is really moving downstream. And so we are not doing much about prevention, really, in this. And it would be like with the smoking stuff, only doing cessation and not doing the truth campaign and not raising the price of cigarettes and stopping advertising, or for polio just building more iron lungs. So we really do need to move upstream.

The point is there is no silver bullet in prevention either. It really does take a comprehensive, communitywide approach that involves everybody. It doesn't take a lot of money, but it actually does take concerted effort in doing a needs assessment, figuring out why kids are starting, what they are starting with, how they are getting the drugs. For are the most part we know it is from the medicine cabinets and from friends and families. So we do need to do a lot more raising awareness, education, reducing access and availability, changing prescribing practices. And the point is, all of that together is really what is going to solve this upstream.

Mr. PALLONE. Well, I think I agree with you. I am sure you realize that many of us, all of us probably, on the committee are so frustrated because we see the opioid problem getting worse. And we know that we need additional resources for prevention and enforcement, and that is why I am happy that the budget deal has that extra $6 billion. But there is no easy answer. And I always go out of my way to say, look, I don't have any easy answers, because I don't want anybody to think the committee is going to magically pass some bill or throw some money and that is going to eliminate the problem. But thank you so much.

Thank you, Mr. Chairman.

Ms. THAU. Thank you.

Mr. BURGESS [presiding]. The gentleman yields back. The chair thanks the gentleman.

The chair recognizes the gentleman from Oregon, the chairman of the full committee, Mr. Walden, 5 minutes for questions, please.

Mr. WALDEN. Well, thank you, Mr. Chairman. Again, thanks to all of our witnesses on these various panels. I think you will hear from all the committee members how concerned we are and how helpful we want to be to all of you and the people in our communities that are dealing with this terrible, terrible situation.

As you may know, we are also doing an investigation through our Oversight Investigative Subcommittee arm and have been for well over a year, and it is pretty disturbing what you learn on that side of this as well. The goal is then to get to good public policy and try and help people back home. So I just appreciate your comments today, all of you.

And, Ms. Thau, how can community-based prevention and multisector coalition approaches effectively reduce the rates of youth substance abuse, especially prescription opioids? And I was meeting with some people from Oregon this morning in my office. And voters legalized marijuana in Oregon. I just came from a meeting with some of the community action folks, and they talked about a young kindergartner who they thought maybe had been born drug-addicted and all, and later realized, later in the afternoon of meeting with this young girl, that she was just actually high on marijuana from the morning; that that is what they think it was. And you see that happening, you see this happening.

And so, we all want to get our hands around—obviously, the adults in the room are part of the problem, but what can we do from a community-based prevention multisector coalition approach?

Ms. THAU. Well, basically what we can do is get everybody around the table, all 12 sectors, as I mentioned before: parents, the schools, law enforcement, the faith community, youth serving organizations. And then we really do need to do what we call the strategic prevention framework. We need to look at how the problem presents in a community, who is using, where they are getting, how they are accessing what they are using, what the social norms are, and then do is a strategic communitywide plan where everybody has a part in implementing it. And then evaluate where you are.

And I can tell you I have three case studies, one of which I talked about a minute ago from the epicenter of the opioid epidemic, so Carter County, Kentucky; Scioto County, Ohio, where Dreamland, the book, was actually written about; as well as Jackson County, West Virginia.

Mr. WALDEN. There you go.

Ms. THAU. These are places a decade ago where people were dying of fentanyl overdoses. Like in West Virginia and Jackson County, they had 17 overdoses in this tiny thing of fentanyl a decade ago. And they built the coalition, and they have been able to build down demand and stop the pipeline to addiction by lowering the usage rates among their youth, and it is exponential reductions. So they have seen less need for treatment and fewer people overdosing.

Now, there are always going to be people who use and we always need treatment and recovery. But the point is that the fewer people who start using, the fewer people who are going to get in trouble downstream. So it is critical, I think, that we do everything we can to build this comprehensive community capacity.

Mr. WALDEN. I was with an oncologist yesterday from Oregon, Dr. Bud Pierce. And he talked about years ago, years ago, they had to take 8 hours of mandatory education on pain management, where they were told that it would be malpractice not to prescribe opioids and manage the pain. You think about how far we have come to now realizing what a horrible thing we have built as a result, in part by that false knowledge and a push from the government, frankly, in how we reimburse. That was one of the criteria, what kind of smiley face do you have on pain when you left the hospital or wherever.

And it strikes me that this new Veterans Department study that showed that people who took Tylenol or that type of pain reliever, in this study, reported less pain than those who were on opioids. Now, that really makes you stop, and you wonder, do we need all of this? Are there alternatives that are better in terms of pain management?

So it seems to me we have got an addicted age group here, if you will, and to get to where you are at is preventing that from ever starting with these children is a goal. Do you have anything else you want to add, or any of the other panelists? Anybody else?

Well, at least nobody disagrees with that analysis, so thank you for that. I really appreciate you being here on a snowy day.

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

Mr. BURGESS. The gentleman yields back, and the chair thanks the gentleman.

The chair now recognizes the gentleman from Virginia, Mr. Griffith, 5 minutes for your questions, please.

Mr. GRIFFITH. Thank you very much, Mr. Chairman. I appreciate you all being here and appreciate your testimony. Iapologize for not being here when you all started your testimony because I was on the floor with some others, as you have heard earlier, on another bill.

But we are working on a lot of bills here today. And I have to tell you I was really interested in hearing this, because last week, my 18-year-old stepdaughter had her wisdom teeth out and was prescribed oxycodone. She took two of them. The rest of the prescription is at home. So you all talked about how that is where the danger starts.

Dr. Holaday, I am going to let you respond first. And I have to tell you, I have a 12-year-old and a 10-year-old at home too. And your product reminds me a little bit of a completely different subject, but not only will it help us get rid of a problem, but for my 10- and 12-year-old, I think that would be fun, the way it fizzes up.

But can you go back in and explain a little bit about how the polymers work? And you said you could eat the stuff, and I was assuming that you meant you could eat it before it was mixed with the oxycodone. But maybe once it is mixed with the various polymers, with the secret sauce as you called it, it is inert afterwards. But I would suspect it has still got some negative properties.

But can you explain some of that? And then I will open it up for anybody else to discuss. Otherwise, we might look at it and what do I do now. When I go home this week, what do I do with that remnant prescription?

Mr. HOLADAY. First thing you do is go to Walmart, they will give you a free packet of this product——

Mr. GRIFFITH. So they will give me that.

Mr. HOLADAY [continuing]. That you would put into your prescription vial with some water, shake it up, and throw it away.

The idea for this is so simple. When you buy flowers, there is always a little packet with the flowers. You put it in the water and preserve them. Why not, when you get a prescription for an opioid or an abusable drug, get a little packet, something, by which you can then dispose of the product safely and conveniently?

Mr. GRIFFITH. Well, if Walmart is giving it to me—now, we did not get our prescription at Walmart. Will they still give it to me?

Mr. HOLADAY. Yes.

Mr. GRIFFITH. And if they are going to give it to me, what is the cost? It can't be a whole lot if they are giving it away.

Mr. HOLADAY. It is a very small cost. Retail, this is $1.50 per packet.

Mr. GRIFFITH. So if I were in a community without a Walmart, could I purchase it somewhere or buy it on the internet?

Mr. HOLADAY. We are putting arrangements together to have this purchasable online through a facility that is going to make this available in units of six. But again, the price would be less than $1.50 per packet and less than 10 bucks for a six packet of product.

Mr. GRIFFITH. That is a pretty cheap fix for a serious problem.

Mr. HOLADAY. And it is permanent.

Mr. GRIFFITH. That's great. Now explain to me, it combines, it forms polymers. And once it does it—because you said it was then safe to go in the landfills. I don't know if it was safe to put in the water supply or not, I don't remember if you said that or not. But tell me how that works, and is it basically inert once you go through that process?

Mr. HOLADAY. It is basically inert, and then what happens is it biodegrades. So one of my colleagues calls me up about 7 or 8 months ago and said, oh, unfortunately, we have got mold growing in our product. That is not nice. But this is biodegrading, so the drugs and its contents and this matrix that we have got is all biodegradeable. I am not the genius that came up with the secret sauce; I just had the idea. So the chemical engineer that came up with this actually mixed it first in his kitchen. You hear those types of stories. Then he spilled some on the driveway and his wife was upset because he couldn't get it off. But this is a permanent and simple solution to a lot of issues that begin with drug abuse in the medicine cabinet.

Mr. GRIFFITH. Well, I have already texted my wife. I will call her when I get out of here and say, OK, go to Walmart and get this stuff. And again, tell me what the name is.

Mr. HOLADAY. Pardon?

Mr. GRIFFITH. What should she ask for?

Mr. HOLADAY. DisposeRx.

Mr. GRIFFITH. DisposeRx. DisposeRx, got it.

Mr. HOLADAY. I have got several packets, I will leave——

Mr. GRIFFITH. Because I think if she showed up and asked for the secret sauce, they might not know what she was talking about.

I have got a little bit of time left. Does anybody want to add anything that they think we ought to be looking at or other folks ought to be looking at?

Yes, ma'am.

Ms. THAU. I just want to add too that when we gave out the 300,000 Deterra deactivation packets throughout Florida and D.C., that was 13.5 million pills that were just gone. And when we went back and did a study, 90-something percent of the people were like, this is great. Exactly, we don't have to leave the house. We just sort of get rid of it and we are done. It is inert and it is not subject to abuse in any way.

So anyway, I would also say it is a very good way to get rid of unused and unwanted meds without leaving your home.

Mr. GRIFFITH. Well, thank you all very much, and thank you for your time today on this very serious subject.

I yield back.

Mr. BURGESS. The gentleman yields back. The chair thanks the gentleman.

The chair recognizes the gentleman from Florida, Mr. Bilirakis, for 5 minutes of questions.

Mr. BILIRAKIS. Thank you, Mr. Chairman. And I want to thank the panel for their patience this afternoon; appreciate it so very much.

This question is for the panel. I know there is no silver bullet in solving this opioid crisis. However, if you had one recommendation, one suggestion in addressing this crisis, what would that be? If you had any suggestions for us, one particular suggestion.

Let's start with you, ma'am. What would that be?

Ms. THAU. Mine would be a lot more investing in multisector prevention to basically stop use before it starts and reduce population level rates of initiation of all drugs.

Mr. BILIRAKIS. Very good. Thank you.

Ms. ESHAM. I think what we are focused on is really, again, everybody is talking about today there are serious problems we have to address today, but we don't have to accept the status quo. So, a lot of what we are trying to think about is how can we change the future, still treat pain, treat addiction better in the future.

And so I think, in those terms, a lot of the recommendations we outlined are really designed to create collaborations and engagement with the regulators as well as people developing these innovative drugs to make sure that there is a signal to investors that this is a top priority and this is something we should be investing in, and that we are able to, in a most efficient way possible, provide these alternatives to opioid treatment and better treatment for addiction in the future. So I think that is what we are focused on.

Mr. BILIRAKIS. Thank you. Thank you.

Mr. FRANCER. I would say it is about education. And we just talked about the end user education, the patient education. It is also the prescriber education. And we just talked about how the physicians and the other prescribers, their education is changing as we speak, and we have to encourage that.

Mr. BILIRAKIS. Would you mandate the schools and the curriculum in the schools prevention and the effects of opioid and drug use and even alcohol use? Would you make sure that that is mandated in the schools?

Mr. FRANCER. We are hoping to support some voluntary programs that colleges, universities, and now even high schools can implement. And these are online training, so it has obviously got a huge economy of scale. And I don't think——

Mr. BILIRAKIS. Training the students, the teachers?

Mr. FRANCER. In terms of the types of behaviors that we have been talking about today, proper disposal, what do you do if you have extras, who do you give them to, who shouldn't you give them to? But really, truly, it is not up to me to decide. I think right now,

it is very much a decentralized decision with colleges, universities, and secondary schools.

Mr. BILIRAKIS. I would start even earlier. I would start in maybe in the middle schools, elementary schools. The chairman just mentioned the child on marijuana in the elementary school. That is really scary.

Yes, sir.

Mr. HOLADAY. I would like to echo my colleagues. Education is going to be key. It is part of our passion. As we tell people about what we do, we work with sheriffs' offices with various high schools and others to tell people about the best way to get rid of drugs and stop the cycle of addiction and overdose is to get them out of your medicine cabinet. And the most convenient way to do that is through a home solution, whether it is ours or others that are available.

We also think that it might be useful for it to be considered that, much like the Poison Prevention Packaging Act of 1970 that required child-resistant closures, that something also perhaps be legislated that requires a means by which to dispose of a drug be dispensed with that drug, particularly for those that are abusable, including opioids, benzodiazepines, Adderalls, and others which can be addictive and abused.

Mr. BILIRAKIS. Thank you very much.

I have a little more time, Mr. Chairman.

State and, in some cases, local level PDMPs undoubtedly are a critical tool used to support the fight against the current opioid epidemic. However, challenges exist in the current system, such as the lack of interoperability with health IT and the lack of true real-time data reporting. These challenges are preventing clinicians, both prescribers and dispensers, from having access to all the information needed to make the best clinical decision.

Would having standardized information available in real time to prescribers and dispensers aid in ensuring appropriate medication is being prescribed and dispensed? That would be for Mr. Francer, please.

Mr. FRANCER. We support increased use of these programs and increased operability, I think. It is especially interesting here where we have D.C, Maryland, and Virginia, you don't want patients to be able to take advantage of weaknesses in the system.

Mr. BILIRAKIS. So you would agree that it would?

Mr. FRANCER. Yes.

Mr. BILIRAKIS. OK, very good.

OK. I will yield back, Mr. Chairman. Appreciate it.

Mr. BURGESS. The chair thanks the gentleman.

The chair recognizes the gentlelady from Indiana, Mrs. Brooks, 5 minutes for questions, please.

Mrs. BROOKS. Thank you, Mr. Chairman.

I think we have talked about education throughout. I have heard you all mention the importance of education. And something that the committee has been exploring, but I know there is always hesitation. Even, Mr. Francer, I know you noticed that mandating any type of education is controversial. No one really likes anything mandated. However, we are at a crisis, and we have been sitting here all morning—although, I will tell you that I wouldn't say—and

I was just looking at the CADCA website. I wouldn't say we get a lot of calls from constituents about this. Our newspapers pay attention to it, we know we all talk about it as elected officials, but because of the stigma of drug addiction still, I wouldn't say that we all get flooded with phone calls about bills we are proposing and so forth.

But one thing I know and we are certainly talking about is how do we reduce the number of prescriptions that are written? Of course, we want people who have legitimate pain and who have gone through surgeries or who have chronic illness or cancer and so forth that have pain, but I really do feel strongly that prescribers of all type need more education. I know med schools are doing a better job now, but there is still a lack of education out there on the amount of prescriptions. Indiana has a 7-day law now. And there can be exceptions for that, but the prescriber just has to say what the exceptions are.

So I am really curious about a bill that we are working on to potentially require of all prescribers 3 hours of continuing medical education about opioids, for all prescribers, not just about prescribing, but about identifying addicts, their own patients and/or how to help them get into recovery. So I am just curious, it obviously could put a dent in the use of your product, Dr. Holaday, but I think it is critically important, and I applaud you and the others for those types of products, but why do we have so many leftover prescription drugs in our medicine cabinets to begin with? What a waste of resources in so many ways. And I applaud your product.

But, Mr. Francer, talk to me about 3 hours prior to, say, a DEA license renewal, over a 3-year period.

Mr. FRANCER. The FDA already requires some amount of education, not necessarily 3 hours, but they have a risk management program for certain types of opioid products. And I think Dr. Gottlieb would like to expand on that, which we would applaud. I think that it doesn't seem unreasonable to expect 3 hours before you get your DEA license approved, given the amount of risk involved.

Mrs. BROOKS. From CADCA point of view?

Ms. THAU. Well, we totally agree with you. We support it, and we also think that some of that education should be about understanding addiction as well. Because there is very little training in medical schools, and everybody should actually be asked whether they have a substance use disorder before they are actually given anything that could cause them to relapse, and a lot of people do not ask the question.

Mrs. BROOKS. Does the data show, though, that people admit they have a substance use disorder?

Ms. THAU. Well, I think that they do to their doctors. And I don't know if you had heard Dr. Jones when he said he had an anesthesiologist when he was having a colonoscopy—because he is in recovery, he told that to the committee. He had to demand that they not actually give him Propofol, because they kept saying it wasn't going to be dangerous. So people, I think, need a lot more education.

Mrs. BROOKS. And the education, and I know that is what CADCA is very focused on, is creating those coalitions in our communities and so forth. And I do think that over the years, whether

it was Mothers Against Drunk Driving or Students Against Drunk Driving, there was that impact that was made for a whole generation really younger than me, I might say. It really wasn't as effective at my age group, but it certainly has been for the younger generation.

But yet, we don't really have a set protocol of education for young people right now back to that point. Is there anything that has been proven that really is very effective in our schools?

Ms. THAU. Yes, there is a lot of evidence-based prevention of the issue or two; one to say yes, I think it was, Congressman Bilirakis, do we need something that is mandated even in school base stuff? We were trying so hard with every child succeeds act not to put too many restraints and requirements on schools and school districts that they can decide how to use Title IV, and there are a hundred different uses for it. And drug/alcohol education and intervention is one of them, but it is not required. And I think that at this point it should be, and then schools should be working with their broader communities. The schools can't own this by themselves, but they do definitely have a piece of this.

Mrs. BROOKS. Thank you all for your work.

I yield back.

Mr. BURGESS. The gentlelady yield back. The chair thanks the gentlelady.

The chair recognizes the gentleman from North Carolina, Mr. Hudson, 5 minutes for questions, please.

Mr. HUDSON. Thank you, Mr. Chairman. And thank you to the panel for braving the storm to be here today. It is a really important topic and it is one that touches all of our constituents all across the country in all demographics. And it is one that deserves our attention, and so I appreciate you being here to help us understand this problem more.

Dr. Holaday, glad to see you here. I am proud to say that DisposeRx is a company based in my district in North Carolina. And you are on the front line helping to fight this epidemic, and so I welcome you here today particularly.

In your testimony, you noted that 70 percent of people studied do not use the drug take-back programs, such as mail back envelopes; and further, that take-back programs dispose of only about 0.3 percent of controlled substances that are dispensed.

Do you think the end users don't use this program because they just don't see a need or don't want to dispose of their medication? Or you think it is because of the inconvenience?

Mr. HOLADAY. First, I would like to thank you, sir, for your leadership in working with the opportunities to prevent drugs in the medicine cabinet from finding their way into abuse, misuse, and pollution. And so we are a proud North Carolina company in your district.

I think that the numbers of people that use take-back facilities and kiosks are small, first of all, because it is inconvenient. You have to get in your car and go do something, that you are likely to say, why would I want to do that? I have got enough opiate in case I ever need it. I will just leave it in the medicine cabinet.

But things have to change. What we do is disruptive. It changes the way people do things, just like seatbelts. Just like other changed behaviors, recycling.

So we think with appropriate education that we can train people that they have got leftover drugs that are a problem for them, for their families, and for others. Oddly, I know of a real estate agent that told me stories of people that would follow her around and go to housewarmings and go to the medicine cabinets and take out the leftover drugs. So the urgency to get these drugs out of circulation is a real one.

It is inconvenient to go to take-back facilities and kiosks because people don't want to do that. They are not very effective. Often the products are diverted from that, and it is a liability for the pharmacies. If you do it at home, then you prevent that liability. Throw it in the trash, it biodegrades, and it is not usable for anybody to abuse.

Mr. HUDSON. In our first hearing on this opioid crisis here at the Energy and Commerce Committee at the end of February, I know the story of a woman I talked to who said that she had moved her prescription opioids from medicine cabinet to medicine cabinet over 5 years that she moved from apartment to apartment.

You mentioned that less than 20 percent of patients have reported receiving education from their provider on how to dispose of unused medications. I heard you testify earlier that you think education is a key element here. What exactly should the provider be educating their patients about when they give them a prescription for an opioid? What is the nature of what education they need to receive?

Mr. HOLADAY. I think that begins with the physician that prescribes the drug to begin with, talking about not only pain relief, but also the problems that total with prescriptions not used and how you ought to get rid of it. I think that Dr. Carter might agree that the pharmacist has a role, a very important role in educating the people that come to the pharmacy and say, look, you are taking home a product that is toxic, you will need it for your pain relief, but when you are done with it, get rid of it so it is not going to cause further problems.

Mr. HUDSON. Does anybody else on the panel want to touch on that?

Ms. ESHAM. I will. I think if you think about what is happening and some of the comments made earlier, I think what you want to have as we say, you want patients to have knowledge of and access to all available treatment. So if you present yourself and you are going into a postsurgical situation and you tell your doctor you are an at-risk person for addiction, you want that doctor to be able to clearly tell you here is an alternative and have that discussion. If you are a person that is going in to have a procedure being treated for pain, you want the ability to say I have children at home, is there an abuse-deterrent formulation.

And the public should not be solely responsible for that. You want to have a very informed provider community that is able to help ensure that people are making the best choices possible.

Mr. HUDSON. Right. Anybody else want to chime in? I have got 30 seconds.

Ms. THAU. I think we also have to really inform the public on exactly the questions to ask; what to do with this stuff? And just to end, a lot of our coalitions are working with realtors because in open houses people are going through medicine cabinets and actually stealing people's medications.

So there is also a need for locked medicine cabinets and, you know, whatever else we can do to keep these medicines out of the wrong hands.

Mr. HUDSON. Great. Well, I appreciate all your testimony very much.

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

Mr. BURGESS. The gentleman yields back. The chair thanks the gentleman.

The chair recognizes the gentleman from Georgia for 5 minutes for questions, please.

Mr. CARTER. Thank you, Mr. Chairman.

And thank all of you for being here. We really appreciate your participation in this.

Dr. Holaday, I will start with you and, first of all, thank you for this very innovative product that you have come up with. This is certainly something that we can find very useful.

I can tell you, as a practicing pharmacist for many years, I wished I had a dollar for every time someone tried to bring their medication back to the pharmacy, saying "Here," a loved one had passed or whatever and, "Will you dispose of these for me?" And, of course, we can't do that. By law, we can't do it, and I don't want to do it. There have been some take-back programs that have worked well, and some of the local police agencies had had some programs that worked well, and some of the drugstore chains have had some that worked well.

But this is a safe and convenient way to get rid of it. One of the things, as you know, that we don't want to encourage is to have them flush everything. It can cause a lot of problems environmentally, particularly with some drugs.

I am telling my age here, but I can remember, I was a nursing home consultant for many years, and I had to do drug disposal at the nursing homes. And we would burn them and flush them and everything. That was a long time ago, but it is a serious problem.

But I do thank you for what you have come up with and do encourage people, because it is safe; it is convenient. We have always encouraged them to create a slurry and put in the trash as opposed to flushing it. So it is very innovative, and I congratulate you on that and thank you for that.

I wanted to go next to Ms. Esham and ask you, one of the things that I have been concerned about and that I have been on the pharmaceutical manufacturers about is the fact that there is a big gap between what physicians can write for for pain relief and what they can't write for.

Once you get past ibuprofen and tramadol, you go to the opioids, and there is really nothing in between. Now, you could argue you could use Neurontin, but, I mean, basically there is nothing in between. So I have been trying to encourage them, you know: You have got to come up with something innovative.

Over the years of practice I have been in pharmacy, I have seen them come up with nothing short of miracles in the innovation they have come up with through research and development. But there is a big gap there.

One of the things that—and this is not necessarily a drug, but what we talked about before was the abuse deterrent formulations of opioids and how that can help. I just wanted to ask you, do you find that Medicare coverage creates some barriers sometimes to this?

Is that something that you have noticed that perhaps they are requiring a prior approval or you have got to try something else first? Are these barriers that cause us not to be able to use these medications more?

Ms. ESHAM. The short answer is yes. At BIO, a majority of our membership are actually small, emerging companies that rely on venture capital. So, again, you have to take into account, if there is a lack of understanding or an understanding that you will not be able to get your products covered in the market, you are not going to get strong investment into those therapeutic areas.

And particularly when we look at pain and the addiction space, I think CARA went a long way to try to address some care limits for people suffering from addiction. But is there more work to do? Yes, and we stand ready to do that.

In terms of practices, I think, there are barriers in the way that pain medication is often bundled at hospitals. It sort of prevents, again, alternatives or full discussion and full access to the array of medicines available.

There are fail-first protocols in place that we think need to be re-examined. Step therapies, again, we think, need to be reexamined. Basically what we want is a smart patient/doctor informed decisionmaking process and not have outdated or outmoded approaches to coverage that are actually getting in the way of providing that best care.

Mr. CARTER. Right.

Mr. Francer, I wanted to ask you, as part of CARA, we allow for the partial filling of C2 prescriptions. And I was really in favor of that and think that that is something that we need to do. Have you had any experience with it? Does it seem to be working better?

Mr. FRANCER. I don't. Happy to try to get back to you after the hearing though.

Mr. CARTER. OK. Well, I really do think that that was something that we needed to do. And right now, it is up to the patient and to the physician. But even if we can extend it to where the pharmacist might have some input on that as well, I think that could help as well.

But, again, I want to thank all of you. This is the boots on the ground, if you will. And this is the type of thing that we need. And all of you are doing great work in helping us with what is obviously a big problem and obviously a problem that is not going to have just one solution. It is going to take all of us and many solutions to help with this. So thank you.

And I yield back, Mr. Chairman.

Mr. BURGESS. The chair thanks the gentleman.

The gentleman yields back.

And, Mr. Francer, I am going to recognize myself 5 minutes for questions now. And, too, my apologies; I was with Mr. Griffith on the floor doing a bill between our panels.

Let me ask you, when you get back to Mr. Carter on the partial filling issue, I would like for you to share that information with our office as well. I would probably have a different perspective than Mr. Carter, having written a lot of prescriptions myself.

I kind of want to know that my patient has filled what I ask them to fill, and if they didn't, perhaps I need to know that because I might be asked to refill. So, anyway, I would appreciate your follow-through on that.

Now, Ms. Esham, I will just ask you: I have been on this committee now since January of 2005. One of the first hearings that I was here for was a hearing on why doctors don't prescribe enough pain medicine.

So I was intrigued, in your testimony, you said the importance of ensuring that patients suffering from pain or addiction are able to receive the right treatment at the right time with the right support without stigma, and so I certainly agree with you on that.

You have any other thoughts that you would like to share with the subcommittee in that regard?

Ms. ESHAM. So I would like to highlight a couple things in addition to the coverage barriers and the NIH data analysis proposals we have put forward.

Again, going back to my earlier statements about the importance of signaling to investors that the development of treatments that are better, that provide improved quality of care, and are safer are our top priority. There are lots of ways to create an environment that will stimulate investment.

And at the FDA, there are development issues as we look over lessons learned of some innovative treatments that maybe have not been able to obtain approval. We have identified some problematic areas that we think would benefit from collaboration and discussion and perhaps additional guidance.

For example, when you talk about benefit-risk assessment, we want to make sure we understand that the context of presenting and proving that your drug is safer, or provides better care, how that benefit-risk assessment will be done in the context of existing options.

We need to find better ways to develop medicines for broad chronic pain indications. So, right now, you have a lot of requirements. You have to do many, many trials. And, again, so people are like, "Well, maybe I can't spend that much money in this risky environment to do that many trials for a single indication."

Additionally, I think we really need to look at how we can better measure and assess pain. So this is both in a clinical trial setting as well as in the clinic. Are we really doing the best we can?

Are we diagnosing in the best way possible to understand what the needs are of a patient with acute pain versus patients with chronic pain versus a patient that has psychological or psychic pain? So there is a lot of work that we think would benefit from collaboration and further guidance in those areas.

Mr. BURGESS. Well, we heard Dr. Gottlieb address that issue about the datasets that we have for assessing pain.

I will tell you that I am old enough to remember the introduction of a compound called Stadol that was supposed to be the answer to providing pain relief without any of the untoward side effects of opiates, and it turns out it was probably just as bad, if not worse.

So I am always very skeptical when someone says, "Oh, I have got something now here that you can now use for pain that has none of the stigma or the side effects."

And, again, I think we heard Dr. Gottlieb address that.

But can you just talk a little bit more about some of the ways where you might think that private sector, Congress, and the FDA could work together as far as developing some of these novel approaches?

Ms. ESHAM. So, again, we find there is a lot of value, again, in just holding public—where you have a topic, you hold a public meeting, you bring the best and brightest together to discuss critical issues. And then the next step that is critical to making this impact change is to come up with recommendations for change and get public reaction and expert input on that and then implement change.

Mr. BURGESS. That is what we are doing.

Ms. ESHAM. It is really wash, rinse, and repeat, right. We have done this before.

And I would like to, just if I can indulge for a moment, we did just put out a report really examining the historical state of innovation for pain and addiction treatments that you, particularly as a physician, may find interesting in the sense of really looking at targets that didn't work but really highlighting some new ways and new thinking that we have that I think do hold, again, a lot of promise.

Again, sometimes not everything turns out the way you had hoped, but I think there are a lot of exciting things in the pipeline.

Mr. BURGESS. Very well.

And, Dr. Holaday, before we finish up, I don't know if I heard the answer to Mr. Griffith's question. You have got this stuff emulsified in the gel. Is it inert at that point, or could you use it as a Jell-O shot if you were so inclined?

Mr. HOLADAY. It is inert. And if you were to swallow the whole thing, pills and all, you would just pass it through because nothing extracts from this once it has been formed. It is a gel. It is an inert gel. It is biodegradable.

Mr. BURGESS. But if you chewed it, would you release the active compounds?

Mr. HOLADAY. No, you would not.

Mr. BURGESS. So the active compounds are indeed——

Mr. HOLADAY. They are chemically and physically bound, or sequestered, in a matrix from which they can't be extracted.

Mr. BURGESS. OK. And I am just asking for a friend. I was not going to chew the emulsified pills.

Mr. Green, did you have a redirect?

Mr. GREEN. No.

Mr. BURGESS. You have been sitting here so patiently.

And I will yield back my time. Seeing that there are no other members wishing to ask questions, I once again want to thank our witnesses for being here today.

I would also like to submit for the record a statement from the Substance Abuse and Mental Health Services Administration expressing support for Congress, examining the alignment of part 2 with HIPAA.

Mr. BURGESS. That is the wrong one.

We are not going into recess.

Mr. GREEN. I did that earlier, Mr. Chairman.

Mr. BURGESS. Oh, we are going into recess? Oh. That is right. We have got to do this all over again.

The subcommittee will now go into recess, and we will reconvene for the third and fourth panels tomorrow morning at 10:00 a.m.

The committee stands in recess.

[Whereupon, at 3:12 p.m., the subcommittee recessed, to reconvene at 10:00 a.m., Thursday, March 22, 2018.]

[Material submitted for inclusion in the record follows:]

February 23, 2018

Dear Speaker Ryan, Minority Leader Pelosi, Chairman Frelinghuysen, and Ranking Member Lowey:

On behalf of the undersigned organizations we write to urge you to include an increase of $100 million to the viral hepatitis programs at the Centers for Disease Control and Prevention (CDC) to address the alarming increases in the number of new hepatitis B (HBV) and hepatitis C (HCV) cases, and other infectious diseases, such as HIV, sexually transmitted diseases (STDs), endocarditis and skin infections, in the United States in the final FY2018 Labor, Health and Human Services, Education, and Related Agencies Appropriations bill. The undersigned organizations were pleased that $6 billion over two years was included in the *Bipartisan Budget Act of 2018* to assist in this nation's fight against the opioid epidemic. We urge you to allocate $100 million of that amount to the CDC to address infectious diseases.

The nation's infectious disease public health infrastructure is an underutilized resource in our collective response to the opioid epidemic. The systems and programs built over the last two decades to respond to HIV and viral hepatitis are well poised to conduct outreach, engagement, and early intervention services with individuals who use drugs. A comprehensive response to the opioid epidemic, which resulted in over 33,000 opioid overdose deaths in 2015 and over 64,000 overdose deaths in 2016, must include wide-ranging infectious disease prevention efforts, strategies to reduce fatal overdose, increased substance use treatment, and reductions in the infectious disease consequences of the opioid epidemic, particularly rising cases of HBV, HCV, HIV, and other STDs.

In FY2017, the CDC's viral hepatitis programs received only $34 million. Funding levels have long been insufficient to combat the growing number of viral hepatitis cases in the country. It is imperative that we act on the urgent need for additional funding at CDC to respond appropriately to the recent explosion of opioid use in the United States that has created tremendous risk for HCV, HBV and HIV outbreaks.

Over the last several years, the opioid epidemic has led to alarming increases of new viral hepatitis and HIV infections attributed to injection drug use. According to the CDC, the number of new cases of HCV increased 290% between 2010 and 2015, mainly due to the increase in injection drug use. The opioid crisis also reversed a steady decline in the number of new HBV cases, causing a 20% increase in 2015. A recent CDC study also shows that between 2004 and 2014, admissions to drug treatment programs for patients who inject opioids increased by 93%, while acute HCV infections rose in parallel by 133%. The sharpest increases in new HCV cases were among 18- to 29-year olds - a staggering 400% rise over a ten-year period.[1]

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[1] Jon E. Zibbell et al. "Increases in Acute Hepatitis C Virus Infection Related to a Growing Opioid Epidemic and Associated Injection Drug Use, United States, 2004 to 2014", *American Journal of Public Health* 108, no. 2 (February 1, 2018): pp. 175-181.

Outbreaks of HIV and HCV related to the shared use of syringes have occurred in Indiana, San Diego, Kentucky and elsewhere in the past two years. The CDC has identified 220 counties across 26 states that are vulnerable to outbreaks of HCV and HIV. Over 93% of those 220 counties vulnerable to outbreaks do not currently have comprehensive syringe service programs. Without these programs and the resources needed to provide sterile injection materials, transmission rates will continue to increase. Multiple studies have shown that, the presence of comprehensive syringe service programs at the community level is effective at decreasing HIV prevalence.[2]

Increasing funding would allow CDC's hepatitis program, in concert with other programs, including those for HIV/AIDS and STD prevention, to focus on the following activities:

- Enhance existing, and create new, program and clinical infrastructure at locations serving vulnerable populations to effectively increase viral hepatitis and HIV testing and linkages to substance use prevention services, care and treatment for those who are newly diagnosed with viral hepatitis and/or HIV and opioid use disorders. This infrastructure should include linkages to medication-assisted therapies and overdose prevention medications, such as naloxone. Additionally, support for and linkages to STD screening and treatment and access to hepatitis A and B vaccines should also be included.
- Increase education to high risk groups and affected communities, including pregnant women, about the intersection of the opioid epidemic and infectious diseases, such as viral hepatitis, HIV and STDs. Increase training for Disease Intervention Specialists (DIS) and other clinicians and providers about substance use, risk of infectious disease and current medical treatments and effective linkage techniques.
- Increase viral hepatitis surveillance infrastructure in state health departments to detect acute viral hepatitis infections and enhance ability to conduct cluster identification and investigations.
- Increase capacity of community coalitions, state and local health departments, and community based organizations to implement effective primary infectious disease prevention programs and services tailored to persons who use drugs and have opioid use disorders.
- Increase access to, and proper disposal of, sterile injection equipment, where legal and with community support.

Changing the course of the opioid epidemic and its infectious disease consequences requires an honest and critical examination of efforts among all stakeholders. With your continued leadership on this issue, CDC will be able to better prioritize and implement effective public health programs addressing the continuum of prevention and treatment services. We strongly encourage you to allocate at least $100 million of the $6 billion over two years that was

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[2] Gibson DR, Flynn NM, Perales D, Effectiveness of syringe exchange programs in reducing HIV risk behavior and HIV seroconversion among injecting drug users, AIDS 2001;15:1329–1341

recently agreed to in the bipartisan budget agreement be allocated to address the infectious disease consequences of injection drug use.

Sincerely,

Asian Services In Action, Cleveland, Ohio
Access Support Network, San Luis Obispo, California
Access Support Network, Salinas, California
ADAP Advocacy Association, Washington, DC
African American Health Alliance, Maryland
AIDS Action Committee, Boston, Massachusetts
AIDS Alabama, Birmingham, Alabama
AIDS Alliance for Women, Infants, Children, Youth & Families, Washington, DC
AIDS Foundation of Chicago, Chicago, Illinois
AIDS Resource Center of Wisconsin and Rocky Mountain CARES, Wisconsin and Denver, Colorado
AIDS United, Washington, DC
Americal Academy for HIV Medicine, Washington DC
American Association for the Study of Liver Diseases, Alexandria, Virginia
American Sexual Health Association, Research Triangle Park, North Carolina
Asian American Health Coalition dba HOPE Clinic, Houston, Texas
Asian Center - Southeast Michigan, Southfield, Michigan
Asian Health Coalition, Chicago, Illinois
Asian Pacific Liver Center at St. Vincent Medical Center, Los Angeles, California
Association of Asian Pacific Community Health Organizations, San Leandro, California
Association of Nurses in AIDS Care, Uniontown, Ohio
Bailey House, Inc., New York, New York
BOOM!Health, Bronx, New York
BRONX LEBANON HOSPITAL Family Medicine, Bronx, New York
Buddy's Purpose, Cherry, Illinois
CAEAR Coalition, Washington, DC
California Hepatitis Alliance, San Francisco, California
CARES, Kalamazoo, Michigan
Caring Ambassadors Program, Inc., Oregon City, Oregon
Cascade AIDS Project, Portland, Oregon
Center for Pan Asian Community Services, Atlanta, Georgia
CenterLink: The Community of LGBT Centers, Fort Lauderdale, Florida
Coalition on Positive Health Empowerment, New York, New York

Community Access National Network (CANN), Washington, DC
Community Health Outreach Work (CHOW) Project, Honolulu, Hawaii
DC Fights Back, Washington, DC
Digestive Disease National Coalition, Washington, DC
Drug Policy Alliance, Washington, DC
End AIDS Now, New York, New York
Equality North Carolina, Raleigh, North Carolina
Equitas Health, Columbus, Ohio
Family & Medical Counseling Service, Inc, Washington, DC
Georgia AIDS Coalition, Snellville, Georgia
Harlem United, New York, New York
Harm Reduction Coalition, New York, New York
HealthHIV, Washington, DC
Hep B United, Washington, DC
Hep Free Hawaii, Honolulu, Hawaii
Hepatitis B Foundation, Doylestown, Pennsylvani
Hepatitis C Allies of Philadelphia (HepCAP), Philadelphia, Pennsylvania
Hepatitis C Association, Scotch Plains, New Jersey
Hepatitis C Mentor and Support Group, Inc., New York, New York
Hepatitis Education Project, Seattle, Washington
HIPS, Washington, DC
HIV Dental Alliance, Atlanta, Georgia
HIV Medicine Association, Arlington, Virginia
Hope House of St. Croix Valley, Stillwater, Minnesota
Howard Brown Health, Chicago, Illinois
Human Rights Campaign, Washington, DC
Immunization Action Coalition, Saint Paul, Minnesota
Infectious Disease Specialist, Tampa, FL
Infectious Diseases Society of America, Arlington, Virginia
International Community Health Services, Seattle, Washington
John Snow, Inc. (JSI), Boston, Massachusetts
Lambda Legal, Chicago, Illinois
Latino Commission on AIDS, New York, New York
Life Foundation, Honolulu, Hawaii
Liver Health Connection , Denver, Colorado
Los Angeles LGBT Center, Los Angeles, California
Michigan Coalition for HIV Health and Safety, Michigan
Minnesota AIDS Project, St. Paul, Minnesota
NASTAD (National Alliance of State and Territorial AIDS Directors), Washington, DC
Nashville CARES, Nashville, TN
National Association of County and City Health Officials, Washington, DC

National Coalition for LGBT Health, Washington, DC
National Viral Hepatitis Roundtable, Washington, DC
National Working Positive Coalition, New York, New York
Noflweb.org, Pensacola, Florida
North Carolina AIDS Action Network, Raleigh, North Carolina
North Carolina Harm Reduction Coalition, Wilmington, North Carolina
Ohio Asian American Health Coalition, Columbus, Ohio
Orlando Immunology Center, Orlando, Florida
Perfectly Flawed Foundation, LaSalle, Illinois
Prevention Access Campaign, Brooklyn, New York
Prism Health, Portland, Oregon
Project Inform, San Francisco, California
Racial and Ethnic Health Disparities Coalition, Maryland
Rural AIDS Action Network, St. Cloud, Minnesota
Ryan White Medical Providers Coalition, Arlington, Virginia
Southern AIDS Coalition, Birmingham, Alabama
Southern HIV/AIDS Strategy Initiative, Durham, North Carolina
The AIDS Institute, Washington, DC
The Aliveness Project, Minneapolis, Minneapolis
The Perfectly Flawed Foundation, LaSalle, Illinois
Treatment Action Group, New York, New York
University of Miami, Miami, Florida

NACCHO
National Association of County & City Health Officials
The National Connection for Local Public Health

March 14, 2018

The Honorable Leonard Lance
2352 Rayburn House Office Building
Washington, DC 20515

Dear Representative Lance:

On behalf of the National Association of County and City Health Officials (NACCHO) and nearly 3,000 local health departments, I am writing today in support of the Eliminating Opioid Related Infectious Diseases Act of 2018. NACCHO represents city, county, metropolitan, district, and tribal health departments that work every day to help ensure prevention and treatment options and resources are available to those affected by the opioid epidemic.

Local health departments are key partners in protecting the health and well-being of their community and are instrumental in slowing the opioid epidemic. In addition to concerns about opioid overdose, there are additional risks for poor health outcomes and blood-borne infections, including HIV, hepatitis C virus (HCV), and hepatitis B virus (HBV) among injection drug users. Substantial progress has been made in reducing HIV infections among injection drug users, but increases in injection drug use stemming from the opioid epidemic present a new set of challenges, particularly in rural and suburban communities. These areas often lack the public health and healthcare infrastructure and services to comprehensively address the epidemic, leaving communities vulnerable to infectious disease outbreaks.

A comprehensive response to the opioid epidemic, which resulted in over 64,000 overdose deaths in 2016, must include wide-ranging infectious disease prevention efforts, strategies to reduce fatal overdose, increased substance use treatment, and reductions in the infectious disease consequences of the opioid epidemic, particularly rising cases of HBV, HCV, and HIV. Your bill would help to decrease the toll of infectious disease by encouraging robust surveillance of infections associated with injection drug use. It would also support health professionals on the front lines of infectious disease outbreaks by providing education and training in the detection and control of infections.

NACCHO looks forward to continuing to work with Congress to realize its goals of controlling the opioid epidemic. Thank you for your attention to the devastating impact of infectious disease on people who inject drugs. Please contact Ian Goldstein, NACCHO Government Affairs Specialist for further information at 202-507-4273 or igoldstein@naccho.org.

Sincerely,

Laura A. Hanen

Laura A. Hanen, MPP
Interim Executive Director & Chief of Government Affairs

NASTAD

444 North Capitol Street NW, Suite 339
Washington, DC 20001
(202) 434.8090 | NASTAD.org

March 16, 2018

Congressman Leonard Lance
2352 Rayburn House Office Building
Washington, DC 20515

Dear Congressman Lance:

On behalf of NASTAD (the National Alliance of State and Territorial AIDS Directors), I am writing to offer our support for the "Eliminating Opioid Related Infectious Disease Act of 2018." NASTAD represents public health officials in all 50 U.S. states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, seven local jurisdictions receiving direct funding from the Centers for Disease Control and Prevention (CDC), and the U.S. Pacific Island jurisdictions. This legislation is a critical first step in addressing the increase in hepatitis C and B and HIV infections related to the nation's ongoing opioid epidemic.

The Eliminating Opioid Related Infectious Disease Act focuses resources on assisting States and other partners in identifying and investigating cases of hepatitis and HIV stemming from drug use. Increasing efforts to ensure individuals who inject drugs know that they are at heightened risk of acquiring certain infectious diseases and linking them to appropriate counseling, testing and treatment services are key interventions needed to stem the tide of increasing new infections.

Health department HIV and viral hepatitis programs continue to develop innovative and expanded programs to address the health needs of individuals who inject drugs and are in desperate need of resources to assist with increasing hepatitis C infections.

Thank you very much for your continued commitment to addressing the infectious disease consequences of the opioid epidemic.

Sincerely,

Murray C. Penner

Murray C. Penner
Executive Director

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Johanne Morne, New York
Demetre Daskalakis, New York City
Diana Jordan, Virginia
Beth Crutsinger-Perry, Washington

Executive Director
Murray C. Penner (ex officio)

NVHR
National Viral Hepatitis Roundtable

March 19, 2018

The Honorable Greg Walden, Chairman, House Energy & Commerce Committee
The Honorable Michael C. Burgess, Chairman, Health Subcommittee

RE: H.R. __, Eliminating Opioid-Related Infectious Diseases Act

The National Viral Hepatitis Roundtable (NVHR) is a broad coalition of 500 organizations working to end the hepatitis B and C epidemics in the United States. On behalf of the nearly 5 million people living with hepatitis B or C, we appreciate this opportunity to express support for H.R. __, the Eliminating Opioid-Related Infectious Diseases Act.

Skyrocketing rates of infection with hepatitis C and hepatitis B are among the devastating public health consequences of the opioid crisis in the United States. Hepatitis C is the deadliest infectious disease in America, killing nearly 20,000 people in 2014 alone,[1] and injection drug use is the cause of most new infections.[2] From 2010 to 2015, the number of new hepatitis C infections jumped by 294 percent, with particularly sharp increases among states hardest hit by the opioid crisis.[3] Reported cases of hepatitis B, which can also be transmitted via injection drug use, increased 20.7 percent in 2015.[4] Because of the direct link between injectable opioid use and hepatitis C and B, any initiative to tackle the opioid crisis in America must include a robust effort to screen, vaccinate, and treat people for these viruses.

The underfunding of surveillance and testing programs for hepatitis B and C has contributed in part to the explosion of these epidemics. By steering funding toward the prevention of infectious diseases spread by injection drug use, the Eliminating Opioid-Related Infectious Diseases Act of 2018 would take a step in the right direction. Even a modest increase in funding would ensure that more people are tested and linked to care for hepatitis B and C, preventing more infections and saving countless lives. NVHR strongly supports the Eliminating Opioid-Related Infectious Diseases Act because it would allocate badly needed resources to the fight against hepatitis B and C. We urge the Committee to begin addressing these epidemics with its approval of this legislation today.

---

[1] Centers for Disease Control and Prevention, "Hepatitis C Kills More Americans than Any Other Infectious Disease" (May 2016), available at https://www.cdc.gov/media/releases/2016/p0504-hepc-mortality.html.
[2] Campbell, Canary, Smith, et al. State HCV Incidence and Policies Related to HCV Preventive and Treatment Services for Persons Who Inject Drugs — United States, 2015–2016. MMWR MORB MORTAL WKLY REP 2017;66:1-2.
[3] *Id.*
[4] Centers for Disease Control and Prevention, "Surveillance for Viral Hepatitis – United States, 2015" (June 2017), available at https://www.cdc.gov/hepatitis/statistics/2015surveillance/commentary.htm.

Respectfully submitted by,

Elizabeth Paukstis, M.A., J.D.
Public Policy Director
National Viral Hepatitis Roundtable
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39 Broadway, Suite 2700, New York, NY 10006-3003
Tel: 212-668-1000 | fax: 212-483-8179
www.liverfoundation.org

National HelpLine 800-GO-LIVER (800-465-4837)

March 19, 2018

The Honorable Greg Walden
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairmen Walden and Ranking Member Pallone,

I write today on behalf of the American Liver Foundation (ALF) in support of the *Eliminating Opioid Related Infectious Diseases Act* led by Congressman Leonard Lance. This legislation addresses a significant and urgent public health crisis. It is our hope that the Energy & Commerce Committee will work with all necessary haste to authorize the additional programs and resources called for by the bill.

ALF was created in 1976 by the American Association for the Study of Liver Disease (AASLD). This organization of scientists and healthcare professionals was concerned with the rising incidence of liver disease and the lack of awareness among both the general public and the medical community. The mission, the programs and the services provided by American Liver Foundation complement the great work of AASLD. American Liver Foundation makes a measurable difference in the fight against liver disease by providing financial support for medical research, education for medical professionals, and advocacy and information for patients and their families, and by creating public awareness campaigns about liver wellness and disease prevention.

ALF is encouraged to see that Congress is beginning to address what the Centers for Disease Control and Prevention (CDC) has dubbed a "dual epidemic" at the nexus of the opioid crisis and the spike in rates of infectious diseases. The increase in rates of hepatitis and HIV/AIDS in communities ravaged by opioids is alarmingly high. Further, impacted individuals within this new wave of infections tend to be younger, not traditionally screened for hepatitis and HIV/AIDS, and unaware of their health status. If we do not act now to authorize dedicated resources and relevant activities, there will be worsening public health consequences as well as significant compounding healthcare costs. Moreover, research suggests that awareness of one's health status is a key factor in reducing or eliminating opioid abuse moving forward.

Thank you for considering this timely and essential legislation. Please consider ALF a resource if you have any questions or require any additional information.

Sincerely,

Tom Nealon
CEO
American Liver Foundation

THE AIDS INSTITUTE

March 16, 2018

The Honorable Leonard Lance
U.S. House of Representatives
2352 Rayburn House Office Building
Washington, DC 20515

The Honorable Joseph Kennedy III
U.S. House of Representatives
434 Cannon House Office Building
Washington, DC 20515

Re: Support of the **"Eliminating Opioid Related Infectious Diseases Act of 2018"**

Dear Representative Lance and Representative Kennedy,

The AIDS Institute, a national non-profit organization dedicated to supporting and protecting health care access for people living with HIV/AIDS, viral hepatitis, and other chronic and serious health conditions is pleased to offer its strong support of the **"Eliminating Opioid Related Infectious Diseases Act of 2018"**. This bill would provide much needed resources to state and local governments and others to help improve the nation's response to the growing number of new cases of infectious diseases, such as HIV and hepatitis, due to injection drug use associated with the opioid crisis.

Communities across the country have watched with great concern as the opioid crisis has driven rates of new cases of infectious disease to skyrocketing levels. Between 2010 and 2015 new cases of hepatitis C (HCV) rose by a staggering 290 percent nationwide. It is estimated that 70 percent of those cases are a direct result of injection drug use. Deaths associated with HCV now surpass deaths associated with all 60 other notifiable infectious diseases combined. While we have been making progress in reducing the number of new HIV infections in the country, including the number of new cases associated with injection drug use, the opioid epidemic can reserve this trend. In fact, the Centers for Disease Control and Prevention (CDC) reports that in 2015 there was a 4 percent increase in the number of new HIV cases associated with injection drug use. Certain communities and areas of the country, including those who are young and living in rural areas, are experiencing increases of HIV due to injection drug use.

National Policy Office
1705 DeSales St NW, Suite 700 Washington, DC 20036 | Ph: 202-835-8373
Program, Policy, and Administrative offices
17 Davis Blvd, Suite 403, Tampa, FL 33606 | Tallahassee, FL | 813-258-5929
theaidsinstitute.org

The Scott County, Indiana HIV and HCV outbreak cast a spotlight on the risk of rapid transmission of infectious disease among people who inject drugs and the lack of sufficient state and local resources to rapidly respond. The CDC has identified 220 counties across 26 states that are vulnerable to similar outbreaks. Your bill will help address future outbreaks and prevent them from happening in the first place.

Providing the CDC with additional resources for surveillance, testing, and linkage to care and treatment for infectious diseases exacerbated by the opioid crisis, along with prevention and education efforts, will go a long way in helping the country successfully combat increases in infectious disease cases. At the same time, these activities can link people to substance use treatment and reduce injection drug use, thus helping to curb the opioid crisis.

The AIDS Institute congratulates you both on the **"Eliminating Opioid Related Infectious Diseases Act of 2018,"** urge other members to support it, and hope Congress will pass it at its earliest opportunity. While we believe $40 million per year is an excellent start, additional resources to combat the growing number of infectious diseases associated with injection drug use will be needed. Thank you very much.

Sincerely,

Carl E. Schmid II
Deputy Executive Director

Congress of the United States
Washington, DC 20515

March 19, 2018

The Honorable Tom Cole
Chairman
Appropriations Subcommittee on Labor,
Health and Human Services, and Education
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Rosa DeLauro
Ranking Member
Appropriations Subcommittee on Labor,
Health and Human Services, and Education
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Cole and Ranking Member DeLauro:

Thank you for your continued support of the Minority Fellowship Program (MFP) at the Substance Abuse and Mental Health Services Administration (SAMHSA). For almost 45 years, this program has successfully been encouraging more racial and ethnic minorities to join the behavioral health workforce and helping to improve behavioral health outcomes for racial and ethnic minorities.

Ethnic minorities make up more than 28 percent of the nation's population, yet less than 20 percent of America's behavioral health workforce consists of ethnic minorities. By 2025, minorities are projected to account for 40 percent of the U.S. population. According to the Department of Health and Human Services (HHS), minorities are less likely to receive diagnosis and treatment for their mental illness, have less access to and availability of mental health services and often receive a poorer quality of mental health care. Minorities can face several challenges when seeking care including racism, bias and discrimination in treatment, stigma, language barriers, and an overall lack of availability of services, as well as barriers to treatment and recovery.

Culturally competent behavioral health services are necessary to meet demand and behavioral health challenges facing communities across the United States, including the opioid epidemic. According to SAMHSA, significant behavioral health disparities persist in diverse communities across the United States. There are persistent health disparities between different racial and ethnic populations, and health equity remains a challenge with minorities receiving less mental health and addiction treatment and lower-quality care.

To meet this need, the MFP has been increasing the number of culturally competent behavioral health professionals providing mental health and substance use disorders services to underserved populations. The MFP provides support to behavioral health professionals in the fields of psychiatry, psychology, social work, nursing, marriage and family therapy, counseling and addictions.

PRINTED ON RECYCLED PAPER

The bipartisan 21st Century Cures Act (P.L. 114-146) authorized $12,669,000 for this important program. To that end, we urge you to provide the authorized amount so that we can continue to support the only federal program that supports culturally competent mental health and substance use disorders professionals.

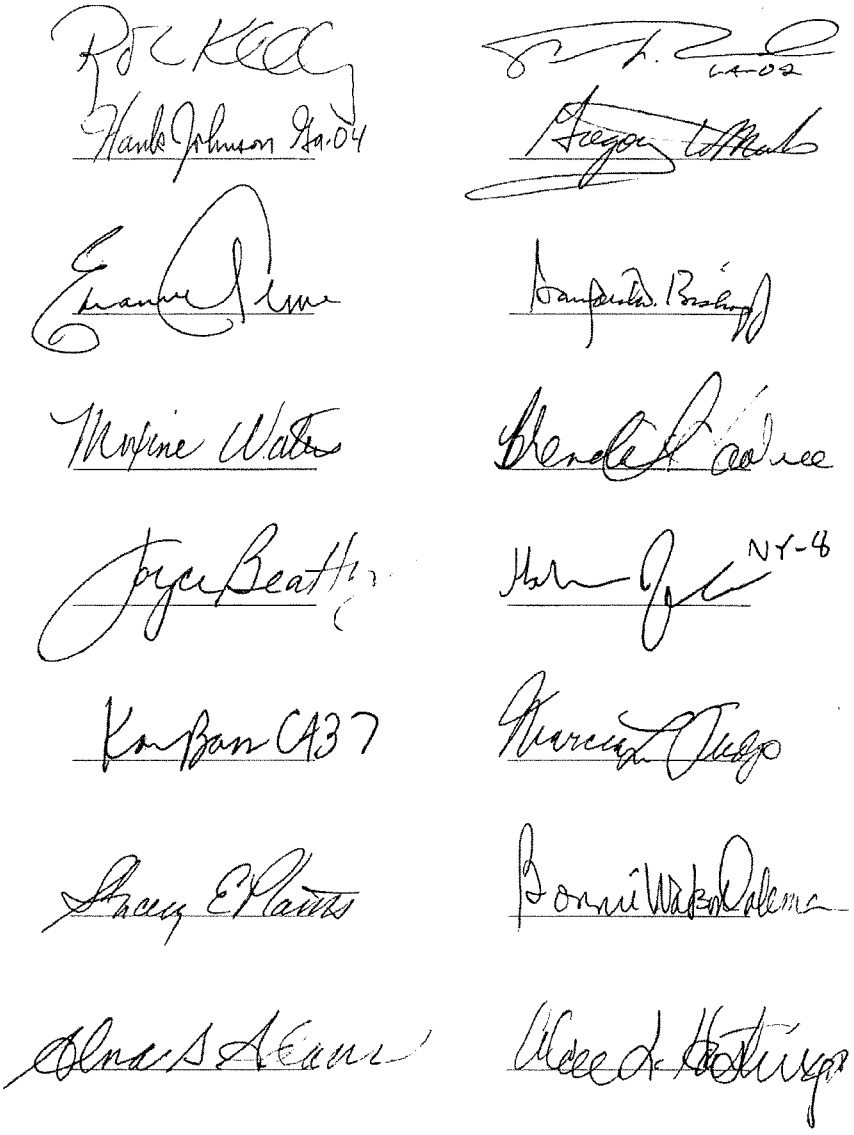
We are grateful for your support for the MFP and hope you can accommodate our request for FY 2019.

Thank you very much.

Very truly yours,

G. K. Butterfield
Member of Congress

John Katko
Member of Congress



Paul D. Tonko
NY-20

Steve Cohen
TN-09

FL-24

VA-09

NM-03

Danny K. Davis
IL-7

Bobby L. Rush
IL-01

Norma J. Torres
CA-35

NY-13

Grace F. Napolitano
CA-32

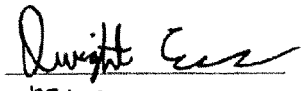
Raúl M. Grijalva
AZ-03

Tony Cárdenas
CA-29

Tulsi Gabbard
HI-02

CA-34

MI-04
DE. AL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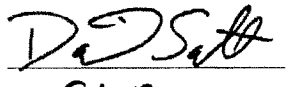
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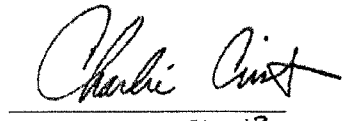
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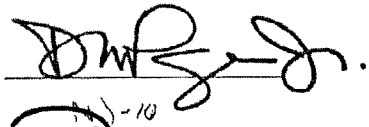

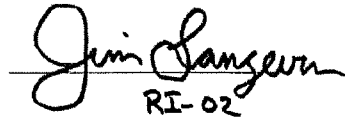
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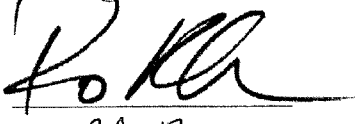
CA-17

EVERFI

March 20, 2018

The Honorable Michael C. Burgess, M.D.
Chairman, Health Subcommittee
Energy and Commerce Committee
United States House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Gene Green
Ranking Member, Health Subcommittee
Energy and Commerce Committee
United States House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Burgess and Ranking Member Green:

Our company EVERFI provides over 20,000 K-12 schools and 1,800 colleges and universities with proven prevention education programs. EVERFI's digital learning platform helps students, faculty and staff at schools address some of the most intractable issues, including alcohol abuse, sexual assault and drug abuse. EVERFI has been the education leader behind the *Prescription Drug Safety Network*.

We are writing to submit to the record associated with your March 21-22, 2018 hearing, "Combating the Opioid Crisis: Prevention and Public Health Solutions," this acknowledgement of the leadership role that our partner, the Association for Accessible Medicines (AAM), is taking in educating the public about the safe use, storage and disposal of prescription drugs, including opioids.

In November 2017, the President's Commission on Combating Drug Addiction and the Opioid Crisis released its final report that included these recommendations:

- Development of a national prevention strategy using "big data analytics" to devise targeted prevention messages that employ cutting-edge methods of marketing and communications.
- Evidence-based prevention programs for schools, and tools for teachers and parents to enhance youth knowledge of the dangers of drug use, as well as early intervention strategies for children with environmental and individual risk factors.

At the start of the academic year three months prior, EVERFI and AAM together made available to any college or university in the United States, EVERFI's evidence-based prevention program that closely adheres to what the Commission eventually recommended. The program (1) enhances youth knowledge of the dangers of drug misuse and (2) produces data and research that will help us better understand the scope of the challenge and how best to address it.

AAM, through its generosity, offers the EVERFI prevention education program, free-of-charge to any college or university that wants to make it available to its students.

Since its launch, 37,000 students have taken the Prescription Drug Abuse Prevention program.

EVERFI

Schools from all over the United States are providing the course to their students and their ranks continue to grow. These include colleges and universities large and small, from Arizona to Massachusetts, and from Minnesota to Texas. The digital course is helping these students make healthier decision about prescription drugs. Our data tells us that three-quarters of the students who have taken the course report they are now more confident in their ability to intervene if a friend is misusing prescription drugs. Almost the same percentage tell us that the course has helped them know where to find resources for drug abuse at their school.

AAM is working closely with EVERFI to further increase utilization of the higher education program. EVERFI is promoting it to our network of schools and AAM is exploring how to encourage university administrators to adopt prevention education programming for their institutions.

One thing that became quickly apparent as we developed and launched this specific higher education program, is that earlier intervention is critical. Just this month, the journal *Pediatrics*, published a study that said the number of children who admitted to hospitals for opioid overdoses has nearly doubled since 2004. Fifteen hundred children were admitted to hospitals for opioid overdose between 2012 and 2015, up from 797 patients between 2004 and 2007. Recognizing this youth challenge, many states are also looking to require prevention education at the K-12 education level.

EVERFI has a network of 20,000 plus K-12 schools across the nation where we help teachers equip students with critical life skills through digital learning. EVERFI is now bringing together state government officials, national business leaders, and pharmaceutical supply chain partners to be part of the *Prescription Drug Safety Network* to provide the financing necessary to scale our age appropriate prescription drug safety program to K-12 schools in some of the hardest-hit communities in our country.

EVERFI is committed to helping young people make smart choices about their bodies and their lives. The support of AAM and other partners allow us to reach tens of thousands of students with important prevention education to help tackle the opioid crisis in America. We are proud to partner with AAM on this important initiative.

We thank the Committee for its consideration and wish it well in its deliberations.

Sincerely,

Tammy M. Wincup
Chief Operating Officer
EVERFI, Inc.

Testimony of Congressman Hakeem Jeffries on H.R. 449 the "Synthetic Drug Awareness Act of 2017" before the House Energy and Commerce Subcommittee on Heath "Combating the Opioid Crisis: Prevention and Public Health Solutions" March 21, 2018

Chairman Burgess and Ranking Member Green, thank you for holding a hearing on the opioid crisis and for considering my bill, H.R. 449.

H.R. 449 addresses a critical and sometimes overlooked threat, the use of synthetic drugs by teenagers. It requires the Surgeon General to prepare a report on the public health effects of synthetic drug use by 12 to 18 year olds in America. With the information this study will provide, Congress can work to prevent substance abuse by younger Americans through an enhanced and enlightened lens.

It is not news that the opioid crisis has ravaged families across the country without regard to zip code, income, race, religion or gender. However, this public health emergency is now taking hold of our nation's youth. Nationwide, the drug overdose death rate has more than doubled during the past decade among younger Americans. Many experts believe this troubling phenomenon results from the rise and availability of potent and dangerous substances like illicit fentanyl—a substance that can be 50 to 100 times stronger than morphine—and other synthetic drugs.

Teenage fentanyl use is a vicious cycle: adolescents have a still-developing prefrontal cortex, which can facilitate drug-seeking behavior. The drug then alters the development of this area of the brain, making that behavior permanent. The majority of adults who develop a substance abuse disorder begin using before they are 18 years old. In order to address the multifaceted public health crisis, we must consider both the cause and effect.

H.R. 449 has significant support among Republicans and Democrats and has been incorporated into the legislative agenda for the Bipartisan Heroin Task Force. Furthermore, a number of health and patient advocacy groups are supportive of this bill, including the American

Academy of Pediatrics, American Association of Nurse Practitioners, American Academy of Child & Adolescent Psychiatry, American Psychological Association, College on Problems of Drug Dependence, Community Anti-Drug Coalitions of America, Friends of the National Institute on Drug Abuse, Healthy Teen Network, Mental Health America, National Association of County and City Health Officials and National Association of Police Organizations.

Thank you again for your consideration of H.R. 449. I look forward to working with you to ensure this bill advances from the Energy and Commerce Committee so that it may be considered by the entire House of Representatives.

Statement for the Record – Rep. Ann McLane Kuster
House Energy & Commerce Subcommittee on Health
"Combating the Opioid Crisis: Prevention and Public Health Solutions
March 21, 2018

Chairman Burgess, Ranking Member Green, and distinguished Members of the Energy & Commerce Subcommittee on Health, thank you for allowing me the opportunity to testify today.

As the founder and Democratic co-chair of the *Bipartisan Heroin Task Force* (Task Force), I would like to extend my gratitude to this Committee for considering so many important pieces of legislation today. As you all know, the nation's opioid and heroin epidemic has devastated the lives, families, and communities of so many Americans. It is not a scourge that discriminates, nor does it show mercy. With the help of Congressmen Tom MacArthur, Donald Norcross, and Brian Fitzpatrick, our Task Force has worked tirelessly to heighten awareness of this epidemic for both the public and Members of Congress since its founding in 2015.

I am also pleased that Members of this Committee are considering a number of bills featured in the Task Force's *Legislative Agenda for the 115th Congress*. These bills are important pieces of legislation that will increase the efficacy of treatment and improve our understanding of the crisis.

HR 5009, Jessie's Law, led by Congressman Tim Walberg and Congresswoman Debbie Dingell would allow for important patient information to be securely provided to treatment providers to improve efficacy of substance use treatment by increasing a provider's understanding of a patients physical and mental health history. I applaud the Committee for working with my colleagues to improve this bipartisan piece of legislation.

HR 449, the Synthetic Drug Awareness Act, led by Congressman Hakeem Jeffries would require the Surgeon General to conduct a study on the use of synthetic drugs by our teenagers. As we have learned, substance misuse is often started in one's youth. Understanding the pattern of drug use during adolescents could improve our ability to not only combat the opioid epidemic but predict future, deadly drug epidemics.

HR 3692, the Addiction Treatment Access Improvement Act, led by Congressmen Paul Tonko and Ben Ray Lujan would expand access to medication-assisted treatment (MAT) by allowing nurses and other non-physician providers to prescribe buprenorphine, an effective medication for opioid treatment. The bill would also increase the treatment cap permanently to 275 patients. Increasing access to treatment remains a challenge and this bill would provide the framework for ensuring effective medication is available.

I am also cosponsor of HR 4686, the Ensuring Access to Quality Sober Living Act, led by Congresswoman Judy Chu. This bill would improve recovery housing by requiring SAMHSA to develop best practices. Recovery housing offers a supportive recovery environment that can help people maintain their treatment outside of a standard treatment facility. It is imperative that we find innovative techniques to sustain one's recovery since the chances of relapse are so high.

Lastly, I would like to speak on behalf of my draft bill to improve fentanyl surveillance and testing. As information released in December 2017 by the Centers for Disease Control and Prevention (CDC) clearly shows, the opioid epidemic is getting worse. Overdose deaths are now being driven primarily by the use of fentanyl and synthetic opioid use. There are indications that overdose mortality and the prevalence of opioid use disorder is currently *underreported.* More robust surveillance is necessary to better direct resources and save lives. My bill would address these issues in three ways.

My bill would provide funding to public health laboratories to improve the capacity for state and local authorities to address and respond to the crisis. These laboratories assist public health officials in understanding the progression within our communities of disease or health crises; the opioid epidemic should be treated like other serious crises, such as the HIV/AIDS epidemic. The bill would also require these laboratories to share their information with other public health labs to improve the quality of information and, hopefully, act as an "early warning" system for future drug crises.

The bill would also fund the expansion of the CDC's Enhanced State Opioid Overdose Surveillance (ESOOS) program. Currently, CDC has expanded the program to 32 states and Washington, DC. Unfortunately, it needs additional funding to fully expand to include the whole nation. The bill would also require CDC to incorporate early warning data from the National Institute of Drug Abuse, state and local public health officials, and public health laboratories.

Lastly, the bill would authorize a pilot program to examine the efficacy of fentanyl testing technology. It would provide grants to up to five state or local public health departments to create drug checking stations. These stations would utilize existing technology to allow users to test drugs for fentanyl. A recent study published would provide an important moment for intervention; a recent study conducted by Brown and Johns Hopkins Universities indicated that nearly three-fourths of drug users would change their behavior if they knew the drugs they purchased contained fentanyl. Additionally, these drug checking stations would improve fentanyl surveillance by understanding the movement of illicit drugs within hard-hit communities. Not only does this promise to save lives, but it also provides another source of valuable information on the nature and progression of this public health emergency.

I urge my colleagues to support these bills considered before the Committee. These are important policies that can have a real and immediate impact on addressing the opioid and heroin epidemic. I know the Committee will continue its hard work to address the crisis. Thank you.

Campaign to Protect Patient Privacy Rights

March 21, 2018

VIA ELECTRONIC MAIL

Representative Greg Walden
Chairman of the U.S. House of Representatives
Energy and Commerce Committee
2185 Rayburn House Office Building
Washington, DC 20515

Representative Frank Pallone, Jr.
Ranking Member of the U.S. House of Representatives
Energy and Commerce Committee
237 Cannon House Office Building
Washington, DC 20515

RE: U.S. House of Representatives, Energy and Commerce – Subcommittee on Health: "Combating the Opioid Crisis: Prevention and Public Health Solutions;" Amendment in the Nature of a Substitute to H.R. 3545 - "Overdose Prevention and Patient Safety Act"

Dear Chairman Walden and Ranking Member Pallone:

We, the undersigned national, state, and local organizations *strongly support maintaining the core protections of the federal substance use disorder patient confidentiality law ("42 U.S.C. § 290dd-2") and its regulations "42 CFR Part 2,"* (referred to collectively as "Part 2,") to effectively protect the confidentiality of patients' records. The Substance Abuse and Mental Health Service Administration ("SAMHSA") recently twice amended the patient privacy regulations in order to facilitate the objective of providing integrative care between substance use disorder ("SUD") and other health care information.

We remain concerned that using a weaker HIPAA Privacy Rule standard of allowing disclosures of SUD information without patient consent for treatment, payment, health care operations, or other purposes other than those currently allowed by Part 2 – will contribute to the existing level of discrimination and harm to people living with substance use disorders. This will only result in more people who need substance use disorder treatment, being discouraged and afraid to seek the health care they need during the nation's worst opioid crisis.

We strongly support maintaining Part 2's core protections for SUD information, instead of those of a weaker HIPAA Privacy standard as described in the Amendment (in the Nature for a Substitute) for H.R. 3545 for the following reasons:

1. The heightened privacy protections in Part 2 are as critical today as they were when they were they were enacted more than 40 years ago and must be preserved.
2. In the midst of the worst opioid epidemic in our nation's history, we must do everything possible to increase – not decrease – the number of people who seek treatment.
3. SUD is unique among medical conditions because of its criminal and civil consequences and the rampant discrimination people face.
4. With so much at stake, patients in SUD treatment should retain the right to consent when and to whom their records are disclosed, as currently found in Part 2.
5. Effective integration of SUD treatment with the rest of the health care system is critically important, and information exchange in accordance with confidentiality law and current technology is now possible. To facilitate that process, SAMHSA recently amended the Part 2 regulations to further promote the integration of confidential SUD information into general health records.

We respectfully request that the House Energy and Commerce Committee maintain the current confidentiality protections of Part 2 to support individuals entering and staying in SUD treatment and recovery services.

Sincerely,

CAMPAIGN TO PROTECT PATIENT PRIVACY RIGHTS:

A New PATH

Addiction Haven

Addictions Resource Center, Waukesha, WI (ARC, Inc.)

Advocates for Recovery Colorado

AIDS United

Alano Club of Portland

Alcohol & Addictions Resource Center, South Bend, IN

American Association for the Treatment of Opioid Dependence (AATOD)

American Group Psychotherapy Association

Apricity
Arthur Schut Consulting LLC
Atlantic Prevention Resources
California Consortium of Addiction Programs & Professionals (CCAPP)
Capital Area Project Vox–Lansing (MI)'s Voice of Recovery
Center for Recovery and Wellness Resources
CFC Loud N Clear Foundation
Chicago Recovering Communities Coalition
Colorado Behavioral Healthcare Council
Community Catalyst
Connecticut Community for Addiction Recovery (CCAR)
Council on Addiction Recovery Services (CAReS), Inc.- Olean, NY
DarJune Recovery Support Services & Café
Davis Direction Foundation - The Zone
Daystar Center
Delphi Behavioral Health Group–Maryland House Detox
Detroit Recovery Project
The DOOR-DeKalb Open Opportunity for Recovery
Drug and Alcohol Service Providers Organization of Pennsylvania
Faces & Voices of Recovery
Faces and Voices of Recovery (FAVOR)-Grand Strand-SC
Faces and Voices of Recovery (FAVOR)-Greenville, SC
Faces and Voices of Recovery (FAVOR)-Low Country: Charleston, SC
Faces and Voices of Recovery (FAVOR)-Mississippi Recovery Advocacy Project
Faces and Voices of Recovery (FAVOR)-Pee Dee, SC
Faces and Voices of Recovery (FAVOR)-Tri-County: Rock Hill, SC
Facing Addiction
Fellowship Foundation Recovery Community Organization
Foundation for Recovery
Friends of Recovery-New York
Georgia Council on Substance Abuse

Greater Macomb Project Vox

Harm Reduction Coalition

Home of New Vision

HOPE for New Hampshire Recovery

Jackson Area Recovery Community-Jackson, MI

Latah Recovery Center

Legal Action Center

Lifehouse Recovery Connection

Long Island Recovery Association (LIRA)

Maine Alliance for Addiction Recovery

Massachusetts Organization for Addiction Recovery

Message Carriers of Pennsylvania

Mid-Michigan Recovery Services (NCADD Mid-Michigan Affiliate)

Minnesota Recovery Connection

Missouri Recovery Network

National Advocates for Pregnant Women

National Alliance for Medication Assisted Recovery (NAMA Recovery)

National Association for Children of Addiction (NACoA)

National Association of County Behavioral Health and Developmental Disability Directors (NACBHDD)

National Association for Rural Mental Health (NARMH)

National Center on Domestic Violence, Trauma & Mental Health

National Council on Alcoholism and Drug Dependence, Inc. (NCADD)

National Council on Alcoholism and Drug Dependence-Central Mississippi Area, Inc.

National Council on Alcoholism and Drug Dependence-Maryland

National Council on Alcoholism and Drug Dependence-Phoenix

National Council on Alcoholism and Drug Dependence-San Fernando Valley

Navigating Recovery of the Lakes Region

New Jersey Association of Mental Health and Addiction Agencies

Northern Ohio Recovery Association

Oklahoma Citizen Advocates for Recovery and Transformation Association (OCARTA)

Overcoming Addiction Radio, Inc.
Parent/Professional Advocacy League
Peer Coach Academy Colorado
Pennsylvania Recovery Organizations-Alliance (PRO-A)
People Advocating Recovery (PAR)
Pennsylvania Recovery Organization–Achieving Community Together (PRO-ACT)
Portland Recovery Community Center
Public Justice Center
REAL-Michigan (Recovery, Education, Advocacy & Leadership)
Recover Project/Western MA Training
Recover Wyoming
Recovery Alliance of Austin
Recovery Allies of West Michigan
Recovery Cafe
Recovery Communities of North Carolina
Recovery Community of Durham
Recovery Consultants of Atlanta
Recovery Epicenter Foundation, Inc.
Recovery Force of Atlantic County
Recovery is Happening
Recovery Resource Council
Recovery Organization of Support Specialist
Revive Recovery, Inc.
Rhode Island Cares About Recovery (RICARES)
Rochester Community Recovery Center
ROCovery Fitness
Safe Harbor Recovery Center
SMART Recovery (Self-Management and Recovery Training)
S.O.S. Recovery Community Organization
SpiritWorks Foundation
Springs Recovery Connection

Tennessee Association of Alcohol, Drug & other Addiction Services (TAADAS)
The Bridge Foundation
The Courage Center
The McShin Foundation
The Ohana Center for Recovery
The Serenity House of Flint
The Phoenix
The RASE Project
The Recovery Channel
Tia Hart Community Recovery Program
Together Our Recovery Center Heals (T.O.R.C.H.), Inc.
Treatment Trends, Inc.
Trilogy Recovery Community
U MARC (United Mental Health and Addictions Recovery Coalition)
Utah Support Advocates for Recovery Awareness (USARA)
Vermont Recovery Network
Voices of Hope for Cecil County, MD
Voices of Hope Lexington
Voices of Recovery San Mateo County, CA
WAI-IAM, Inc. and RISE Recovery Community
Wisconsin Voices for Recovery
Young People in Recovery

National Alliance for Medication Assisted Recovery, Inc.
435 second avenue new york, ny 10010
phone/Fax (212) 595-nama

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Affiliated Groups and Chapters
AZ NAMA Recovery, Boston NAMA Recovery
CT NAMA Recovery, CT Capitol NAMA Recovery
Delaware NAMA Recovery, DC WAMA NAMA Recovery
The MAG IND, Boston NAMA Recovery
Philadelphia NAMA Recovery, NJ NAMA-R Advocates
NYC NAMA Recovery, N Texas NAMA Recovery
New England NAMA Recovery (VT)
Wisconsin NAMA Recovery

International
Australian IV League, HOPE (Bulgaria)
Méta d'âme' (Canada), CRAMA (Croatia)
Brugerforeningen (Denmark), ACCES (France)
Methadone Indonesia, UISCE Ireland
Italy Gruppo SIMS, Recovering Nepal
LIBERATION (Poland), INTEGRATION (Romania)
Svenska BrukarForeningen (Sweden)
Methadone Alliance (UK)

Projects
Medication Assisted Recovery Support Project (MARS)

March 21, 2018

Representative Greg Walden
Chairman of the U.S. House of Representatives
Energy and Commerce Committee
2185 Rayburn House Office Building
Washington, DC 20515

Representative Frank Pallone, Jr.
Ranking Member of the U.S. House of Representatives
Energy and Commerce Committee
237 Cannon House Office Building
Washington, DC 20515

RE: U.S. House of Representatives, Energy and Commerce – Subcommittee on Health: "Combating the Opioid Crisis: Prevention and Public Health Solutions;" Amendment in the Nature of a Substitute to H.R. 3545 ("Overdose Prevention and Patient Safety Act")

Dear Chairman Walden and Ranking Member Pallone:

The National Alliance for Medication Assisted Recovery (NAMA-Recovery) represents the thousands of patients receiving Medication Assisted Treatment (MAT) and those not able to it because of barriers. NAMA Recovery *strongly supports maintaining the core protections of the federal substance use disorder patient confidentiality law ("42 U.S.C. § 290dd-2") and regulations ("42 CFR Part 2")* (referred to as "Part 2). Without these protections persons with a Substance Use Disorder (SUD) needing treatment will be afraid to attempt to access treatment. Current patients that know about these attempts to void Part 2 are already considering to decide to taper because of the fear that prejudice will have on them and their families.

Continued

Walden/Pallone, 3-21-2018 Page 2

Furthermore once any information about addiction enters the general healthcare system patients will be denied life insurance, housing, employment, community services, education, vocational services as well as receiving poor medical care. There could be many unintended consequences of voiding Part 2, such as local police entering treatment programs to arrest patients. They currently sit outside looking for patients and pull patients over for driving under the influence that are leaving programs.

The stakes are high and patients need protection. The prejudice towards persons with a history of addiction have not improved since Part 2 was enacted but rather are worse. Currently we have a serious opioid epidemic and patients and persons entering treatment need protection.

No attempts have been made to even review the consequences that further changes to Part 2 could have. Fast decisions can result in adverse results. I implore you to consider any changes to Part 2 to be taken with thoughtfulness and extreme care.

Sincerely

Carmen Pearman-Arlt, LCSW, LCAC, CMA
President

Joycelyn Woods

Joycelyn Woods, MA, CARC, CPAS, CMA
Executive Director

Enc.

Together, we can make a difference.

PRO-A
Pennsylvania Recovery Organizations Alliance
900 S Arlington Ave, Suite 254A
Harrisburg, PA 17109-1014

March 20th, 2018

The Honorable Chairman Greg Walden,
The Honorable Ranking Member Frank Pallone
House Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515

RE: Hearing on Combatting the Opioid Crisis: Prevention and Public Health Strategies - Amendment to HR 3545 the Overdose Prevention and Patient Safety Act"

The Honorable Chairman Walden & Ranking Member Pallone,

Thank you for the opportunity to comment on the proposed Amendment to HR 3545, "the Overdose Prevention and Patient Safety Act." The agency I represent is the Pennsylvania Recovery Organizations – Alliance (PRO-A), the statewide recovery community organization of Pennsylvania founded in 1998. We represent thousands of recovering persons across the state of Pennsylvania. We are dedicated to ending stigma, providing public education about addiction, providing recovery opportunities and to expand access to drug and alcohol services.

We continue to believe strongly that the existing federal confidentiality requirements for substance use conditions information established in 42 U.S.C. § 290dd-2 and 42 CFR Part 2 ("Part 2"), as recently amended twice by SAMHSA, do not require further modifications that would diminish our patient privacy protections in order to achieve the important goal of facilitating the provision of integrated care between substance use disorder information and overall health care.

We remain very concerned that applying the HIPAA Privacy Rule ("HIPAA") standard of allowing without our consent disclosures of our substance use condition records for treatment, payment, health operations or any purpose other than those currently enumerated in Part 2 will result in discrimination against and harm to people living with substance use conditions. The result will be to discourage individuals from seeking SUD treatment even as our number one goal needs to be to encouraging millions more Americans to enter treatment during the worst opioid epidemic in our nation's history.

Section (C) (2) on page 4 of the amendment in the section titled "Use of Records in Criminal, Civil, or Administrative Investigations, Actions or Procedures" identifies a threshold of "absent good cause" for ruling out the use of our information in Criminal, Civil, or Administrative Investigations. This is an ambiguous standard at best and provides insufficient guidance. This will inevitably result in our own information disclosed by seeking help with a substance use condition to be used against us. This will have a chilling impact on the ability of our community to seek help without fear of prosecution.

The Amendment would allow broad access to highly sensitive and personal information. It would be opened up to a vast array of individuals and entities well beyond the counselor treating the person in need and the immediate care provider who need it and can access it under current regulation with our consent.

Additionally, as this information "flows out" to business associates and contracted entities, control over what happens to it decreases while the likelihood of the information being misused or stolen through a breach increases. In instances in which a person has had their information used in a way that caused harm to them, it will become virtually impossible for the patient to determine who was responsible for improperly releasing their information. It is the proverbial wall with a gate open and a pot of gold within.

Our information is that proverbial "pot of gold" and we are deeply concerned about broad dispersal of highly sensitive and personal drug and alcohol related information proposed by the amendment and the lack of clear accountability to us, the patients. It will create conditions favorable to those who would use our information to discriminate against us in a myriad of ways. This includes employment, housing, education and insurance coverage. We have faced the constant drumbeat of the weakening of our protections by business related groups who are perpetually advocating for further weakening and / or elimination of this critically important rule. If one does a google search on medications like "Narcan" or "Buprenorphine" coupled with the term "Life Insurance" one will find how information available within patient records are being used to deny life insurance to people. Turning on the news this week, one is confronted with how Cambridge Analytica used a research clause to gain information on people to use as Kompromat. Drug and Alcohol patient records would be a primary target of other such groups working to gain access to our highly sensitive information. Treatment will become unsafe to participate in.

The sad reality is that there are compelling reasons for entities to obtain and use this information to discriminate against us for their own material gain. The vast majority of persons who will have this happen to them will lack the resources to determine who used their information in an improper way. Even if they did, in most cases individuals would not do so as by the very act of trying to assert their rights would acknowledge drug addiction in a way that would open them up to prosecution and discrimination. In that sense the Amendment has toothless penalties as due process will be un-obtainable by those so harmed.

The Amendment endangers the fragile therapeutic alliance and may well reduce access to care as who gets our patient information becomes unknowable to the patient. It will be no longer possible for the person in care to determine who gets their information and how it will be used (or misused). Information could now go in a myriad of directions once entered into the medical data base. If the information is used to discriminate against us, it is also nearly impossible from the patient perspective to determine how such a violation occurred and who was responsible.

Under this Amendment, as the treating clinician (I have nearly three decades of direct care experience) I would have to tell my clients that I have no idea who will get their patient information, or how it will be used. I will note that I am a person in long term, continuous recovery for over 31 years. *Under this amendment, I would have not entered treatment or self-edited my disclosures in a way that would have undermined my own care.* Without strict protections, I would not have gotten help, obtained an education and have had the opportunity to be a productive citizen. It is quite possible I would not have survived. This is not just my story, this is true for so very many of us in recovery.

Please understand that there is much greater stigma around substance use conditions than other kinds of medical conditions, and the very acknowledgment of having a substance use condition can open us up to

discrimination and in many instances, place us in legal jeopardy. We will face a Hobson's choice when seeking help under the proposed amendment.

We implore you to not further weaken our confidentiality rights. We are concerned that these proposed changes add many layers of legalese, complexity and ambiguity to the regulations and will serve only to create further confusion. It is worth noting that even with our simpler, current standard many direct care professionals do not understand that they can access all the clinical information they need with a properly executed consent. It is also worth noting that each revision of the standard has made it more complex and harder to understand, which is in and of itself a barrier to care for patients. Others seem to not want to bothered to honor our privacy rights.

We believe that the patient should retain control over who gets this information and how it is used. It is important to note that substance use conditions are almost always fatal without help, that few people can afford to pay out of pocket for care as a direct result of the condition and that treatment at times can be compulsory. The bottom line is that if information that can harm us is widely available, we are left with no real choices beyond avoiding care or risking the use of our information to discriminate against us after it flows to covered entities and beyond based on "absent probable cause" language, business, research allowances and many other ways.

We believe that expanding access to our information opens it up to misuse and urge policymakers to protect us from the misuse of our information and to hold those who use it to discriminate against us accountable to protect our information. This is the standard that Congress strived for back in 1972, which we believe is just as relevant now:

> *"The conferees wish to stress their conviction that the strictest adherence to the provisions of this section is absolutely essential to the success of all drug abuse prevention programs. Every patient and former patient must be assured that his right to privacy will be protected. Without that assurance, fear of public disclosure of drug abuse or of records that will discourage thousands from seeking the treatment they must have if this tragic notional problem is to be overcome."*

We staunchly believe that sharing of addiction and recovery information is an individual choice to be made by the individual **who retains control over how it is used and honors the need to limit access to highly sensitive information** – we think that this is fundamental to quality care and consistent with the original statutes and we ask that the original intent be honored.

Respectfully Submitted,

William Stauffer, LSW, CCS, CADC
Executive Director

Congress of the United States
Washington, DC 20515

March 21, 2018

The Honorable Michael Burgess, M.D.
Chairman
Subcommittee on Health
House Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

The Honorable Gene Green
Ranking Member
Subcommittee on Health
House Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

Dear Chairman Burgess and Ranking Member Green:

We write in support of **H.R. 5102, the Substance Use Disorder Workforce Loan Repayment Act of 2018 (SUD Workforce Loan Repayment Act).** This bipartisan bill encourages professionals to join the fight against the growing opioid epidemic and helps reinforce our desperately overstretched substance use disorder treatment workforce in the parts of the country that need it most.

The United States is in the midst of a national health crisis. In 2016, 64,000 Americans lost their lives as the result of a drug overdose, and that number is expected to rise even higher for 2017. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), more than 20 million adults struggle with a substance use disorder of some kind.

Yet, between the rising cost of education, low pay, and high burnout from the emotionally taxing work, we are struggling to maintain the substance use disorder treatment workforce we need to help the growing number of Americans fighting a substance use disorder. The need for a highly-trained, dedicated class of treatment experts has never been more urgent. Now, more than ever, it is critical that we invest in building up the full spectrum of substance use disorder treatment workers, including physicians, nurses, social workers, and all of the other personnel needed to provide real, wraparound care for this devastating illness.

The SUD Workforce Loan Repayment Act would address the treatment workforce shortage by offering student loan repayment of up to $250,000 to treatment professionals who agree to serve for up to six years in direct patient care treatment roles, in areas with either a shortage of mental health professionals or an above average rate of drug overdose deaths. The bill leverages the already existing Mental Health Professional Shortage Areas identified under the National Health Service Corps while also targeting areas of the country that specifically have high rates of overdose deaths so that treatment experts funded under this Act will serve where they are most desperately needed. Further, because these metrics are already available, the program can start

PRINTED ON RECYCLED PAPER

to work as soon as possible. By allowing participants to agree to work for any length of service, up to six years, while repaying one sixth of participants' loans per year, the SUD Workforce Loan Repayment Act will have the dual effect of attracting new candidates to the treatment profession and also encouraging those experts to stay long-term—both currently significant challenges in the field. The Act also allows the Department of Health and Human Services flexibility to add qualifying types of treatment professionals and facilities as the field continues to evolve, ensuring the program's ability to adapt to changing conditions.

Every additional treatment expert means another chance at survival for someone struggling with a substance use disorder. No one else should die waiting for help that never came because we did not have the workforce to provide it.

We thank you for holding this vital hearing and considering this legislation, and we look forward to working with you in the future as we continue to seek solutions to this terrible health crisis.

Sincerely,

Katherine Clark
Member of Congress

Hal Rogers
Member of Congress

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

April 20, 2018

The Honorable Scott Gottlieb
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Gottlieb:

Thank you for appearing before the Subcommittee on Health on March 21, 2018, to testify at the hearing entitled "Combatting the Opioid Crisis: Prevention and Public Health Solutions."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on May 4, 2018. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.dareshori@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

U.S. FOOD & DRUG ADMINISTRATION

The Honorable Michael C. Burgess, M.D.
Chairman
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

JUL 27 2018

Dear Chairman Burgess:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the March 21, 2018, hearing before the Committee on Energy and Commerce, Subcommittee on Health, entitled "Combatting the Opioid Crisis: Prevention and Public Health Solutions." This letter is a response for the record to questions posed by the committee.

If you have further questions, please let us know.

Sincerely,

John Martin
Principal Associate Commissioner
for Legislative Affairs

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Your questions are restated below in bold, followed by FDA's response.

The Honorable Michael C. Burgess, M.D.

1) **Dr. Gottlieb, my discussion draft being considered at today's hearing directs the Food and Drug Administration to issue guidance on how the agency will specifically provide accelerated approval and breakthrough therapy status for medicines developed to treat pain and addiction.**

   a) **Should this bill pass Congress and be signed into law, would FDA be better equipped to facilitate the accelerated approval process for these therapies while engaging with the necessary stakeholders?**

   The Administration has not taken a position on this legislation. We believe further consideration is needed on whether legislation is needed to accelerate the development of non-opioid therapies to treat pain and addiction. As a part of our commitment to the expedited programs authorized by FD&C Act section 506, FDA has already published detailed process guidance providing key information for a developer who might be interested taking advantage of breakthrough therapy designation, fast track designation and accelerated approval (as well as priority review, a related tool authorized in PDUFA). While this guidance is not product area-specific, it provides the needed information for a developer who might be interested in making use of designations and pathways for novel pain and addiction treatment therapies.

   Typically, FDA refrains from issuing product area-specific guidance documents unless there is a need to address scientific or clinical issues specific to those products. It is not clear what scientific or clinical issues specific to application of our expedited programs to non-opioid or non-addictive medical products to treat pain or addiction would benefit from FDA guidance. To the extent sponsors have questions about how FDA's expedited programs apply to their specific products, such questions are addressed in our existing guidance on the use of expedited programs in general and in meetings or other communications between FDA and individual sponsors. These latter interactions with FDA permit targeted, product-specific discussion of a type that is typically not possible in guidance – even product area-specific guidance.

   b) **Do you have any additional thoughts about the draft legislation that you would like to share?**

   FDA is committed to re-evaluating whether it would be beneficial to issue additional guidance on the applicability of the expedited programs to non-opioid and non-addictive medical products to treat pain or addiction. Such additional guidance, if needed, could be provided either by updating our existing guidance on expedited programs or issuing product area-specific guidance, if appropriate.

   We recognize the importance of ensuring that sponsors (and other stakeholders) are aware that non-opioid and non-addictive medical products to treat pain or addiction may be eligible for one or more expedited programs. We believe, however, that the sponsors and potential sponsors of such products are already aware of these programs, and have been taking

advantage of them. We also believe that to the extent there is a need for additional outreach on application of the expedited programs to these products, FDA has, and is committed to using, other means to accomplish this, such as public meetings and discussion with individual sponsors.

COMBATING THE OPIOID CRISIS: PREVENTION AND PUBLIC HEALTH SOLUTIONS, DAY 2

THURSDAY, MARCH 22, 2018

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

The subcommittee met, pursuant to call, at 10:02 a.m., in room 2123 Rayburn House Office Building, Hon. Michael Burgess (chairman of the subcommittee) presiding.

Members present: Representatives Burgess, Guthrie, Upton, Shimkus, Latta, McMorris Rodgers, Lance, Griffith, Bilirakis, Long, Bucshon, Brooks, Mullin, Hudson, Collins, Carter, Walden(ex officio), Green, Engel, Schakowsky, Matsui, Castor, Sarbanes, Luján, Schrader, Kennedy, and Eshoo.

Also present: Representatives Walberg, Tonko, and Johnson.

Staff present: Mike Bloomquist, Staff Director; Adam Buckalew, Professional Staff Member, Health; Daniel Butler, Staff Assistant; Karen Christian, General Counsel; Zachary Dareshori, Legislative Clerk, Health; Margaret Tucker Fogarty, Staff Assistant; Adam Fromm, Director of Outreach and Coalitions; Caleb Graff, Professional Staff Member, Health; Jay Gulshen, Legislative Associate, Health; Peter Kielty, Deputy General Counsel; Ed Kim, Policy Coordinator, Health; Mark Ratner, Policy Coordinator; Kristen Shatynski, Professional Staff Member, Health; Jennifer Sherman, Press Secretary; Danielle Steele, Counsel, Health; Austin Stonebraker, Press Assistant; Hamlin Wade, Special Advisor, External Affairs; Everett Winnick, Director of Information Technology; Jacquelyn Bolen, Minority Professional Staff; Jeff Carroll, Minority Staff Director; Waverly Gordon, Minority Health Counsel; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Tim Robinson, Minority Chief Counsel; Samantha Satchell, Minority Policy Analyst; Andrew Souvall, Minority Director of Communications, Outreach and Member Services; Kimberlee Trzeciak, Minority Senior Health Policy Advisor; and C.J. Young, Minority Press Secretary.

Mr. BURGESS. I ask all of our guests to please take their seats. The Subcommittee of Health will come to order. I want to welcome everyone to our second day of our hearing on Combating the Opioid Crisis through Prevention and Public Health Solutions. I want to thank our witnesses for taking time to testify before the sub-

committee today. The good news for you is you don't have to listen to us, we spoke yesterday.

So we will hear from you this morning. Each witness will have the opportunity to give an opening statement that will be followed by questions from members. As I mentioned to some of you as we started, the brief housekeeping detail, we will have a vote on the floor probably around 10:30 to 10:40 and the committee will recess briefly when we have to go vote on the floor.

But today we are going to hear from Dr. Eric Strain, the Director for the Center for Substance Abuse Treatment and Research at Johns Hopkins University; Dr. Kenneth Martz, Special Projects Consultant, Gaudenzia; Mr. Brad Bauer, Senior Vice President of New Business Development and Customer Relationships; Dr. William Banner, Medical Director of the Oklahoma Center for Poison and Drug Information and the Board President of the American Association of Poison Control Centers; and, Dr. Michael Kilkenny, Physician Director, Cabell-Huntington Health Department of West Virginia. We appreciate all of you being here today. Dr. Strain, you are recognized for 5 minutes to summarize your opening statement, please.

STATEMENTS OF ERIC C. STRAIN, MD, DIRECTOR, CENTER FOR SUBSTANCE ABUSE TREATMENT AND RESEARCH, JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE; KENNETH J. MARTZ, PSYD MBA, SPECIAL PROJECTS CONSULTANT, GAUDENZIA, INC.; BRAD BAUER, SENIOR VICE PRESIDENT OF NEW BUSINESS DEVELOPMENT AND CUSTOMER RELATIONSHIP MANAGEMENT, APPRISS HEALTH; WILLIAM BANNER, MD, PHD, MEDICAL DIRECTOR, OKLAHOMA CENTER FOR POISON AND DRUG INFORMATION AND BOARD PRESIDENT, AMERICAN ASSOCIATION OF POISON CONTROL CENTERS; AND, MICHAEL E. KILKENNY, MD, MS, PHYSICIAN DIRECTOR, CABELL-HUNTINGTON HEALTH DEPARTMENT OF WEST VIRGINIA

STATEMENT OF ERIC STRAIN

Dr. STRAIN. Thank you. Thank you, Chairman Burgess, Ranking Member Green, and members of the subcommittee. Thank you for inviting me to participate in today's hearing and for devoting 2 full days to legislative solutions to address the opioid crisis and the scourge of addiction in our communities, a topic which has been the focus of my professional career.

My name is Eric Strain. I am a physician who practices as a psychiatrist and conducts substance abuse research, and I am the director for the Johns Hopkins Center for Substance Abuse Treatment and Research. I have seen the devastating impact of drug abuse and the current federal regulations that limit the use and disclosure of patients' substance abuse treatment records and I am pleased that this Congress is taking a proactive step to update the law to be more in keeping with modern-day, multidisciplinary medical practice and the best patient care.

The Amendment in the Nature of a Substitute to H.R. 3545 as offered by Representative Mullin will enhance our ability to share vital health information in a timely manner. Though well inten-

tioned at its enactment more than 40 years ago, 42 CFR Part 2 is outdated and, worse, it can result in harm to patients and impedes the relationship between providers and their patients. Full alignment of federal privacy rules with HIPAA for the purposes of treatment and healthcare operations will ensure that patients with substance use disorders receive accurate diagnoses, integrated and coordinated treatment, and patient-centered care.

Under 42 CFR Part 2, substance use disorder records must remain separate and segmented from any other medical record and cannot be shared with a patient's primary care provider or other specialist without the express written consent of the patient. Obtaining this consent can be a challenge under a variety of scenarios and the current segmentation of records runs counter to the idea of holistic and coordinated treatment of the patient. Not knowing a patient is in substance abuse treatment increases risks, for example, with medication interactions or in delivering care under an emergency situation.

It also can interfere with effective integrated care. Let me give you an example. The Johns Hopkins Center for Addiction and Pregnancy is a substance abuse treatment program that helps pregnant women and their babies and includes substance use staff as well as OB-GYN, pediatrics, and psychiatry. This multidisciplinary program needs ready communication between providers. Full information is essential to support clinicians' efforts to care for the pregnant woman pre-term and then both patients, the mother and her child, postpartum. This example clearly demonstrates the varied teams of caregivers such as neonatologists, obstetricians, case managers, et cetera.

Our healthcare system does not put records for other medical conditions such as HIV and AIDS in a separate and protected system. We don't put a patient's social history behind a wall and tell other providers they can't have ready access to information about what may be sensitive topics. The various workarounds that are offered introduce more impediments in an already busy healthcare system and further contributes to the perception that substance use is different from all other medical care.

In my opinion, continuing to consider substance abuse disorder information distinct from other medical information actually perpetuates stigma. Concerns about inappropriate release of information are addressed in the Mullin amendment which includes vital antidiscriminatory language as well as protections against criminal prosecution.

Finally, I have reviewed Jessie's Law as well and I support any effort to promote dialogue that encourages coordination of care and the sharing of necessary information so long as it is paired with the Mullin amendment. Jessie's Law relies on patient-volunteered information and it is my experience that through no fault of the patient, patient-volunteered information is sometimes inaccurate or incomplete, or places a large burden on the patient.

Therefore, as I have already expressed, a system that relies on consents or patient-volunteered information is fundamentally flawed. Healthcare providers are on the front lines of treating opiate and other substance use disorders. We are uniquely positioned to help but we cannot do so without an unobstructed view of a pa-

tient's medical records. You have an opportunity to move us forward in these efforts and help those on the front lines of treating people who suffer from drug abuse.

I urge the committee to report out legislation amending 42 CFR Part 2 that allows the responsible sharing of patient records for the purposes of treatment and healthcare operations. Thank you and I would be pleased to answer any questions you may have.

[The prepared statement of Dr. Strain follows:]

Testimony for the Record
Submitted to the
House Committee on Energy and Commerce
Subcommittee on Health
for the Hearing
"Combatting the Opioid Crisis: Prevention and Public Health Strategies"

March 22, 2018

Eric C. Strain, M.D.
Director, Center for Substance Abuse Treatment and Research

Chairman Burgess, Ranking Member Green and members of the Subcommittee, thank you for inviting me to participate in today's hearing and thank you for devoting two full days to legislative solutions to end the opioid crisis and address the scourge of addiction in our communities, a topic which has been the focus of my professional career.

My name is Eric Strain. I am a psychiatrist and have spent over 30 years at Johns Hopkins, where I direct the Center for Substance Abuse Treatment and Research and serve as medical director of the Behavioral Pharmacology Research Unit.

In my practice and as a clinician leader at Johns Hopkins Medicine, I have seen the detrimental impacts of the current federal regulations 42 CFR Part 2 that limit the use and disclosure of patients' substance abuse treatment records and I am pleased that this Congress is taking a proactive step to update the law to be more in keeping with modern-day, multidisciplinary medical practice and the best patient care.

The amendment in the nature of a substitute to H.R. 3545 as offered by Representative Mullin goes a long way toward enhancing physicians' ability to share vital health information in a timely manner, while protecting patient confidentiality consistent with the Health Insurance Portability and Accountability Act (HIPAA).

Though well-intentioned at its enactment more than 40 years ago, 42 CFR Part 2 is outdated and, worse, it can result in harm to patients and inhibit new delivery system models, such as Accountable Care Organizations (ACOs) and bundled payments.

Full alignment of federal privacy rules with HIPAA for the purposes of treatment, payment and health care operations will ensure that patients with substance use disorder (SUD) receive accurate diagnoses, integrated and coordinated treatment, and appropriate patient-centered care.

42 CFR Part 2 poses a serious safety threat resulting from possible drug interactions.

Adverse drug interactions are one of the leading causes of morbidity and mortality in the United States and one of the greatest risks associated with 42 CFR Part 2 and its prohibition on sharing

SUD information with other medical professionals for treatment purposes. For example, if a patient is suffering from depression while in SUD treatment, he or she may be prescribed a sedating antidepressant by a psychiatrist who is unaware of the patient's SUD. This could lead to a severe adverse drug reaction if the patient is also taking methadone or buprenorphine to address his/her SUD. Such an adverse effect would otherwise be completely avoidable and preventable if the psychiatrist were aware of the patient's methadone prescription.

Another example involves treatment for HIV. Some common medications that are prescribed to treat HIV may hasten the metabolism of methadone and undercut the benefits of that drug. Several prescription medications that may otherwise be benign, actually slow the metabolism of methadone, causing adverse side effects. Finally, there are medications that essentially negate the benefit of methadone, undercutting the entire purpose of controlled methadone maintenance therapy.

Without legislative changes to 42 CFR Part 2, we will continue to see patients suffer as the result of these avoidable and often significant adverse drug interactions simply because non-SUD providers lack vital information about the patient's treatment.

PDMPs are prevalent, but patients do not fully benefit from them.

States, in partnership with the federal government, have spent hundreds of millions of dollars to set up prescription drug monitoring programs (PDMPs) and health information exchanges (HIE) to prevent avoidable, dangerous and potentially deadly drug interactions by permitting providers real-time medication history information on patients they are treating. However, because of 42 CFR Part 2, SUD records must remain separate and segmented from any other medical record and cannot be shared with a patient's primary care physician, psychiatrist or other specialist without the express, written consent of the patient, so the benefit to PDMPs and HIEs is undercut for patients suffering from SUD.

In dire situations, patient consent may not be possible.

Patients brought into the hospital emergency department (ED) after a serious accident, may be unconscious and therefore unable to communicate to the treating provider that they are in treatment for, or have a history of SUD. Without this important information, the ED provider may prescribe an opioid to alleviate pain and the patient may relapse as a result.

The "emergency" exception is insufficient and confounds early intervention.

We recognize that there is an "emergency" exception under 42 CFR Part 2 that would permit an SUD program to provide information to the ED physician without the patient's consent in a bona fide emergency, but there are limitations to this exception. Most importantly, the ED provider would have to know there was SUD information to request and would have to know from which SUD provider to request the information, which is rarely the case. Additionally, even if the ED provider were aware that there was SUD information to be requested, the SUD provider would have to be available and willing to provide the requested information, which is not always possible in an emergency.

With the advent of HIEs, PDMPs and electronic medical records (EMRs), most information is readily available to ED physicians 24 hours a day, and it has become the standard of care to check

these systems for evidence of past medical histories that guide a provider in delivering appropriate care. Unfortunately, due to 42 CFR Part 2's consent requirement, SUD information often is not available in these systems and is therefore not available to ED staff, a factor that has real and significant consequences for patients.

Additionally, most providers prepare for a patient encounter by reviewing the patient's medical records in advance. If the non-SUD physician must wait until the actual encounter to learn the patient has a history of SUD, it is too late for the physician to get a consent and obtain the records from the SUD program even if the patient is willing to share the information. As a result, the physician must rely on the patient to accurately disclose their medical regimen, dosage information, and plan of care, which may lead to inaccurate information in the patient's record.

Lack of transparency shortchanges patients who could benefit from additional care at the time of service.

Many patients undergoing SUD treatment have co-occurring conditions that may have come about as a result of, or are otherwise related to, their SUD, such as cardiovascular disease, HIV/AIDS, STDs, hepatitis C, depression, injuries and other illnesses. Segregating care and disorders into silos without sharing the information with other treating providers does a disservice to the patient and those providers who do not have the benefit of the SUD-related information.

42 CFR Part 2 tends to focus upon the "program" as the level of service delivery unit, and 42 CFR Part 2's privacy restrictions are limited to care rendered within the four walls of these programs. The development and approval of a variety of pharmacotherapies for SUDs (e.g., acamprosate, buprenorphine, naltrexone) has resulted in treatment occurring in primary care provider offices, as well as other general clinical settings. This expansion of treatment into other integrated care settings has been successful in getting patients the SUD care they need while also treating their other medical conditions.

Relying on consent is often not practicable in these contexts, and it may diminish the value of the integrated care programs. While our experience has been that a majority of patients will sign a consent form because they understand the benefits of the program communicating to the physician and trust their providers to do what is in their best interest, there is no mechanism for effectively treating patients in these interdisciplinary programs if they do not consent to sharing the information with other specialists involved in their treatment. Following are three examples:

- Johns Hopkins Bayview Medical Center (Bayview) offers an outpatient program through the Center for Addiction and Pregnancy (CAP) that helps mothers and infants deal with the physical, emotional and social problems caused by SUDs. This program offers coordinated and multidisciplinary care to drug-dependent mothers and their drug-affected babies. The program is less effective and patients lose the benefits of coordinated care when information is not freely shared between the CAP program and the Bayview Ob/Gyn Department, the Pediatrics Department, the Psychiatry Department and hospital social workers and case managers. In addition, when a drug-affected baby is treated in the Neonatal Intensive Care Unit (NICU), the NICU clinical staff may not have access to the mother's full SUD history, including what drugs may be affecting the newborn baby. Because 42 CFR Part 2 requires CAP to obtain written consent to share SUD information with the other departments, a

pregnant patient who requires SUD treatment but who is unwilling to sign a consent neither she nor her baby will receive the comprehensive care and treatment they need. The effectiveness of the Bayview program depends on the clinicians' ability to share relevant clinical information with all who are involved in patient care.

- Johns Hopkins' inpatient Chemical Dependence Unit (CDU) provides safe, medically supervised withdrawal in a monitored environment for individuals dependent upon alcohol, benzodiazepines and opioids. In addition to the SUD providers at the CDU, the patient benefits from consultations from other specialists outside the program. Because of the requirements of 42 CFR Part 2, the patient will not receive the full benefit of these other consultations if he or she is unwilling to provide the legally required consent.

- The buprenorphine component of Johns Hopkins' Bartlett Clinic -an HIV treatment site- relies on other departments within Johns Hopkins — but outside of the SUD program — to treat patients and meet their medical needs. The departments of medicine and psychiatry and SUD providers work together to holistically treat the patient within the same facility and health system, but outside the legally identified SUD program.

The foregoing examples illustrate how the limitations imposed by 42 CFR Part 2 are hindering effective care in an integrated care setting where our patients could benefit from multidisciplinary care in one place and during the same encounter.

42 CFR Part 2 hides the successes of treatment and perpetuates stigma.

Continuing to segregate SUD information from other medical information perpetuates stigma associated with SUD treatment. Ideal patient care occurs in a comprehensive manner. Systems and regulations that dissect and localize a particular treatment or illness are ultimately flawed in that they fail to appreciate and care for the whole person and create barriers to providing effective lasting treatment.

Those who would be permitted to receive SUD information under this amendment would be only those who are already subject to strict confidentiality restrictions pursuant to the regulations issued under HIPAA, which offers relevant privacy protections. These regulatory restrictions, coupled with the existing requirement to secure a specialty court order before SUD information could be introduced in litigation or a criminal proceeding, would enable providers to share potentially lifesaving information while still giving patients the confidence that their SUD information would remain protected and not used for purposes outside the treatment context.

Additionally, the Mullin amendment includes language to protect against loss of employment, housing, child custody, criminal arrest, prosecution and incarceration in the event SUD treatment becomes known to third parties. The proposed amendment includes strong anti-discrimination provisions that offer additional protections. We strongly support keeping the specialty restrictions available under 42 CFR Part 2 to keep SUD information from law enforcement professionals, employers and divorce attorneys.

Alignment with HIPAA for health care operations and payment should be included.

Health care delivery is moving from volume to value, and the value added by organizations such as health plans and ACOs should be considered in any attempt to amend 42 CFR Part 2. Health plans and other organizations, such as ACOs, have filled in gaps left by resource-strapped SUD programs by offering comprehensive care management programs to patients. But to do so, they must have a mechanism to identify who those patients are, and this can be best achieved by free communication between health plans, ACOs and SUD programs.

When ACOs cannot receive full data on all attributed patients, either from CMS or from relevant SUD programs, due to 42 CFR Part 2,the ACO then has an incomplete picture of their attributed patient population and what conditions may need to be addressed. Such data could allow the ACO to institute programmatic initiatives to more effectively address particular SUDs in its population. We are losing an opportunity for the ACOs to further help in this crisis. ACOs have been unable to focus on SUD interventions because they lack population-wide information about the incidence of SUD in their attributed beneficiary populations.

Additionally, SUD providers need to be able to share SUD information with a patient's health plan for payment purposes. As groups work to increase access to SUD care to address the current epidemic, treatment programs must be properly reimbursed for their services so that they can remain financially viable and open. Patients could retain the ability to keep their SUD treatment from their health plans by choosing to pay out-of-pocket for services, which is a right granted under HIPAA. However, SUD programs risk insolvency if they are not able to bill for their services in all other scenarios.

It is time to bring appropriate sharing of substance use records into the 21st century.

The current system of separate sets of rules and regulations for SUD information and general medical information no longer reflects the contemporary state of care for, or management of, patients. Optimal patient care occurs in a comprehensive and integrated manner, with information in a patient's entire medical record, including their SUD history shared across all specialties and providers.

We are in the midst of an epidemic. My training tells me we need to respond accordingly, with the broadest possible intersectional collaboration, with initiatives for both patients and populations, and with mapping and deployment of all possible resources. And most importantly, we need strategic and thoughtful information management. Providers on the front lines of treating substance use disorders. They are uniquely positioned to be a resource, but they cannot do so without an unobstructed view of their patients' medical records. I urge the committee to report out legislation amending 42 CFR Part 2 that allows the responsible sharing of patient records for the purposes of treatment, payment, and health care operations.

Thank you and I would be pleased to answer any questions you may have.

The opinions expressed herein are my own and do not necessarily reflect the views of The Johns Hopkins University.

Mr. BURGESS. Thank you, Dr. Strain.
Dr. Martz, you are recognized for 5 minutes, please.

STATEMENT OF KENNETH MARTZ

Mr. MARTZ. Good morning. Thank you so much, Chairman Burgess and Ranking Member Green, for this opportunity to come here and testify on this important issue. This is an issue that is affecting 23 million Americans who are in recovery from substance use disorder and who have had their experience with treatment and are now working through the system in addition to those who are actively in substance use disorder.

I am Dr. Ken Martz. I am a licensed psychologist. I am working with Gaudenzia. I have been working in multiple States in private practice and in State government settings, in public settings as well as private, for 25 years. This has been my life's work and my passion and I love this work and I really appreciate this opportunity.

42 CFR's protections are critical to maintain, to ensure that people enter treatment for substance use disorder. This is something we know from SAMHSA, which has studied this extensively, and they find that the top reasons why people do not go to treatment continue to be fear of stigma. What will my employer think? What will my neighbors think? What harms will come of me if I disclose those secret harms and guilts and shames? The research finds that this fear of impacts is a primary reason.

And the Congress recommended this as well, back in 1972, they stated that, "The conferees wish to stress their conviction that the strictest adherence to the provisions of this section is absolutely essential to the success of all drug abuse prevention programs." This was echoed by the Supreme Court as well, which affirmed "like the spousal and attorney client privileges, the psychotherapist patient privilege is rooted in the imperative need for confidence and trust."

Treatment by a physician for his physical ailments can often proceed successfully on the basis of physical examination and the results of diagnostic tests. Effective psychotherapy, by contrast, depends on the atmosphere of confidence and trust in which the patient is willing to make a frank and complete disclosure of facts, emotions, memories, and fears. For this reason, the mere possibility of disclosure may impede the development of the confidential relationship necessary for successful treatment. I urge you to remember the wisdom of these chambers.

Oddly, it is funny. We walk in here today and the news of the day is about hacking and data breaches and Cambridge Analytica with a new focus on there being death penalty for those who have a substance use history and have sold a drug. So if my child hands over some drugs to his girlfriend, she dies, he is now potentially at risk. We don't know what the laws will change in the future. This has a chilling effect on people being willing to attend treatment.

The impacts on patients, I know you know you are hearing from many healthcare organizations that find this very inconvenient, but this is not about inconvenience. This is about patient care. This is about patient health and being able to access exactly what they need. If we want to discuss coordinated care the best way to do

that is direct conversation with the patient and direct conversation therapist-to-therapist which is not impeded by 42 CFR protections. It actually gives the patient the respect of being involved in that process.

If you are going to share my information about my trauma and my trauma histories, please do me the respect of asking me and letting me know where it is going to go to before it gets shared to thousands of other people potentially having access. Now, put simply, some of the important protections included that once they are labeled it can affect clinical decision making for a lifetime. It cannot be amended and you cannot fix things like prison time or loss of employment.

These are professionals we are talking about like teachers, physicians, government workers, who may avoid treatment for fear of harm, for fear of being disclosed, and therefore they may get worse because they didn't get the care that they needed because they have delayed. The stigma is still alive long and strong.

Looking at some recent comments, one was said, overdose is nature's way of taking out the trash. Oh my gosh. Overdose is nature's way of taking out the trash.

I have plenty of compassion for those who deserve it. I have no compassion for those who made their own problems such as dopers, pedophiles, and murderers.

It is hard to even say these words. These are the levels of stigma that is out there today that our clients are facing on a daily basis and it is very difficult to identify and manage these harms that may arise. Eliminating these Part 2 protections will brand these individuals with like a scarlet letter so they when they walk in the door they can be identified immediately as having this problem, as having this history as well as the risks associated.

Stigma affects all of us in many different ways. Remember that making these changes is every time we make these changes, every time changes are made as a provider I need to learn about them, I need to train the field and, worse, tell the client that every day what they told me yesterday in private is no longer private today. In all my years, I can't tell you how important this is. And if there was only one other thing that you could possibly do, and in addition to this I would be happy to answer other things, please get rid of that IMD exclusion. It is harming people and stopping care. Thank you.

[The prepared statement of Mr. Martz follows:]

March 22, 2018

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Re: Confidentiality of Substance Use Disorder Patient Records, Combatting the Opioid Crisis, Prevention and Public Health Solutions

We appreciate the opportunity to provide input to the Committee on Energy and Commerce, Subcommittee on Health. **It is our position that Part 2's heightened protections for substance use disorder records promote patient care, health outcomes and privacy, and that it is vitally important to maintain patient confidentiality in order to ensure that people enter treatment for substance use disorders.**

I am a licensed psychologist and have worked across three states treating substance use disorder (SUD) in a range of settings including outpatient, intensive outpatient, residential, hospital and prison settings. Further, I have worked with clients who can afford to pay by cash for fear of disclosure of their private information, as well as those who cannot afford treatment unless it is funded by government agencies. In these 25 years of experience in the field, there are some consistent concerns as I will outline below.

I am writing representing Gaudenzia Inc, a non-profit treatment provider specializing in SUD, with programs spanning outpatient, intensive outpatient, and residential treatment programs. Celebrating 50 years in operation, Gaudenzia operates 151 programs at 82 facilities throughout Pennsylvania, Delaware, Maryland and Washington, DC. System-wide last year, 17,087 individuals were admitted into treatment. Over 1,000 Gaudenzia staff reflect the diverse treatment population with numerous employees at all levels who have many years of experience in recovery, understanding the role of treatment, recovery and privacy protections.

Any discussion of proposed changes must first begin with the context of why these protections exist. The stated purpose remains: "They are intended to ensure that a patient receiving treatment for a substance use disorder in a part 2 program is not made more vulnerable by reason of the availability of their patient record than an individual with a substance use disorder who does not seek treatment." 2.2(b)(2) There are a number of these adverse impacts which one is vulnerable to ranging from housing, life insurance coverage, loans, employment, licensure and a range of related discrimination that may be intentional or merely passive.

Put simply some of the importance of privacy protections include the following risks:

- Once labeled, it can affect clinical decision-making for a lifetime.
- Some violations that cannot be amended, such as prison time, loss of employment etc.
- Serious losses/damage in people's lives, employment and relationships.
- Individuals not seeking treatment/delaying onset of treatment.
- Individuals not sharing key information regarding guilt/shame/trauma for fear of disclosure.
- Professionals such as teachers, physicians, government workers and others may avoid treatment for fear of harm, causing the SUD to progress into greater severity before being treated.
- Damage to treatment leads to increased rates of SUD and associated societal impacts (overdose, crime, child welfare, health conditions).
- Denial of proper medical care (e.g. refusal of pain medication, even in cases of acute trauma or end-stage cancer).

The protections of 42CFR Part 2 highlight similarities and differences with HIPPA. While we have made great strides in understanding that SUD is a disease, not a moral failing, this does not mean that every disease is treated the same. Simply stated, SUD is unique in a number of ways. For example, you do are not incarcerated for having a heart attack, you are not fired for having cancer, and you are not denied visitation to your children due to severe acne. Disclosure of SUD has tangible vulnerabilities that are not the same as other medical conditions.

In order to understand the impact, it is important to consider any further changes from the perspective of the individuals with SUD, from the SUD counselors who treat them, as well as the historical and current landscape:

- **It is critical to understand the issue of confidentiality protections from the perspective of those with a substance use disorder, who are often afraid of harms associated with disclosure of their personal information.** Remember that many of these individuals in active addiction do not have a voice because they are not even aware of this debate over their protection of confidentiality, happening thousands of miles away.

Their lack of voice may not be an indication that they are not concerned about confidentiality protections. The National Survey on Drug Use and Health continues to survey thousands, showing that shame and fear of retribution remain key reasons why people avoid treatment, afraid of the impacts on employment and judgement in the eyes of their neighbors and friends. Their focus should be on their treatment and establishment of recovery not on politics aimed at protecting their right to privacy, Appendix A contains a list of examples of the intensity of judgement of faced directly and indirectly by those with SUD. Appendix B contains a list of examples of harms associated with disclosures of private information. These harms and discrimination are difficult to identify or prosecute. Worse, inappropriate disclosures are virtually impossible to remedy since there is no way to "undisclose" what has been shared. A most egregious case example is that of individuals being denied life insurance because they have a history of being prescribed naloxone, the overdose reversal medication. Remember that the one's purchasing naloxone, are often not the person with SUD, but the mothers, brothers and children trying to prepare to save the lives of a loved one.

- **It is important to consider the will of those we are representing.** Often discussions of confidentiality are centered around the inconvenience of obtaining releases or other nuisances to the health care system which is too busy to learn about rules for licensing and confidentiality protections. This focus ignores the individuals who are at risk themselves, who could simply be asked the information directly. This disrespect suggests an underlying stigma that we know better than the patient, or worse an outright contempt for "those people" who are simply scamming for medication.

- **With the intense emphasis on the opioid epidemic, it is important to remember that most individuals with SUD do not use opioids.** Data from the National Survey on Drug Use and Health reveals that 65 million Americans 12 and Older admit to binge drinking in the past month. Of these, 16 million admit to being heavy drinkers. We should also be aware that 24 million people admit to being past month users of marijuana. These numbers alone suggest the magnitude of the issues we are confronting today, as they exceed the 3.4 million people who admit to past month use of pain relievers and the 475,000 who admit to past month users of heroin. This highlights the broad range of individuals affected, most of whom are in the workforce, including doctors, lawyers, teachers and others.

- **In the context of an opioid epidemic, it is important to consider the effect that any changes have on the treatment process which is predicated on the establishment of a safe environment where individuals with SUD can explore the causes and solutions to their disease.** Treatment occurs in the context of a supportive relationship, where individuals feel safe to explore their deepest underlying fears, beliefs and judgments that trigger escape into substance use. Confidentiality is the key element in creating the safe relationship where recovery can take root and grow. Every time the confidentiality protections are changed, every clinician needs to learn about it, consult with lawyers to

determine the application of the changes, develop new informed consents/policies/procedures, and train counseling and supportive staff on the changes. Perhaps worst of all, we must then go to each client and inform them of the change, along with the new agreement of what will or will not be protected. This is incredibly damaging to the treatment relationship and trust that is necessary for an individual to share his/her most vulnerable information. Clinical records may contain very personal quotes regarding a person's fear, shame, or victimization that should only be shared by the individual, when they are ready, and in the context of trusting relationship, rather than through broad dissemination of this information without context. Engagement with a positive therapeutic alliance is critical to successful outcomes. This includes a patient's trust that they may remain in control of their most sensitive information. While some may choose to disclose personal information, that must remain their choice so that these decisions are not made without those whose information is at risk.

- **Historical perspectives should be remembered, so we do not repeat the mistakes of the past, since the stigma and adverse impacts of disclosures are as much a concern today (if not more) as they were in the days of the original implementation of 42CFR Part 2.** The original confidentiality protections were established at a time when there was rampant opioid use, as well as risks of prosecution for those who were using drugs. Appendix C includes examples of the types of rulings and discussions from the day. Courts and congress through the decades have reiterated the central role of privacy in the treatment relationship. In one example they indicate that this is even more sensitive than the relationship with a physician, instead comparing the nature of the counseling relationship to that of priest/penitent. Today, individuals with SUD continue to face the risk of discrimination, loss of employment, loss of their children, and criminal charges for the behaviors associated with their disease.

- **The current landscape includes regular public discourse on the risks of "hacking", "leaks", "ransomware", and outright data breaches of public and medical information, making digital sharing of private information more risky, in a way that was not possible years ago.** Years ago, inappropriate disclosures would only share the protected information to a limited number of individuals. Today, when personal records can be merely data to be bought and sold, inappropriate disclosures can expose one's history to thousands. This can lead to widespread harm that is very difficult to undo. Appendix D outlines some recent data breach materials. Additionally, every electronic health record (EHR) is different, which creates risks of error. Functionally, my EHR would upload to a regional EHR hub, which would then connect to a state or national level EHR, before it would then be shared down to another regional EHR and ultimately to another program, which could have yet another EHR system. This complexity creates

risks of error in data sharing that could result in misinformation about an individual, leading to improper treatment decisions.

With regard to Part 2's effect on patient care, health outcomes, and patient privacy, Gaudenzia supports the following principles:

- **Part 2's heightened privacy protections are as critical today as they were when they were enacted more than 40 years ago in order to protect patient care, health outcomes, and patient privacy.** If patients are afraid that their treatment records will be used to criminally investigate or prosecute them, or deny them insurance or a job, or be used against them in a divorce or child custody proceeding, they will not enter treatment in the first place. Part 2 prevents patient records from being used against them in such proceedings without an individualized inquiry into the relevance of the patient records and the potential harm to the patient upon disclosure, whereas HIPAA's lower privacy standard provides no such protections. In the midst of a national emergency and growing rates of fatal drug overdoses, Part 2 provides a crucial guarantee to the millions of people in treatment and the many millions more with an unmet need for treatment, that it is safe to enter treatment.

- **Patients in substance abuse disorder treatment should retain the power to decide when and to whom their records are disclosed, given the continued prevalence of discrimination in our society.** This includes disclosures to the general health care system, health information exchanges ("HIEs"), health homes, accountable care organizations, and coordinated care organizations. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on redisclosure. In addition, we worry that some individuals may not fully understand the implications of giving this information while in withdrawal or frightened.

- **Electronic Health Record ("EHR") systems must accommodate heightened protections for health information – not the other way around.** It is both necessary and technologically possible to integrate substance use disorder information and maintain patient confidentiality. Moreover, Part 2's heightened privacy protections are just one of many heightened privacy protections in state and federal law for sensitive health information – including state laws protecting mental health, HIV status, reproductive health, and domestic violence history – and eliminating Part 2 will not absolve EHR systems from addressing the need to meaningfully segment health information data.

- **It is damaging to initiate additional changes to Part 2.** SAMHSA has recently reviewed feedback from hundreds of entities and updated Part 2. New amendments made to Part 2 by SAMHSA in 2017 and 2018 have made it even easier to allow (with patient

consent) for the sharing of health information between Part 2 programs and other health care providers. Many vendors, health care providers, and substance use disorder treatment programs do not understand these new amendments and how to utilize Part 2 as effectively as possible. Every time there are changes, it impacts treatment providers who need to develop new training. Every change also erodes the trust of those with addiction making them less likely to access treatment and remain in treatment.

In light of these principles, we recommend the following:

- Refrain from further changes to 42 CFR Part 2.
- Strengthen the enforcement of sanctions on those who disclose or re-disclose protected information.
- Fund infrastructure for development of information technology systems that can safely handle this information with appropriate permissions for different users, and inter-program communication to prevent inadvertent data errors in upload/downloads.
- Fund programs to hire data entry processers, train all staff, purchase equipment and upgrade data systems.
- Remember that SAMHSA has already conducted an extensive review and "final" ruling on this matter, and that the continued discussion has a chilling effect on those who are desperately in need of a safe haven to begin their recovery journey.
- Remember that this is not a matter of inconvenience, but rather a critical protection so that individuals feel safe to enter treatment, safe to explore their deepest fears, as they work to establish recovery. Without this protection, treatment fails.

We urge the Subcomittee to consider our comments and think carefully before taking any steps that may further increase the vulnerability of substance use disorder treatment records. Based on the reasons outlined, we oppose additional damaging changes to 42 CFR Part 2 at this time.

Thank you for your careful consideration in this complex issue that is so sensitive in the context of the current epidemic.

Sincerely,

Ken Martz, Psy.D.

Ken Martz, Psy.D., MBA, CAS
Licensed Psychologist
Gaudenzia Inc.

Appendix A

Examples of Public Stigmatized Attitudes

Consider the rampant depth of stigma from recent blog posts such as:

- "Overdose is nature's way of taking out the trash"
- [re: Naloxone] "Thanks for saving him. Now he can continue to steal to support his habit."
- "Very mixed feelings here. Do I care if some drug user dies? Not really. Do good people make mistakes and deserve a second chance? Yes."
- [Re: Naloxone] "Should make a one per person law. If someone survives because of this miracle drug and they still can't appreciate their life and are stupid enough to use, don't waste the money/time on trying again.
- **"I have plenty of compassion for those who deserve it. I have no compassion for those that made their own problems such as dopers, pedophiles and murderers"**

Recently, the opioid epidemic has increased negative attitudes toward those with SUD due to their repeated returns to the emergency departments, and law enforcement who has responded and revived the same individual repeatedly.

Appendix B

Examples of Adverse Impacts

Stigma leads to subtle and obvious discrimination. Consider the numerous examples cited by the Legal Action Center in their response letter to these proposed changes dated June 25, 2014, and from Faces and Voices of Recovery's response:

- "A young father in recovery who was being denied visitation with his children because he was in methadone treatment, despite the fact that he was not using any illegal substances;"
- "A mother in recovery who had her 2-month-old infant removed from her custody after the hospital where she gave birth reported her for having legally prescribed methadone in her system;"
- "A young mother who was being threatened with eviction from a shelter because she was taking prescribed methadone for her opioid addiction (another young mother had already been evicted from the same facility for the same reason, and had become homeless; neither woman was using illegal substances);" and
- "A young man whose employer refused to allow him to return to work after he successfully completed treatment for alcoholism, saying that he was a safety threat even though his physician had cleared him to return to work with no restrictions."
- "A 29 year old mother who lost her 3 year old in a child custody case because, after the unlawful disclosure of her addiction treatment records, she was deemed unfit by a judge and her child was put in the custody of child protective services.
- "A bright young lawyer who learned after two weeks at her new job that she would be terminated because the fact she was on methadone came up in a background check."
- "A small businesswoman had to give up her dream of owning her own business because she could not get a health insurance policy for her employees;" and
- "A husband with four children who was in a high risk fisheries job was unable to get life insurance to protect his wife and children."

In addition to these personal examples, with the widespread use of naloxone, cases are emerging of adverse impact such as denial of life insurance. To receive this sanction, the only crime these individuals committed is that they love someone with SUD.

Appendix C

Examples of Historical Considerations Still Relevant Today

The discussions that occurred in about confidentiality protections in the 1960's and 1970's are as relevant today as they were then:

- "The psychiatric patient confides more utterly than anyone else in the world. He exposes to the therapist not only what his words directly express; he lays bare his entire self, his dreams, his fantasies, his sins, and his shame. Most patients who undergo psychotherapy know that this is what will be expected of them, and that they cannot get help except on that condition. . . . It would be too much to expect them to do so if they knew that all they say-and all that the psychiatrist learns from what they say-may be revealed to the whole world from a witness stand." (Cited in *Duke Law Journal*, Soffin, 1985)
- "First, communications from a patient to a psychotherapist do originate in the expectation of confidentiality. Psychiatric patients divulge to their therapists secret thoughts and emotions that they would not reveal even to their families or close friends. Communications that are made during therapy may reveal unattractive and antisocial tendencies of the patient; thus psychotherapy patients expect and demand confidentiality in return for their open disclosure. Second, this element of confidentiality is essential to a complete and satisfactory relationship between the parties. In order for treatment to be successful, patients must be able to communicate their thoughts and emotions freely and fully, even when such thoughts are abhorrent to society. **If patients suspect disclosure of their confidences, they will hesitate to consult a psychotherapist and may forego needed treatment.** Emotional and social problems, if untreated, are detrimental to both the individual and society. (Cited in *Duke Law Journal*, Soffin, 1985)
- "Among physicians, the psychiatrist has a special need to maintain confidentiality. His capacity to help his patients is completely dependent upon their willingness and ability to talk freely. This makes it difficult if not impossible for him to function without being able to assure his patients of confidentiality and, indeed, privileged communication...[While] there may be exceptions to this general rule, there is wide agreement that confidentiality is a sine qua non for successful psychiatric treatment. The relationship may well be likened to that of the priest-penitent or the lawyer-client. Psychiatrists not only explore the very depths of their patients' conscious, but their unconscious feelings and attitudes as well. Therapeutic effectiveness necessitates going beyond a patient's awareness and, in order to do this, it must be possible to communicate freely. A threat to secrecy blocks successful treatment. (*Taylor v. US, 1955*)
- "In regard to mental patients, the policy behind such a statute is particularly clear and strong. Many physical ailments might be treated with some degree of effectiveness by a doctor whom the patient did not trust, but a psychiatrist must have his patient's confidence or he cannot help him. "**The psychiatric patient confides more utterly than anyone else in the world. He exposes to the therapist not only what his words directly**

express; he lays bare his entire self, his dreams, his fantasies, his sins, and his shame. Most patients who undergo psychotherapy know that this is what will be expected of them, and that they cannot get help except on that condition…It would be too much to expect them to do so if they knew that all they say — and all that the psychiatrist learns from what they say — may be revealed to the whole world (*Taylor v. US, 1955*)

- "The conferees wish to stress their conviction that the strictest adherence to the provisions of this section is absolutely essential to the success of all drug abuse prevention programs. Every patient and former patient must be assured that his right to privacy will be protected. Without that assurance, fear of public disclosure of drug abuse or of records that will attach for life will discourage thousands from seeking the treatment they must have if this tragic national problem to be overcome." (*U.S. Code Congress & Admin. News*, 1972)

Appendix D

Data Breaches in the Modern World

The scope of risk of adverse impact must be considered in light of the context of data security. In February 2015, Anthem, Inc., the largest for-profit managed health care managed health care company in the **Blue Cross and Blue Shield Association, disclosed that criminal hackers had broken into its servers and potentially stolen over 37.5 million records that contained personally identifiable information from its servers.**

Such cyberattacks are on the rise and are now expected to be a constant source of concern throughout the healthcare industry as patient information is shared across various technology platforms. The publication Becker's Hospital Review regularly collects and reports the latest data breaches, often on a monthly basis. The data security of insurance companies, outpatient providers and other entities that work with patient information is variable, posing a never-ending danger that patient information could be compromised and that the outcomes will be troubling for those persons whose healthcare information is obtained in this nefarious manner. **Russell Branzell, president and CEO of the College of Healthcare Information Management, has said that "Healthcare is ground zero for cyberattacks."**

According to the Department of Health and Human Services, while all industries continue to face a growing threat of attacks on their information systems, the size and scope of attacks on health care information systems have accelerated particularly rapidly in the past two years. The Department recently announced the members of its Health Care Industry Cybersecurity Task Force, representing a wide variety of organizations within the health care and public health sector, including hospitals, insurers, patient advocates, security researchers, pharmacy and pharmaceutical companies, medical device manufacturers, health information technology developers and vendors, and laboratories.

More recently, Aetna allegedly disclosed the names of 13,487 Aetna customers who had the medications were taking HIV medications. This has led to a lawsuit seeking over $20 million. Individuals could receive a settlement of merely $75-$500 to compensate them for any harms associated.

Historically, in the context of paper records, confidentiality violations were very limited due to the need to either access the paper record, or have a clinician purposely disclose information. In the age of big data, each data breach can violate millions of affected individuals, exponentially increasing the risk of harm to this vulnerable population.

Mr. BURGESS. Thank you, Dr. Martz.

Mr. Bauer, you are recognized for 5 minutes, please.

STATEMENT OF BRAD BAUER

Mr. BAUER. Thank you and good morning. Chairman Burgess, Ranking Member Green, and members of the Health Subcommittee, thank you for the opportunity to testify today on the role of Prescription Drug Monitoring Programs or PDMPs in combating the opioid crisis as well as the PDMP discussion draft from Representative Griffith and Ranking Member Pallone.

My name is Brad Bauer and I am Senior Vice President with Appriss Health and have responsibility for our State and Federal PDMP solutions. We provide a common platform and software solution for 42 of the 52 established PDMPs throughout the United States and U.S. territories. State-based PDMPs continue to evolve and innovate in the face of our nation's opioid crisis. While each State faces unique challenges brought on by the crisis, tremendous progress has been made within a few critical areas each of which have been identified by government and research organizations as best practices to ensure effective and impactful PDMPs.

First, the ability for States to share PDMP data with other States provides prescribers and pharmacists with a more complete view of the patient's controlled substance history. In 2011, the National Association of Boards of Pharmacy created a PMP Interconnect with technical assistance from Appriss Health to allow States to securely and efficiently share data in real-time at no cost to the States.

[Slide shown.]

Mr. BAUER. As you can see on the monitors, the numbers of states participating has grown rapidly to 45 PMPs today. For the remaining States not currently participating, policy issues not technology are the only barriers. Most recently, Florida passed legislation allowing the State to share their PDMP data with other PMP Interconnect states effective July 1st, 2018.

Second, and probably the most impactful developments for State PDMPs, has been integration of PDMP data and analytics within the electronic health record or pharmacy dispensation system to enable one-click or in some cases no-click access for prescribers and pharmacists. The majority of States are moving in the direction of active integrations of their data and analytics within clinical workflows with about 20 percent of providers currently having access to integrated PDMP reports.

However, broader adoption has been slow due to the need for funding to cover costs of integrations. Integration of PDMP data and analytics promotes efficient and consistent use of PDMPs by providers when making clinical decisions. For example, Ohio has seen a 1000 percent increase in usage of the PDMP as a result of their statewide PDMP integration effort.

States are also in the process of transforming their basic PDMP systems into substance use disorder platforms that deploy the capabilities necessary to impact the epidemic and bend the overdose death curve down and not just drive down the number of controlled substances prescribed. States like Indiana, Oregon, Michigan, Dela-

ware, Iowa, Ohio, and Virginia are just a few examples of States that have already taken steps to transform their PDMPs.

Examples of new developments in PDMP capabilities include inclusion of additional data sources such as history of nonfatal overdoses; drug court information and toxicology data; patient-at-risk scores to help a practitioner quickly assess the risk and engage the patient accordingly; the ability to refer patients to treatment, often referred to as a warm hand-off within the PDMP; and facilitation of care team communications.

All these capabilities and clinical tools are designed to help the practitioners identify prescription drug overdose sooner versus later, mitigate the chance of an illicit drug encounter, and engage with their patients and assure they have and receive the help they need. The PDMP discussion draft from Representative Griffith and Ranking Member Pallone would incentivize States to continue to improve their PDMPs through evidence-based prevention grants along with evaluating interventions to prevent overdoses and implementing new projects to respond to the evolving crisis in innovative ways.

As you have heard one of the panels yesterday, the Centers for Disease Control is engaged in a number of these activities but the legislation authorized would help to improve on CDC's work. Second, the draft would establish grants for an enhanced surveillance of controlled substance overdoses which would authorize and provide funding for an existing CDC program to collect more comprehensive, timely, and quality data on overdoses.

We would recommend that this data be incorporated into the PDMPs. This discussion draft would allow states to continue their PDMP innovations to provide prescribers and pharmacists with a near instantaneous access to interstate PDMP information combined with the clinical tools to intervene in a meaningful way when a patient presents with a possible risk overdose misuse.

Thank you for your leadership on this critical issue facing so many communities and for the opportunity to address the committee today. I look forward to your questions.

[The prepared statement of Mr. Bauer follows:]

APPRISS HEALTH

Statement by Brad Bauer, Senior Vice President

Appriss Health

on

Combating the Opioid Crisis: Prevention and Public Health Solutions

before

House Committee on Energy & Commerce

Subcommittee on Health

U.S. House of Representatives

March 21-22, 2018

Summary of Key Points

Interstate Sharing of PDMP Data. The current state-based Prescription Drug Monitoring Program (PDMP) approach has made major progress over the last 10 years. In 2011, the National Association of Boards of Pharmacy created PMP InterConnect, with technical assistance from Appriss Health, to allow states to securely and efficiently share PDMP data. Today, 45 PDMPs share data across state borders through this highly effective and secure hub. For the remaining states, state-level policy issues, not technology, are the only barriers preventing them from joining PMP InterConnect and sharing PDMP data with other states.

Workflow Integration for PDMP Data. While the vast majority of states are sharing PDMP data, there is still a gap in usage of the PDMP by prescribers and pharmacists due to ease of use issues. To resolve this, PDMP data should be incorporated directly into the Electronic Health Record, Pharmacy Dispensation System, and Health Information Exchange to allow one click, near instantaneous access to PDMP information. Tremendous progress has been made in this area in the last two years, but much work remains. Today approximately 20% of prescribers have access to PDMP data and information in their EHRs, and additional funding is needed to increase that number.

PDMPs as Substance Use Disorder Platforms. Medication history is simply not enough to fight the evolving opioid crisis, including the rise of illicit substances. PDMPs should incorporate information and tools such as history of nonfatal overdose, patient risk analytics, treatment referral options, and the ability to coordinate amongst a care team. Multiple states have implemented these platforms in recognition that PDMPs need additional capabilities as the epidemic progresses and evolves.

PDMP Discussion Draft. The bill would authorize a number of activities the CDC is currently engaging in, including evidence-based prevention measures and enhanced surveillance of controlled substance overdoses. Grants would allow for more states to integrate data into workflow and explore innovative ways to elevate their PDMP to a substance use disorder platform, among other grant uses.

Chairman Burgess, Ranking Member Green, and Members of the Health Subcommittee, thank you for the opportunity to testify today on the role of Prescription Drug Monitoring Programs (or PDMPs) in combating the opioid crisis, as well as the PDMP discussion draft from Representative Griffith.

My name is Brad Bauer and I am Senior Vice President with Appriss Health and have responsibility for our state and federal PDMP solutions. We provide a common platform and software solution for 42 of the 52 established Prescription Drug Monitoring Programs (PDMPs) throughout the United States and U.S. Territories. The majority of those contracts were awarded through competitive bidding processes over a number of years.

State-based PDMPs continue to evolve and innovate in the face of our nation's opioid crisis. While each state faces unique challenges brought on by the crisis, tremendous progress has been made within a few critical areas, each of which have been identified by government and research organizations as important best practices to ensure effective and impactful PDMPs.

Interstate Data Sharing

The ability for states to share PDMP data in a secure and real time manner with other states provides prescribers and pharmacists with a more complete view of a patient's controlled substance prescription history. Effective and efficient interstate sharing of PDMP data enables a more accurate assessment and identification of a patient's risk towards prescription drug overdose events.

Interstate data sharing has come a long way over the past two to three years as more states have begun to share PDMP data with other states. Today, 45 PDMPs (44 states and the District of Columbia) are doing

exactly that by sharing over 18 million PDMP transactions per month across state borders through a highly effective and mature hub called PMP InterConnect. In 2011, the National Association of Boards of Pharmacy created PMP InterConnect, with technical assistance from Appriss Health, to allow states to securely and efficiently share PDMP data. Sharing through PMP InterConnect is available to all PDMPs at no cost. PMP InterConnect has established common and consistent data sharing standards that respect decades of state laws developed to support inter and intrastate data sharing. For the remaining states not currently participating, policy issues, not technology, are the only barriers and a number of the remaining states are looking to change that. Of the two largest states not currently sharing PDMP data, Florida recently passed HB 21 which will allow the state to join PMP InterConnect and share PDMP data, effective July 1, 2018. California has legislation pending (AB 1751) that would allow the state to participate in the existing PMP InterConnect data sharing hub by the end of 2018, if enacted.

Integration of PDMP Data and Analytics within Clinical Workflow

One of the most impactful developments for state PDMPs is integration of PDMP data and analytics within the clinical workflow for prescribers and pharmacists. State PDMPs have made tremendous strides on this front. In states with voluntary use of PDMPs, usage is typically up to 25%. Forty states now mandate provider use of PDMPs, but even with a mandate, use of PDMPs is typically 75-80%. The best way to increase provider usage of PDMPs is through integration that creates "one click" or in some cases "no click" access.

For the past two years, state PDMPs and Appriss Health have collaborated to create a common methodology to integrate PDMP data and analytics within a prescriber's electronic health record (EHR) and a pharmacist's pharmacy dispensation system. Within that two-year period, state PDMPs have gone from virtually no PDMP integrations to integrating over 288 million patient reports within workflow in

2017. Today, the majority of states are moving in the direction of active integrations of their data and analytics within clinical workflows. However, broader adoption has been slow due to the costs associated with integrations and the need for funding.

Integration of PDMP data and analytics in clinical workflow represents a major step forward in promoting efficient and consistent use of PDMPs by providers when making clinical decisions. For example, Ohio has seen a 1000% increase in usage of the PDMP as a result of their statewide PDMP integration project.

Many states recognize the positive impact of making PDMP data and analytics available within workflow and have made and continue to make tremendous progress. In-workflow PDMP integrations combined with interstate data sharing helps enable practitioners to identify potential misuse and abuse of opioid analgesics in a highly effective manner.

Evolution of the PDMP as a Substance Use Disorder Platform

Appriss Health also provides the nation's most comprehensive platform for early identification, prevention and management of substance use disorder (SUD), with a focus on opioid use disorder.

While interstate data sharing and integration of PDMP data and analytics within workflow are both considered industry best practices and have progressed significantly, there has also been recognition that, to maximize their impact on the crisis, PDMPs must be much more than medication history tools. Simply sharing or integrating raw data is not enough. Big data, analytics, and additional insights from non-PDMP data sets are needed to aid practitioners in identifying patient addiction and overdose risk. And clinical tools and resources must be readily available to aid practitioners in intervening to address that risk. The

CDC recently described the opioid epidemic as three waves and overprescribing represents just the first. The second and third waves represent heroin and fentanyl respectively, and PDMPs must evolve to identify and address those risks as well.

States are in the process of transforming their basic PDMP systems into substance use disorder (SUD) platforms that deploy the capabilities necessary to impact the epidemic and bend the overdose death curve, not just drive down the number of controlled substances prescribed. Indiana, Oregon, Michigan, Ohio, Virginia, Iowa and Delaware are just a few examples of states that have already taken steps to transform their PDMPs. Examples of such capabilities include:

Inclusion of Additional Data

PDMPs are increasingly mandating that additional data sources be included in the database, such as history of non-fatal overdoses, drug court information, and toxicology data. The combination of these data sets and PDMP data provide a robust patient risk model for the prescriber and pharmacist community.

Patient Risk Scores

Patient risk scores are designed to predict the likelihood of adverse events based on established thresholds and risk algorithms. For example, a risk score considers data points such as the number of active controlled substance prescriptions, therapy overlap, number of dispensers and dangerous drug combinations. Numeric scores can help a practitioner quickly assess risk and engage with their patients in ways not previously possible.

Treatment Referral

The ability to refer patients to treatment from within the PDMP platform can ensure that patients in need do not leave the Emergency Department or physician's office without an appointment for follow-up or treatment and clear instructions. PDMPs can play a vital role in helping practitioners identify available treatment options for the patient made available by the already massive investment in the treatment infrastructure. This is often referred to as a "warm handoff."

Care Team Communications

Facilitating effective communications and care coordination among practitioners and pharmacists is a common and unmet need in healthcare. Messaging among practitioners, the sharing of care plans and pain contracts, and the triggering of alerts can all ensure that practitioners are universally aware of a patient's SUD risk and can act in a coordinated fashion to address that risk.

PDMP Discussion Draft

As you can see, states are on the frontlines of using PDMPs in new and innovative ways as the opioid epidemic evolves, and federal policy and grant dollars should encourage this. To that end, the PDMP discussion draft from Rep. Griffith would be very beneficial for incentivizing these activities and enabling more states to take advantage of the latest developments in PDMPs. The Centers for Disease Control and Prevention (CDC) is already doing a number of the activities included in the draft, but the legislation would authorize and improve upon the CDC's work, along with providing funding.

First, the draft would create Evidence-Based Prevention Grants through the CDC. States would be able to use these grants for PDMP improvement activities such as:

- Improving registration of providers;
- Incorporating or improving the use of proactive alerts to flag potential misuse of controlled substances or inappropriate prescribing practices;
- Encouraging integration of PDMP data into Electronic Health Records and Pharmacy Dispensation Systems to improve ease of use and clinical decision making;
- Facilitating additional interstate sharing of PDMP data; and
- Using innovative PDMP capabilities to respond to the evolving crisis, such as incorporating additional data points (e.g., nonfatal overdose or drug court data), data analytics, and clinical tools (e.g., warm handoffs).

The Evidence-Based Prevention grants would also allow states to evaluate interventions to determine the best approaches to preventing overdoses and implementing new projects to respond to the evolving crisis in innovative ways.

Second, the draft would establish grants for Enhanced Surveillance of Controlled Substance Overdoses, which would authorize CDC's existing Enhanced Surveillance of Opioid Overdose Surveillance (ESOOS) program. ESOOS grants would allow states to increase the timeliness of reporting and collect more comprehensive and quality data, and then use the overdose surveillance data to help identify risk factors, among other purposes. We would also recommend that this data be incorporated into a state's PDMP, to the extent permitted by state law. Knowledge of a history of nonfatal overdose is critical information for a prescriber or pharmacist.

Lastly, I understand the Committee, Rep. Griffith and his staff are continuing to work on the discussion draft, including possible additions related to updating and reauthorizing the National All Schedules

Prescription Reporting Act (NASPER). We would support modernizing NASPER to reflect the progress states have made on PDMPs since the law was enacted in 2005. We would also recommend encouraging state PDMPs to provide a timely, consistent and comprehensive deidentified data extract for surveillance and research purposes to help identify important trends and allow for appropriate and more focused resources to combat the opioid epidemic.

We also appreciate and agree with the Committee's view of PDMPs first as a public health tool with law enforcement access in certain circumstances. As such, we view it as appropriate for primary federal involvement in and funding for PDMPs to come from public health-related agencies such as CDC, rather than the Department of Justice.

This discussion draft would allow states to continue to innovate through PDMPs to provide prescribers and pharmacists with near instantaneous access to interstate PDMP information via EHRs and pharmacy dispensation systems combined with the clinical tools to intervene in a meaningful way when a patient presents with a possible risk of opioid misuse.

Thank you for your leadership on this critical issue facing so many communities and for the opportunity to address the Committee today. I look forward to your questions.

Mr. BURGESS. Thank you, Mr. Bauer.
Dr. Banner, you are recognized for 5 minutes.

STATEMENT OF WILLIAM BANNER

Dr. BANNER. Chairman Burgess, Ranking Member Green, and members of the subcommittee thank you for the opportunity to testify in support of the reauthorization of the National Poison Center program entitled, Poison Center Network Enhancement Act of 2018. This legislation was first enacted into law in 2000 and has been reauthorized three times. The measure before the subcommittee today would reauthorize the poison center program through fiscal year 2024.

My name is Dr. Bill Banner and I currently serve as the President of the American Association of Poison Control Centers. I am also the medical director of the Oklahoma Center for Poison and Drug Information. For over 30 years, I have been privileged to care for critically ill children, currently practice in the pediatric intensive care unit at Baptist INTEGRIS Medical Center in Oklahoma City. I also happen to be downsizing to a home in Congressman Mullin's district.

The Nation's 55 poison control centers operate 24/7/365 to cover all U.S. States and territories and receive three million calls annually including about 70,000 calls a year for exposures to opioids. Nearly one quarter of our calls come from emergency rooms and urgent care facilities. Calls are answered by highly trained medical professionals with 24-hour oversight from physicians who are board certified medical and clinical toxicologists, many of whom are trained in addiction medicine. We handle calls related to over 430,000 products and substances and their related toxicities.

Poison control centers are on the front lines of the opioid epidemic handling approximately a half million cases of opioid misuse and abuse since 2011. That is an average of 192 per day, every day. We assist first responders and hospital personnel.

[Slide shown.]

Dr. BANNER. As you can see from the slide, the percent of opioid exposure calls from healthcare facilities to poison centers are on the rise and we believe this will continue in 2018. We deliver countless hours of education on topics like identifying emerging drugs of abuse and the safe storage and disposal of prescription opioids. Through national surveillance activities, poison centers have identified trends involving fentanyl and other opioid analogue penetration into communities which is then shared with Federal, State, and local enforcement.

Centers also educate on the proper use of naloxone. With the rise of heroin mixed with the more potent fentanyl, the administration of naloxone has become far more complex and dangerous for emergency responders to administer. Centers also contribute to medical education on pain management, prescribing, and addiction treatment. Consultation with a poison control center can also significantly decrease the patient's length of stay in a hospital and decrease hospital costs. In fact, poison control centers save more than $1.8 billion annually including $382 million in Medicaid and $307 in Medicare per year.

Poison center data can often be utilized to identify new and emerging drugs of abuse faster than virtually any other resource. For example, this past summer, the Georgia Poison Control Center, which serves Subcommittee Carter's district, was the first public health entity to detect and respond to a novel opioid outbreak. Yellow pills stamped with Percocet that in fact contained a mixture of two synthetic fentanyl analogues that could have remained undetected indefinitely and racked up untold fatalities but for the work of the Georgia center.

This unique capability exists at every poison center in the country. Centers are also a critical resource for emergency preparedness and response. For example, centers have served in response to Zika, Ebola, synthetic cannabinoids, e-cigarettes, H1N1, marijuana abuse and misuse, carbon monoxide, toxic exposures following national disasters, and even the social phenomenon, the so-called Tide Pod Challenge.

Additionally, each center has an educator working to increase public awareness on the dangers of poisoning and opioid misuse. In fact, this week is National Poison Prevention Week. Examples of education outreach surrounding the opioid crisis include presentations to parent groups regarding medicine literacy and substance misuse prevention as well as participation in local community events.

In summary, poison control centers are a unique combination of clinical care, cost effectiveness, public health surveillance, and interaction with those on the front lines of the opioid crisis from first responders to law enforcement and everyone in between.

I want to thank Representatives Brooks, Engel, Barton, and DeGette for their continued support and bipartisan introduction of this critical legislation. It is a proven, highly efficient network most deserving of full congressional support and reauthorization. I am happy to answer any questions you may have. Thank you again for this opportunity.

[The prepared statement of Dr. Banner follows:]

STATEMENT OF:

DR. WILLIAM BANNER, MD, PHD
Medical Director of the Oklahoma Center for Poison & Drug Information
Board President of the American Association of Poison Control Centers

REGARDING THE REAUTHORIZATION OF THE POISON CENTER NETWORK ACT

BEFORE THE HOUSE ENERGY AND COMMERCE SUBCOMMITTEE ON HEALTH

FOR A HEARING ENTITLED: COMBATING THE OPIOID CRISIS: PREVENTION AND PUBLIC HEALTH SOLUTIONS

MARCH 22, 2018

SUMMARY

My testimony is in support of the reauthorization of the national poison center program entitled the "Poison Center Network Enhancement Act of 2018."

The nation's 55 poison control centers, operating 24/7/365, receive approximately 3 million calls annually—nearly one-quarter of which originate from a health care facility. The Poison Center Program is a highly successful, true public-private, federal-state-local partnership that provides a free service and reduces unnecessary hospital visits, length of hospitalizations and health care costs in our country by more than $1.8 billion annually. The Poison Center Program is legislatively mandated to fund poison centers (covering about 15% of their expenses), establish and maintain a single, national toll-free number (800) 222-1222, and to implement a nationwide campaign to educate the public and health care providers about poison prevention. The legislation before the Subcommittee today would reauthorize the Poison Center Program for an additional five years, through FY 2024.

Poison control centers are already on the frontlines of the opioid epidemic, handling approximately 500,000 cases of opioid misuse and abuse since 2011—approximately 192 per day, every day. In addition, centers assist first responders and hospital personnel and deliver countless hours of education, e.g., identifying new and emerging drugs of abuse and the safe storage and disposal of prescription opioids. Through national surveillance activities, poison centers have identified trends in evolving fentanyl and other opioid analogue penetration into communities which is then shared with federal, state, and local law enforcement. Poison control centers are also a critical resource for public health threats and emergencies. In addition, multiple federal agencies use poison control center data. It can be used to assist in identifying real time hot spots with increases in opioid misuse and abuse calls to poison control centers.

FULL STATEMENT

Chairman Burgess, Ranking Member Green, and Members of the Subcommittee, thank you for the opportunity to testify today in support of the reauthorization of the national poison center program entitled the "Poison Center Network Enhancement Act of 2018." My name is Dr. William Banner and I currently serve as the President of the American Association of Poison Control Centers ("AAPCC"). I am also the Medical Director of the Oklahoma Center for Poison and Drug Information and Attending Physician, Pediatric ICU at Baptist Integris Medical Center in Oklahoma City. I am a Diplomate of both the American Board of Pediatrics (Critical Care) and the American Board of Medical Toxicology, have had eleven university faculty appointments, and have the honor of being the only person to ever serve as the Board President of AAPCC, the American Academy of Clinical Toxicology, and the American College of Medical Toxicology.

AAPCC is a non-profit organization that supports the nation's 55 poison control and drug information centers in their efforts to prevent and treat poison exposures, including opioids misuse and abuse. Poison control centers across the U.S. receive approximately 3 million calls annually that cover numerous substances, including prescription and over-the-counter medications, illegal drugs of abuse, cleaning products, pesticides, personal care products, cosmetics, tobacco and nicotine products, painkillers, stimulants, food, plants, dietary and herbal supplements, and animal bites and stings. These calls come from a wide variety of individuals, including the public, health care providers, 911 operators, schools, health departments, law enforcement, and other first responders. In fact, nearly one-quarter of our calls last year originated from a health care facility, which includes emergency rooms as well as urgent care facilities. Poison centers operate 24 hours a day, 7 days a week, 365 days a year and are accessed through a federally funded nationwide toll free number: (800) 222-1222. When someone calls (800) 222-1222, the calls are answered by

highly trained Specialists in Poison Information (primarily pharmacists and nurses), who diagnose, triage, and offer treatment recommendations to callers with 24-hour oversight from physicians who are Board Certified Medical and Clinical Toxicologists. Many of our Medical Directors are also trained in addiction medicine. We answer calls from every state and territory in our nation and provide free access to health care services. In addition to providing these medical services, each center has an educator on staff working to increase public awareness on the dangers of poisonings and opioid misuse.

The national poison center network legislation first passed Congress in 2000 and has been reauthorized three times, most recently in January of 2014 (Public Law 113-77). The Poison Center Program is a highly successful, true public-private, federal-state-local partnership that provides a free service to all who call and reduces unnecessary hospital visits, hospitalizations and health care costs in our country by more than $1.8 billion annually as reported by HRSA in its FY 2018 appropriations justification to Congress.[1] We greatly appreciate the strong, bi-partisan support of this subcommittee and the House since 2000.

The Poison Center Program is legislatively mandated to fund poison centers; establish and maintain a single, national toll-free number (800) 222-1222 to ensure universal access to poison center services and connect callers to the poison center servicing their area; and implement a nationwide media campaign to educate the public and health care providers about poison prevention, poison center services, and the 800 number.

The legislation before the Subcommittee today, the Poison Center Network Enhancement Act of 2018, would reauthorize the Poison Center Program for an additional five years, through

[1] Value of the Poison Center System: Lewin Group Report for the American Association of Poison Control Centers. 2012.

FY 2024. The 55 poison centers throughout the country, including the centers that serve your constituents, receive approximately 15 percent of their funding through this program. This federal support is vital to the existence of the national poison center system. In addition, this bill clarifies that poison centers can be called upon to assist with public health emergencies, responses, and preparedness; requests that enhanced communications capabilities like texting be established; and requests that the FCC work with HHS to ensure that calls to our 1-800 number are properly routed. We provide immediate assistance to callers who often need emergency medical aid and the time squandered trying to figure out the location of a caller can mean the difference between life and death. Unlike 911, telecommunications service providers do not offer accurate caller location information for our wireless callers as our call routing is based on area codes, not the caller's actual location. This reauthorization bill directs HHS to implement call routing based on the caller's actual location. Lives will be saved as a result. The legislation also extends our nationwide public awareness campaign with HHS to promote the use of poison centers and reauthorizes the use of the national toll-free number. I want to thank original sponsors of the bill, Representatives Susan Brooks and Eliot Engel, together with Representatives Joe Barton and Diana DeGette, for their support and bipartisan introduction of the Poison Center Network Enhancement Act of 2018.

According to the CDC National Center for Injury Prevention and Control, poisoning is the leading cause of injury death in the United States.[2] While our poison control centers receive close to 9,000 calls per day, there is much more we would like to provide. Many people do not realize the scope and breadth of coverage our specialists are uniquely equipped to handle, with opioid exposure triage and information being an excellent example. Poison control services extend far

[2]https://www.cdc.gov/injury/images/lccharts/leading_causes_of_injury_deaths_unintentional_injury_2015_1050w760h.gif

beyond the toddler who drank a cleaner found under the sink; rather the poison control network is made up of sophisticated and specially-trained medical professionals who handle calls related to over 430,000 products and substances and their related toxicities.

Poison control centers are already on the frontlines of the opioid epidemic, handling approximately 500,000 cases of opioid misuse and abuse since 2011—approximately 192 per day, every day. In addition to the daily calls, our centers assist first responders as well as hospital personnel; deliver countless hours of educational outreach to community groups, mental health workers, educators, health care providers, law enforcement, and school personnel on a variety of topics including identifying new and emerging drugs of abuse as well as the safe storage and disposal of prescription opioids. Through their local and national surveillance activities, poison centers have identified trends in evolving fentanyl and other opioid analogue penetration into communities which is then shared with federal, state, and local law enforcement. Last year, the Drug Enforcement Administration (DEA) recognized our Pittsburgh Poison Center for their outstanding contribution in assisting narcotics investigations as well as their collaboration with law enforcement. Centers also educate on the proper use of naloxone. With the rise of heroin mixed with the more potent fentanyl, the administration of naloxone is far more complex and dangerous for emergency responders to administer. Our centers are already trained to assist in these increasingly difficult cases. Centers also contribute to medical education on pain management, prescribing, and addiction treatment as well as educate local pharmacy and medical students in their region. In fact, the Medical Director of the Pittsburgh Poison Center, Dr. Michael Lynch, was recently appointed to the HHS Pain Management Best Practices Inter-Agency Task Force, established in the Comprehensive Addiction and Recovery Act (CARA), by Secretary Azar.

In addition to providing lifesaving assistance, poison control centers save the federal government and the American taxpayers well over one billion dollars each year. Multiple studies demonstrate that accurate assessment and triage of poison exposures by poison control centers save money by reducing the severity of illness and eliminating or reducing unnecessary healthcare expenditures. Consultation with a poison control center can also significantly decrease the patient's length of stay in a hospital and decrease hospital costs.[3,4,5,6,7] Also, by treating nearly 70 percent of all of our cases at the exposure site and working directly with local hospital systems, poison control centers save Medicaid $382.4 million and Medicare $307.2 million per year in avoided medical utilization and reduced hospital length of stay.[8] Every dollar invested in the poison center system saves $13.39 in medical costs and lost productivity.[9]

Poison control centers are also a critical resource for emergency preparedness and response as well as for other public health threats and emergencies. For example, poison control centers were primary responders for the recent trend among teenagers to intentionally ingest liquid laundry packets. Centers also served as a point of contact for Zika, Ebola, synthetic cannabinoids, e-

[3] Vassilev ZP, Marcus SM. Impact of a poison control center on the length of hospital stay for patients with Poisoning. J. Toxicol. Environ. Health Part A. 2007; 70(2): 107-110.

[4] Zaloshnja, E.; Miller, T.R.; Jones, P.; Litovitz, T.; Coben, J.; Steiner, C.; Sheppard, M. (2006). The potential impact of poison control centers on rural hospitalization rates for poisonings. Pediatrics. 118(5), 2094-2100.

[5] Healthcare Cost and Utilization Project [HCUP] (2007). 2005 National Inpatient Sample. Rockville, MD: Agency for Healthcare Research and Quality, Department of Health and Human Services.

[6] Zaloshnja, E.; Miller, T.R.; Jones, P.; Litovitz, T.; Coben, J.; Steiner, C.; Sheppard, M. The impact of poison control centers on poisoning-related visits to emergency departments, U.S. 2003. Am. J. Emerg. Med. 2008.

[7] L. S. Friedman, A. Krajewski, E. Vannoy, A. Allegretti & M. Wahl (2014) The association between U.S. Poison Center assistance and length of stay and hospital charges, Clinical Toxicology, 52:3, 198-206.

[8] Value of the Poison Center System: Lewin Group Report for the American Association of Poison Control Centers. 2012.

[9] Id.

cigarettes and liquid nicotine, H1N1, legal (and illegal) marijuana abuse and misuse, carbon monoxide, and other toxic exposures in multiple states following natural disasters.

In addition to providing the public and health care providers with treatment advice on poisonings, another critical function of poison control centers is the collection of exposure and disease surveillance data. Multiple federal agencies, including the Centers for Disease Control, U.S. Food and Drug Administration, U.S. Drug Enforcement Administration, Consumer Product Safety Commission, Environmental Protection Agency, and Substance Abuse and Mental Health Services Administration, use poison control center data.

There is an ongoing need to obtain reliable data on the current opioid crisis. AAPCC is uniquely prepared to address this critical need. AAPCC has a robust database up and running in all 50 states and our territories, the National Poison Data System (NPDS). All 55 poison control centers upload data to NPDS every 8 minutes so this provides a real-time look at poison conditions nationwide. Our data can assist in identifying real time hot spots with increases in opioid misuse and abuse calls to poison control centers through surveillance. For multiple reasons, including NPDS analysis algorithms, poison control centers can often identify new and emerging drugs of abuse faster than virtually any other resource.

For example, this past summer the Georgia Poison Control Center, which serves Subcommittee member Congressman Buddy Carter's district, was the first public health entity to detect and respond to a deadly novel opioid outbreak (yellow pills stamped with "Percocet" that in fact contained a mixture of two synthetic fentanyl analogues) that could have remained undetected indefinitely and racked up untold fatalities. Data collected in real-time from the poison control centers are also an important source of information for federal agencies for the detection, monitoring of, and response to public health and environmental emergencies involving toxic

exposures and pandemics, as well as contamination of the air, water, pharmaceutical, or food supply.

Another example is that in 2016, the FDA cited poison control center data in issuing a final rule deeming tobacco products such as gels, water pipe tobacco, cigars, pipe tobacco, and e-products including e-cigarettes and vaping pens to be subject to inclusion under the Family Smoking Prevention and Tobacco Control Act of 2009.

Additionally, as I briefly mentioned above, all of our poison control centers provide poison prevention, awareness, and educational programming. Each poison control center is responsible for assessing the needs of its service area and prioritizing multifaceted programs for the populations and topics of greatest need. This is accomplished using a variety of strategies, including direct outreach, collaborative partnerships, and traditional and social media campaigns. Examples of education outreach surrounding the opioid crisis includes presentations to parent groups regarding medicine literacy and substance misuse prevention, participation in local community events, such as health fairs and community resource expos, the promotion of medicine disposal locations and drug take back days, disseminating medicine literacy resources to teachers and school nurses, and participation in community partnerships aimed at preventing youth substance abuse.

As tens of millions of American families are well aware, the nation's network of poison control centers is critically important and saves countless lives from unnecessary poisoning deaths and injuries. As a direct result of this federal-state-local-private sector partnership, health care in the United States is also delivered more effectively and efficiently to urban and rural areas alike, resulting in billions in annual health care cost savings to all.

Thank you again for this opportunity to highlight the value and importance of the national poison center program. I also want to again thank Representatives Brooks, Engel, Barton and DeGette for their hard work and bipartisan sponsorship of our most recent reauthorization efforts, the Poison Center Network Enhancement Act of 2018. We strongly support this legislation and will continue to work with the Committee and our sponsors on its passage.

Mr. BURGESS. Thank you Dr. Banner.

The vote on the floor has been called. But, Dr. Kilkenny, let us hear from you and then we will recess until after votes. So you are recognized for 5 minutes.

STATEMENT OF MICHAEL KILKENNY

Dr. KILKENNY. Chairman Burgess, Ranking Member Green, and members of the subcommittee thank you for inviting me today to testify on behalf of local health departments across the country that are facing unprecedented threats in the form of opioid-related death and disease.

My name is Michael Kilkenny. I am the Physician Director of the Cabell-Huntington Health Department in Huntington, West Virginia. I am representing health departments today as a member of the National Association of County and City Health Officials, NACCHO. More than a hundred Americans die each day from overdose with a staggering economic toll impacting the workforce of this generation and threatening generations to come.

My State has Nation leading rates of overdose death, Hepatitis B, Hepatitis C, and neonatal abstinence syndrome. My county along with 28 other counties in my State and 220 counties across the Nation face the real threat of catastrophic HIV outbreaks. These challenges, however, create remarkable opportunities for us to save lives and prevent disease.

In 2015, Huntington leaders implemented a comprehensive opioid response plan that is changing those statistics at home. With help from CDC we started the first sanctioned harm reduction program in West Virginia. We trained and supplied all our law enforcement agencies with naloxone. Cabell County community members and first responders reversed more than 2,500 overdoses last year, saving countless lives and a new Quick Response Team is linking overdose survivors to treatment. Without Federal support we would not have been so successful.

Regarding infectious disease, the opportunity to prevent is now. In my county we have been able to decrease new Hepatitis C cases by 60 percent, using harm reduction strategies and training from CDC. And CDC assistance in surveillance has allowed us to identify and implement specific strategic measures to prevent an HIV outbreak. The Eliminating Opioid-Related Infectious Diseases Act of 2018 authored by Representative Leonard Lance of this committee would provide an additional $40 million to CDC, money needed for Hepatitis C and HIV surveillance activities that help local health departments stop outbreaks before they occur, especially infections associated with injection drug use.

On behalf of NACCHO I would like to suggest the bill be expanded to include surveillance of Hepatitis B. Opioid overdose from prescription and illicit drugs require special surveillance and rapid intervention to address emerging drug threats.

Fentanyl, a particularly deadly opioid due to its potency, struck my city and other parts of our Nation especially hard in 2016. It remains the drug most frequently found in overdose autopsies from my county. Any street drug product might contain fentanyl, and neither users, police officers nor public health officers know if it is there or not. A bill to improve fentanyl testing and surveillance au-

thored by Representative Ann Kuster addresses this threat with assistance to public health laboratories in detecting fentanyl and its many analogues.

NACCHO recommends that in addition to agencies named in this bill, CDC should be included in these efforts. I also support the pilot program authorized in this bill which would allow point-of-use testing that could save lives and modify drug use behavior. Local health departments like mine are working 24/7 to save lives and reduce the risk of opioid overdose and the risk of life-threatening infections.

In closing, I hope that Congress will make an increased investment in funding for CDC and other public health agencies engaged in this fight. We have seized our opportunity in Huntington and we are succeeding. NACCHO represents nearly 3,000 other local health departments, big and small, ready to fight this opioid epidemic and we need your ongoing help. Thank you.

[The prepared statement of Dr. Kilkenny follows:]

NACCHO
National Association of County & City Health Officials
The National Connection for Local Public Health

Statement for the Record
Submitted to U.S. House of Representatives
Energy and Commerce Committee, Health Subcommittee
Combating the Opioid Crisis: Prevention and Public Health Solutions
March 22, 2018
By Michael E. Kilkenny, MD, MS
Physician Director, Cabell-Huntington Health Department
Huntington, WV

I would like to thank the Energy and Commerce Health Subcommittee for inviting me here today to testify on behalf of local health departments across the country that have seen an unprecedented rise in opioid related overdoses and deaths. My name is Dr. Michael Kilkenny and I am the Physician Director for the Cabell-Huntington Health Department in West Virginia. I am here today representing local health departments as a member of NACCHO, the National Association of County and City Health Officials.

Cabell County is currently experiencing the highest overdose rates in West Virginia and one of the highest overdose rates in the country, however, this epidemic is hardly limited to our area. Every day more than 100 American lives are lost due to an opioid overdose. In addition to the cost in lives and human suffering, the White House Economic Council has put a price tag of $504 billion on the economic burden of this crisis. This epidemic is dramatically impacting the next generation of West Virginia workforce and its trajectory will impact our residents for many years and generations to come.

My jurisdiction of Cabell County and the City of Huntington, West Virginia are particularly hard hit by the opioid epidemic and all its related death and disease. Besides

leading the state that leads the nation in overdose death, we also have nation leading rates of Hepatitis B, Hepatitis C, and Neonatal Abstinence Syndrome, forming for us an epidemic of epidemics. Recognizing the rapid rise of these rates in 2015, and with few resources, Huntington leaders put in place a comprehensive opioid response plan. With remarkable collaboration of nearly all community agencies and the support of the Centers for Disease Control and Prevention (CDC) and the West Virginia Bureau for Public Health, we were able to start the first officially sanctioned harm reduction program in West Virginia, and today, there are fifteen such programs, most in local health departments. We have supplied naloxone and training on its administration to all law enforcement agencies operating in the county. In addition, we operate a community naloxone distribution program which, along with Cabell County Emergency Medical Services, reversed more than 2,500 overdoses last year, saving countless lives. A Quick Response Team is contacting overdose survivors to offer support, referral, and transportation to recovery.

Without resources from CDC and other federal sources, our response would not have succeeded. In order to meet surveillance and other prevention needs, CDC must have adequate funding to ensure local health departments are equipped to contain outbreaks and monitor data while still serving other aspects of their community's health.

A sometimes overlooked aspect of the epidemic is the rise in blood-borne infections associated with injection drug use. Historically, substantial progress has been made in reducing HIV infections among injection drug users, but increases in injection drug use stemming from the opioid epidemic present a new set of challenges, particularly in rural and suburban communities. A recent CDC study also shows that between 2004 and 2014, admissions to drug

treatment programs for patients who inject opioids increased by 93%, while acute hepatitis C virus (HCV) infections rose in parallel by 133%. The sharpest increases in new HCV cases were among 18- to 29-year olds - a staggering 400% rise over a ten-year period. This problem can only be solved by support for local efforts to address both opioid misuse and overdose and associated infectious diseases. This challenge was experienced in Scott County, Indiana in 2015, when this rural community experienced an HIV outbreak resulting in over 220 newly diagnosed HIV cases, of which over 90% were also infected with hepatitis C. As we speak, southern West Virginia and northern Kentucky are also seeing increases in new cases of HIV among people who inject drugs.

CDC has identified 220 counties at-risk for an HIV outbreak similar to the 2014-15 outbreak in Indiana. Twenty-eight of 55 West Virginia counties are on that list, including Cabell County, which is just 250 miles upriver from the Indiana outbreak. Twenty-six states with large rural populations, besides West Virginia, had more than one county at risk for an outbreak.

Offering disease testing, linkage to care, peer counseling services, direct referral to recovery, immunizations, contraceptive services, education, naloxone access, and sterile syringe access, the Cabell-Huntington Harm Reduction Program is a comprehensive resource for injection drug users and persons suffering from substance use disorder. With these CDC recommended services available in an agency certified to state standards, acute Hepatitis C declined 60% in 2017, and the portion of acute Hepatitis B cases associated with injection drug use also declined. While there has not been an outbreak of HIV in Cabell County, investigation supported by the West Virginia Bureau for Public Health and CDC, we have been able to link

surveillance to disease tracking to specific local intervention capable of strategic action to reduce identified outbreak risks.

The proposed bill "Eliminating Opioid-Related Infectious Diseases Act of 2018" authored by Representative Leonard Lance (R-NJ), a member of this committee, is a necessary step in reducing the rate of infectious disease outbreaks and would provide CDC with an additional $40 million a year for surveillance activities, helping local health departments to prevent an outbreak before it occurs.

Representative Lance's bill would help to decrease the toll of infectious disease by encouraging robust surveillance of infections associated with injection drug use. It would also support health professionals on the front lines of infectious disease outbreaks by providing education and training in the detection and control of infections. On behalf of NACCHO, I would like to suggest that the bill be expanded to include surveillance of Hepatitis B (HBV) as well as C and HIV. A CDC surveillance program that includes HIV, Hepatitis B and C would help identify where new incidences of infection are occurring fastest, and accordingly target areas to help reduce the greatest burden of infection and support prevention programs to include vaccination against HBV, which is approximately 100 times more infectious than HIV.

Another challenge in my community is the rise in the use of powerful synthetic opioids such as fentanyl and carfentanil, which has exacerbated the epidemic because of the potency of these drugs. Small amounts of fentanyl can immediately send a user into an overdose, and without an overdose reversal drug such as naloxone, that person may die. People at highest risk of a fatal overdose are those who unknowingly take fentanyl that may be unknowingly present in another drug, including heroin. Local health departments are tasked with monitoring the

health of communities through surveillance systems and using data to alert policymakers and inform their programs.

Prescription drug and illicit overdose, including fatalities, must be surveilled in order to monitor opioid use trends and examination of linkages with prescription and illicit drug abuse. A bill authored by Representative Ann Kuster (D-NH), another member of this committee, recognizes this threat and would assist public health laboratories to their efforts to detect fentanyl and other synthetic opioids. Fentanyl testing may prevent overdose deaths in heroin users that are unaware a supply is laced with fentanyl. In addition to involvement from NACCHO recommends in addition to the agencies named in the bill, CDC should be included in these efforts. In addition, I support the pilot program authorized in this bill which would allow point-of-use testing that could save lives. Staying ahead of the supply chain will allow for early detection and prevent large overdose outbreaks.

Local health departments like mine are working 24-7 to save lives and address both the risk of opioid overdose and the risk of infections, and ultimately the burden of injection drug use. Both of these bills will provide support for activities that would help local health departments to prevent infections and overdoses, and allow for priority to high-risk populations.

In closing, I want to highlight the need for Congress to make an increased investment in funding for CDC and other health agencies involved in the opioid crisis to tackle the threats of infectious disease and overdose and death. High risk communities like Cabel-Huntington often lack the public health and healthcare infrastructure and services to comprehensively address the epidemic and need federal support to continue doing this work.

Thank you for the opportunity to speak to you today and to share my perspective from the front line of the opioid epidemic.

Mr. BURGESS. Thank you, Dr. Kilkenny.

Again, the chair observes we do have a vote on the floor. So we are going to take a recess so members can go and be recorded on a procedural vote on the floor of the House and we will reconvene immediately after votes where we will start the member questions. So thank you all for your testimony. We stand in recess.

[Whereupon, at 10:30 a.m., the subcommittee recessed, to reconvene at 11:12 a.m., the same day.]

Mr. BURGESS. I call the subcommittee back to order. Again I want to thank our witnesses for their testimony. We are going to move into the question portion of the hearing, but I do want to recognize the gentleman from Texas for his unanimous consent request.

Mr. GREEN. Thank you, Mr. Chairman. I request unanimous consent to enter into the record a statement from Representative Ann Kuster who actually sat through some of our hearing yesterday in support of her draft under consideration to improve fentanyl surveillance and testing as well as bills featured as part of the Bipartisan Heroin Task Force legislative agenda for 2018. I ask unanimous consent the statement will go in the record.

Mr. BURGESS. Without objection, so ordered.

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

Mr. BURGESS. And the chair will recognize himself 5 minutes for questions.

Dr. Banner, in your testimony you referenced the difficulty of treating fentanyl with naloxone. Could you elaborate on that just a little bit?

Dr. BANNER. That is a pharmacologic and toxicologic problem. As you, I am sure, recognize fentanyl's potency means that naloxone may at times be required to give increased doses to reverse it because it is binding to the mu receptors. And I know I am not talking to most of the people in the room, but——

Mr. BURGESS. Just talk to me. It is OK.

Dr. BANNER. The mu receptor affinities are so high——

Mr. BURGESS. That is why I am sitting in this chair.

[Laughter.]

Dr. BANNER [continuing]. With that affinity it takes a lot of naloxone sometimes to reverse them. Plus, if they are chronically using fentanyl and they get their body burden increases then the apparent duration of action of fentanyl can exceed the duration of naloxone and you may have to give a repetitive dose. And the third issue is that there are pretty good case reports where reversing fentanyl produces such a surge in adrenalin that you actually can get noncardiogenic pulmonary edema, or a flooding of the lungs with fluid, and that of course can convert a life-threatening situation into a life-threatening situation. So, we feel like that has upped the ante quite a bit.

Heroin reverses pretty easily and it has, the duration of action of heroin itself is 7 to 8 minutes so it is a rapid high. If you get in trouble you reverse it and then the naloxone usually covers it. But drugs like methadone when they are involved or some of these fentanyl derivatives can really prolong the toxicity and therefore the need for repetitive doses and it makes it more complex.

Mr. BURGESS. All right, thank you. The way you are in your testimony that administration of naloxone is far more complex and dangerous for emergency responders to administer, I misinterpreted it. I thought for some reason it would be dangerous to the ER doc, but you are saying it is dangerous to the patient——

Dr. BANNER. Yes.

Mr. BURGESS [continuing]. During the administration episode. Very good. Thank you for clearing that up.

And, Dr. Kilkenny, let me just ask you. We started this week in another subcommittee, the Oversight and Investigation Subcommittee, with the acting administrator of the Drug Enforcement Administration and focusing more on the enforcement side of this equation. And your State obviously came up for some discussion because of the delivery of pharmaceutical product to locations that seemed far in excess of the population that would be making itself available to that retail establishment, and I am trying to say that as carefully as I can.

But then in your testimony you talked about in 2016 fentanyl sort of bumped up. Were you aware in your communities that this problem of the excess delivery was occurring? Was that something that was novel when it was discovered? Just let us know what you saw on the ground as those years were unfolding.

Dr. KILKENNY. Because I live there and I have seen the pill mills operating and I knew when I was practicing how that worked, I was not surprised to know that there was an overabundance of supply to very small towns that were servicing certainly the vehicles parked in those parking lots had license plates from all over the country. So I was aware of that practice, but I wasn't aware of the staggering numbers until they came in later.

That distribution I think temporally occurred before the big switch to injection drug use that we saw using heroin. And there was always fentanyl around, but in 2016 something appeared to us to happen in the supply chain. And we saw——

Mr. BURGESS. Let me just interrupt you. The supply chain of fentanyl is not coming through the supply chain, right?

Dr. KILKENNY. We are talking about the illicit supply chain.

Mr. BURGESS. Illicit, OK.

Dr. KILKENNY. The illicit supply chain of fentanyl seemed to change really remarkably in the second half of 2016 and the entry of the fentanyl analogues really picked up then. That is when we started seeing a massive increase in overdoses and overdose death.

Mr. BURGESS. That seems to have been catalyzed by the initial excess distribution phenomenon that was happening in your neighborhoods.

Dr. KILKENNY. I certainly do not argue with that iatrogenic component that this started with prescription drugs.

Mr. BURGESS. And I guess our frustration when we talked to the DEA on Monday was it seems like there was a blinking red light on the dashboard, why didn't anybody check the engine, you know what I mean? I always lived in fear of the DEA when I was in practice. I thought they knew everything about me, every prescription that I wrote, every patient that I treated. Then it turns out on Monday we hear that they really weren't paying that much attention and it was startling information to me.

Dr. KILKENNY. Apparently not, but I don't think we as physicians were as red-flagged as we should have been while we were prescribing under the pain as the fifth vital sign rule.

Mr. BURGESS. Sure.

Let me recognize Mr. Green from Texas 5 minutes for questions. I have some additional questions that I may try to get to at the end. But, Mr. Green, you are recognized for 5 minutes.

Mr. GREEN. Thank you, Mr. Chairman, and I want to welcome our panel here today. I want to thank all our witnesses for joining us.

We agree that the opioid epidemic is a multisided problem and will require a multipart solution. As part of the solution it is essential that we expand access to treatment. We must also identify strategies that encourage individuals with substance use disorders to seek and remain in treatment. I am concerned that the proposed proposal to roll back protections under code federal regulations titled 42 Part 2, commonly known as Part 2, would do the opposite.

Dr. Martz, in your testimony you state that if patients with substance use disorders are afraid their treatment records will be used against them they will not enter treatment. Could you explain the important role of confidentiality plays for individuals with substance use disorders in retaining and entering treatment and working towards recovery?

Mr. MARTZ. Thank you. It plays a critical role. If you are working to decide whether or not I am going to enter treatment, whether or not I am going to deal with the issues that are most relevant in treatment that is a critical protection to have. We know that folks will not come to treatment if they are afraid of what the impacts will be.

So, for example, I worked with parole and probation for quite some time and there would be some question of, someone goes and they are having a holiday party, and they go and they show up and there is drinking there, not a surprise. But then they start to have cravings.

So the work of treatment has to do with having a safe space to be able to discuss these issues clearly and directly without, rather, having to say oh no, I didn't have any problems and nothing was going on here, so that for fear that I would disclose it to somebody else. You know, it is a role like, more like a priest/penitent relationship than just other roles.

Mr. GREEN. Why are the heightened protections provided under Part 2 critical to creating the safe environment for treatment for individuals with substance use disorder that you describe in your testimony?

Mr. MARTZ. It is critical for the safety. One of the key elements in terms of treatment is that there is a therapeutic alliance and sometimes it takes weeks or months to build a relationship. I have had clients that were with me for 6 months before they suddenly say all right, now I am going to tell you the truth about what is really behind this, so it takes time to build a relationship. It takes time to have that safety and anything that is going to damage that safety such as fear that this will be disclosed, it will impact that and prevent them from entering or staying in treatment or working on the critical elements within it.

Mr. GREEN. According to a letter submitted to the Committee from the Campaign to Protect Patient Privacy Rights, rolling back the Part 2 protections to the HIPAA standard will contribute to the existing level of discrimination and harm to people living with substance use disorder and will only result in more people who need substance use disorder treatment being discouraged and afraid to seek the health care they need during the nation's worst opioid crisis.

Dr. Martz, will you discuss how rolling back Part 2 protections to HIPAA standard harms efforts to create a safe treatment environment and potentially leads individuals with substance use disorder not to enter or remain in treatment?

Mr. MARTZ. Thank you. Many of our folks have dealt with trauma, for example, and so one of the things that is a really critical difference between HIPAA and 42 CFR is that with 42 CFR when I disclose to my clinician I know that it is private unless I sign and get information that it will be shared with somebody else. When I share with my clinician about the sexual trauma and assault that I faced previously that is a private conversation and before that gets shared with multiple other people without my knowledge, which is what the standard would be under HIPAA, that is a problem.

So when information comes back to me from some other clinician that gets the information from the clinical record rather than having that conversation with me directly when I am not ready to share it, it is a severe damage to the trust that is needed for a relationship for treatment.

Mr. GREEN. Thank you. I support strongly the efforts to expand access to treatment, encourage individuals to seek and remain in treatment. I am concerned the proposed changes to 42 CFR Part 2 misses the mark.

And in my last few seconds, in my earlier life I did probate work and in Houston, Texas the probate judges are also the mental health judges. And I was honored, I think, when the judge decided he wanted to appoint me to be on the mental health docket for about 3 weeks, and this is before HIPAA. It was in the '80s and we still had that protection, though I don't know if it was under state law or federal law at that time that even the lawyers we had to destroy all our information.

And believe me it would have been really difficult to get people in treatment if they knew that would be available to potential employers and that. Now, if there is a danger we all have a responsibility to that whether you are a medical professional or what. But just that average letting people know someone is under care, it really bothers me.

Thank you, Mr. Chairman. I know I have run out of time.

Mr. BURGESS. The gentleman yields back. The chair thanks the gentleman. The chair recognizes the gentleman from Kentucky, the vice chairman of the subcommittee, Mr. Guthrie, for 5 minutes.

Mr. GUTHRIE. Thank you, Mr. Chairman. I appreciate the opportunity to be here and all the witnesses being here. I am going to focus my questions to direct them to Mr. Bauer who is from back home. We have had several Kentucky witnesses over yesterday and today and have been fantastic witnesses, but only says that we

have a big issue in our State like surrounding States and then it is spreading. So that is why what we are doing here is so important to make sure that we move forward.

But I am going to focus on the Prescription Drug Monitoring Program. So when providers check their PDMPs or Prescription Drug Monitoring Program, to Mr. Bauer, what is the evidence that this actually changes their prescribing or dispensing behavior resulting in improved patient outcomes and lives saved?

Mr. BAUER. I thank you, Vice Chairman, for the question. Today with the PDMP programs one most impactful issue with the program is integration of that information into workflow. And we are finding that that really helps to enable efficient access to the PDMPs, so the PDMPs are checking. There are 40 States that have mandated use laws in place today which mandate the checking of the PDMP in one way, shape, or form.

So we have seen the use of the PDMPs having an impact on the overall volume of opioids prescribed. We think that is in conjunction with policy at a State level as well. From an outcomes perspective there are current studies that are underway, one of which is Appriss Health has a study underway to understand the actual outcome of checking the PDP on opioid death, the death curve. So that study is not completed yet. We are about 3 to 4 months into that study.

Mr. GUTHRIE. Thank you. And also you mentioned that some States are turning the PDMP into a substance use disorder platform. Can you elaborate on what that means and how it would help someone who might be at risk of addiction or substance misuse?

Mr. BAUER. Sure. When PDPs were first formed many years ago they were more of a diversionary tool that was used to understand drug diversion. The programs have since morphed into more of a public safety tool.

So, today, information in the form of data, prescription data, is sent to the prescriber or pharmacist for review. States are now moving past that what they call the phone book of data trying to understand within that information what is the issue with this patient or what is the risk that this patient represents from an overdose perspective. And we are moving that into more of a substance use disorder platform to provide the clinicians, the prescribers, and pharmacists more clinical information so they engage with their patient while that patient is right there in front of them versus trying to read through a phone book of data in the 20 or 30 seconds that they have.

So, adding additional datasets such as nonfatal overdose, providing for referral of treatment while they are in their PDMP, a peer-to-peer communication, et cetera, are all clinical tools that are designed to truly engage that patient before they go to an illicit drug event.

Mr. GUTHRIE. OK, thank you. And I have a final question for you. PDMPs are not only critical to prescribers for identifying beneficiaries that are high users, but also in avoiding potentially dangerous drug interactions. It is my understanding that for the most part PDMPs are not allowed to have data or are prevented from having data on patients receiving methadone. On the other hand, buprenorphine prescribed in an office space setting is typically

filled at a pharmacy which is then submitted to PDMPs. So why are methadone and buprenorphine treated unequally when it comes to PDMPs, and can we do anything to include this information but still protect patient privacy?

Mr. BAUER. Thank you for that question. What we find today from the PDMPs as far as collecting that data such as methadone or buprenorphine prescriptions, buprenorphine, for example, is a prescription that is actually prescribed and typically picked up at a retail pharmacy therefore reported to the PDMP. Methadone on the other hand is typically administered within a substance use, a clinic and therefore by law not reported to the PDMP.

So that is the difference as far as——

Mr. GUTHRIE. Well, could somebody get methadone at a methadone clinic and also have a prescription for buprenorphine, or are they interactive?

Mr. BAUER. The short answer is it is possible.

Mr. GUTHRIE. I guess just to the question because I am about out of time, I know the idea for the methadone is patient privacy. Can we address that?

Mr. BAUER. Yes. Obviously we want to take privacy into consideration from a PDMP perspective obtaining that methadone administration, administered methadone is critical to understanding the overall risk of that patient.

Mr. GUTHRIE. OK, thank you. And I have 5 seconds, I yield them all back.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back. The chair recognizes the gentlelady from California, Ms. Matsui, 5 minutes for your questions, please.

Ms. MATSUI. Thank you. Thank you, Mr. Chairman. And I want to thank the witnesses for being here today.

Dr. Martz, thank you for your testimony. I have been a champion of building greater education and awareness about HIPAA privacy regulations particularly as it applies to tricky mental health situations, because I recognize the necessary balance between patient privacy and access to information for purposes of quality treatment. I appreciated your nuanced understanding of the importance of confidentiality for patients suffering from a substance use disorder and the different ways a stigma plays into the situation.

I am also sympathetic to the caregivers and doctors who are trying to better serve patients and to stories of patients who are harmed because the provider didn't have the right information to make the right clinical decision. I am hopeful that working together we can find the appropriate path forward on this issue. From your perspective, how well do you think patients know their rights under HIPAA and specifically under 42 CFR Part 2 and the recent SAMHSA update?

Mr. MARTZ. Thank you for the question. Patients are pretty widely available and it is usually one of the very questions that will be asked, who is going to get this information? And even if they don't ask that up front, it is our responsibility as clinicians to immediately give them that information about what you are going to be sharing, what are the limits of confidentiality and what are the conditions under which is would be released or excluded.

One of the challenges with the multiple changes we have had in the last year now from SAMHSA is that every time it comes out of the change we have to identify the regulation, we have to update our forms, we have to retrain the field, and re-have that conversation with the client which is very damaging to the relationship that has been built.

Ms. MATSUI. Right. So the familiarity among the doctors and caregivers need to be updated. So do you think it would be meaningful for HHS to conduct more education and awareness?

Mr. MARTZ. Absolutely, across the field not only treating clinicians but also physicians and other allied professionals that are interacting so that we better coordinate the care. Very often, the problems that are found from confidentiality are really training issues rather than actual burdens.

Ms. MATSUI. Sure. Well, do you think there are certain situations or circumstances under which sharing a patient's substance use records would be beneficial to their coordinated care? So, for example, in the case of accountable care organizations that are specifically targeting comprehensive services for those with multiple conditions such as substance use disorder co-occurring with something like diabetes or depression?

Mr. MARTZ. Yes. And it is very common to coordinate care and it is actually an expectation of myself and all the clinicians that I have worked with that we are to coordinate substance use, mental health, medical conditions. The difference is that there is a protected element for them to discuss the private areas and it is a clinical issue to engage them to have that trust to open the relationship and dialogue with the other clinicians to maintain that constant communication.

Ms. MATSUI. OK. Well, thank you.

Dr. Strain, thank you for your testimony. As I mentioned previously, I am committed to advancing coordinated patient care without sacrificing patient privacy, especially around a sensitive and stigmatized disease. Recently, SAMHSA released some regulations that broadened rules about re-disclosure and 42 CFR Part 2. Do you think that it has been helpful to providers;. Alternatively, did it go far enough?

Dr. STRAIN. So I thank you for that question, Representative. I think that we haven't gone far enough. I think that we need to provide a mechanism whereby information can be more seamlessly shared between providers who are not in a substance abuse treatment program and those who are in a substance abuse treatment program. I think that at the end of the day, I am interested in seeing us do better in terms of coordinating care across those two foci, and the current barriers make that difficult.

Ms. MATSUI. Yes. So in your testimony you provided some very compelling examples particularly if a patient is incapacitated. For things like asking patients about history of substance use, what type of training do doctors currently receive about best practices?

Dr. STRAIN. So training by physicians is variable by medical school. There is not a national standard for training, a Federal standard, but there is increasing amounts of training in medical schools and by, for physicians in terms of substance abuse and edu-

cation and it is a critical part. It has become a critical part especially in the current climate.

Ms. MATSUI. I can see that we need more, probably, continuing education about this. Generally, if a patient is incapacitated or unconscious your testimony implies there is no way for a doctor to know if a patient has a history of a substance use disorder. Is that absolutely true? For example, can a doctor make inquiries of next of kin?

Dr. STRAIN. I am sorry?

Ms. MATSUI. Can the doctor make inquiries of next of kin?

Dr. STRAIN. Certainly the doctor can make inquiries of next of kin to attempt to determine that if they are available.

Mr. GUTHRIE [presiding]. Thanks. I know we are pushing up against votes for another round of votes——

Ms. MATSUI. OK, thank you.

Mr. GUTHRIE. Thank you. The gentlelady yields back. I now recognize the gentleman from Virginia, Mr. Griffith, 5 minutes for questions.

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

Over here, and I am going to continue, Dr. Strain.

Doctor, you were just talking about what the doctor can find out by asking the next of kin. And one of the issues that we dealt with, not opioid directly related but dealing with violent tendencies and violence that we were trying to deal with in CURES and in some other things, was trying to figure out how we keep privacy for individuals but at the same time have some family involvement where the family is actually involved in a person's life, because if they have a significant mental illness and maybe also a drug addiction on top of that it is sometimes very difficult for the family to get information because of the HIPAA laws.

So Dr. Martz raises good points, but how do we reach that balance where particularly if you are living in the home with parents or a sibling that they can have enough information to know whether, A, they are in danger, or B, how they can be of most assistance to their beloved family member? Any ideas for us?

Dr. STRAIN. Thanks. It is a critical question, Representative Griffith. And it really comes down to, I think, the provider-patient relationship and that judgment that occurs in that relationship in terms of where do I treat patients, and where do I go in terms of when I have information that I believe has reached a critical point where I need to bring in a family member and inform them that? And there can be instances where I may do that even if the patient is saying I don't want you to do that.

So obviously, for example, if there are issues of abuse of a child or a parent or things like that I may be compelled to do so, or if somebody is reporting that they are suicidal or homicidal. But at the end of the day, it does distill down to I think that relationship and the provider having determination of where do they need to go with the information that they are receiving. I think that trying to create a systematic answer to that may be challenging.

Mr. GRIFFITH. Well, we found it to be a challenge but we are still working on it, because obviously with the number of violent situations we have had in our country, these tragedies that have oc-

curred, we are trying to figure out what is both right for the patient and right for society as a whole.

Switching gears and continuing to talk about the opioid tragedies that are afflicting us, Dr. Kilkenny, you work in Huntington and Cabell County. Do you find that, because in O&I we had an earlier hearing this week on pill dumping and particularly into a couple of towns in West Virginia, do you find that those drugs coming into the small towns outside of your community—about 56 miles away was one of them, Kermit, and the reason I know that is because it is only about 53 miles from my district in western Virginia.

Do you find that that has a spillover with the patients that you are seeing that some of those folks are coming from those rural areas where all these drugs were dumped?

Dr. KILKENNY. I think the evidence in West Virginia indicates that the current injection drug use, the illicit trade was spawned by an overprescribing and then a more responsible set of prescribing.

Mr. GRIFFITH. So it would be reasonable to conclude that your testimony would also affect my district, which is about an equal distance although it takes longer to get through the mountains to get to mine from Kermit or from the other towns, that the problems would be very similar. It would be reasonable to make that conclusion, would it not?

Dr. KILKENNY. I think that Virginia, West Virginia, Kentucky, Tennessee, any of the Appalachian districts in those states are going to be affected the same as we are.

Mr. GRIFFITH. Yes. That is pretty much my district.

Mr. Bauer, thank you for being here as well and thank you for saying some nice things about our draft legislation on PDMPs. I was really pleased to see the graph that showed that just a few years ago there were only a couple of States, one of which was my State in Virginia in 2011, but that now we have more than 40 States and all of the States continuous to my district are now there, because at one point Martinsville had the highest per capita use of—and there is a formula that you would know, the morphine——

Mr. BAUER. Equivalents.

Mr. GRIFFITH [continuing]. Equivalents of any place in the country and North Carolina was not a part of it. So hopefully that will be of some help. Can you explain further what we need to do to get all the States on the same page so that we are able to compare apples to apples, because I understand in some of the PDMPs that there is a difference in the data. Can you give us a few seconds on that?

Mr. BAUER. Yes, I can. Thank you for that question. So today as you know there are 45 States that do share data securely and efficiently with each other. It is up to the States' purview as to what State they wish to share data with. Typically it is the surrounding States and then another concentric circle.

The States that are not sharing data today it is truly a policy issue. The example I mentioned in Florida, Florida just recently passed legislation that will enable them to share, effective July 1st of 2018, California is the same way. So these are certainly policy issues that are involved in not being able to share data right now.

Mr. GRIFFITH. And I am out of time so I have got to yield back, but I would love to know if we can get everybody on the same page. I appreciate it, thank you.

Mr. BURGESS. The gentleman yields back. The chair thanks the gentleman. The chair recognizes the gentleman from New Jersey, the ranking member of the full committee, Mr. Pallone, 5 minutes for your questions, please.

Mr. PALLONE. Thank you, Mr. Chairman. I have some questions of Dr. Martz. I would like to thank all the witnesses for joining us today. I stated in my opening statement yesterday that I was concerned that H.R. 3545, the Overdose Prevention and Patient Safety Act could dangerously erect a barrier to patients seeking and remaining in treatment and therefore harm our efforts to respond to the opioid crisis.

According to the Substance Abuse and Mental Health Services Administration, the disclosure of records of individuals' substance use disorders has the potential to lead to a host of negative consequences including loss of employment, loss of housing, loss of child custody, discrimination by medical professionals and insurers, arrests, prosecution, and even incarceration.

So, Dr. Martz, I am hoping you can help us better understand these consequences. The first question, I understand from your testimony that you have worked in a number of States in a range of settings and served a diverse mix of patients. Based on that experience, can you provide some context on the issues facing individuals with substance use disorder that make Part 2 heightened confidentiality protections important?

Mr. MARTZ. Thank you. Thank you. I think, and in response to your question I may have to respond with a brief note from the last listening session of SAMHSA, some notes that were submitted regarding 42 CFR from the folks that are affected here.

"Dear Administrator Hyde, I have a criminal record and attending recovery. I don't want my history to become a burden. I realize individuals have discussed good medical care for me will be compromised if all medical professionals cannot see my treatment records, but available to ones who must see them. I don't want to risk losing my family or my job or my housing due to someone knowing or finding out I have been treated with addiction. I don't want my past to jeopardize my future because I am doing the right thing. I am writing to ask privacy protections for patient records be maintained. I do not wish for this to be a lifelong burden. My privacy records are very important. I am soon applying for a job and I fear I will never have the chance to better myself in society otherwise. Thank you so much for even considering. We know we are but little value to society, but even if we were to become trash men one day it would be the best for us and for free men."

There are a stack of these letters coming from these individuals. I also worked in the Pathways to Pardons project in Pennsylvania where we worked with folks seeking clemency, and there were many folks who were seeking clemency because they couldn't get jobs, they couldn't become nurses, they couldn't get promoted. They had various challenges that they couldn't work with. So even many, many, many years later there is a lifelong stigma attached.

Mr. PALLONE. All right. Now a recent study published in the Journal of Addiction Medicine found that a significant portion of the study population of ED physicians at Johns Hopkins had low regard for patients with substance abuse. For example, 54 percent of survey responders indicated that they agreed that they, "prefer not to work with patients with substance use who have pain," and 54 percent agreed that patients like that irritate me.

So, Doctor, is this unique to the physicians in the survey or do individuals with substance use disorders sometimes face stigma and discrimination from medical providers?

Mr. MARTZ. Absolutely. There is an old term for, in the profession in some areas what is called a GOMER, Get Out Of My ER. There is just such an absolute disdain. And even in recent weeks and months as I mentioned, there were a couple quotes just out there from recent providers some of which I mentioned before, for example, "Jail, the best way to beat addiction."

"Why is this a problem? Opioids are eliminating the bad folks in our communities—smiley face."

"If they would stop reviving them there would be less usage."

The level of stigma and vitriol out there is widespread and which is what we are trying to protect our folks from, because some of the discrimination will be overt but some will be covert and use other reasons to say you are fired and we are not going to use you, but rather than saying oh, it is because you have a history of this.

Mr. PALLONE. And then my last question deals with the dramatic increase, the presence of substance use treatment records in electronic health records and health information exchanges a lot of these records will be increasingly vulnerable to cyber attacks and breaches. One of my Republican colleagues noted in reference to our committee inquiry to the healthcare cybersecurity that as technology becomes increasingly integrated with all levels of health care, cyber threats pose a challenge to the entire sector.

You want to just explain the impact of such risk? There was a recent Ponemon Institute survey that found that half of HIPAA organizations expose patient data at some point and improper disclosures on patients with substance use disorder. I know we are almost out of time so quickly if you could.

Mr. MARTZ. Absolutely. Cybersecurity has been a growing threat. We know, for example, in February 2015, an Anthem Blue Cross Blue Shield organization had 37.5 million records stolen. Russell Branzell, president and CEO of College of Healthcare Information Management, has said that health care is ground zero for cyber attacks. According to the Department of Health and Human Services, while all industries face this growing threat, the size and scope of the attacks on the healthcare industry have accelerated rapidly in the past few years. This is valuable information that can be bought and sold. And so cyber attacks are a serious risk and have been growing rapidly.

Mr. PALLONE. Thank you. Thank you, Mr. Chairman.

Mr. BURGESS. The gentleman yields back. The chair thanks the gentleman. The chair recognizes the gentleman from Indiana, Dr. Bucshon, 5 minutes for your questions, please.

Mr. BUCSHON. Thank you, Mr. Chairman. First of all, I just want to respond a little bit to this study about ER doctors. There are

people who come to the ER legitimately drug seeking trying to get legal ways to get drugs. This is nothing to people who are drug addicted. They are treated just like everybody else. But if you have ever spent any time in an emergency room, and I have because I was a heart surgeon, there are legitimately large numbers of people trying to get legal prescriptions or legal narcotics through coming to the emergency room.

And it is honestly insulting for studies to try to show that the ER physicians are in some way not treating patients in an ethical and moral way. It is just not right. And let me just also comment on what it is like to be a physician—and my wife is an anesthesiologist by the way also—and have patients taking unknown medications or have an unknown medication history. This is a really serious problem. If you as a surgeon you don't know if they are on opioids, benzodiazepines, and in many cases certain dietary supplements.

I have had myself, personally, two patients who almost bled to death after heart surgery because they were taking supplements for vascular health. And my wife tells me every day, she is still in practice, she still has patients that have unexplained difficulty in being anesthetized with narcotic or benzodiazepine-based anesthetic agents, and looking at the medical record there should be no reason for that and the reason is is because it is undisclosed.

So, look, there is a balance here and Dr. Martz makes some great points. But I just wanted to point that out that it is a difficult problem for medical providers and we need to find a balance.

Dr. Strain, I know there are concerns that if we amended the statute to allow substance use disorder treatment information to be disclosed it could be used in criminal proceedings, cause someone to lose their housing, employment, or even child custody. Does the amendment to H.R. 3545 include safeguards to prevent this from happening?

Dr. STRAIN. Thank you, thank you for those comments and thank you for the question. Absolutely, my understanding is that there are safeguards within the Mullin amendment that does prevent those sorts of concerns.

Mr. BUCSHON. Yes. And many people with substance abuse disorder also struggle with mental illness or have comorbid conditions such as diabetes or hypertension. How does 42 CFR Part 2 prevent quality care coordination?

Dr. STRAIN. So it is a great question. And the dilemma as you actually illustrated earlier is that the provider may be seeing a patient who is in substance abuse treatment and not know about that and then can't coordinate their care in terms of infectious illnesses or other medical problems that have arisen related to their substance abuse. And the patient may not be telling them about that or may not be fully disclosing, for example, what medications they are on through their substance abuse treatment program.

We want to be holistic about treating people. That is at the end of day that is what we should be striving to do and right now we are segmenting out this part.

Mr. BUCSHON. Yes. I also want to point out that, again as a physician, family members may not know the medical history of their loved one and I think Congressman Griffith was talking about that.

And we tried to, in a mental health bill a year or two ago we tried to change HIPAA a little bit to allow parents who have adult children who have severe mental illness to have some minimal access and we couldn't get that done because of the privacy issues. In fact, in your State I think had a State senator whose son had an episode and tried to kill him and then subsequently killed himself and so the system failed both of them, really.

But if you look at, for example, the directed donor program, say you are going to have your hip or your knee done and you want family members to donate blood and put it in the blood bank for you, there is a pretty substantial instance of that blood being rejected by the blood bank because of a blood-borne problem, usually hepatitis history, and family members don't necessarily know that their family member has had that history and they don't want that disclosed and I understand that.

I think we should look back to what happened in the '80s and the '90s with HIV and the critical issue we had there with privacy. And we have worked through that I think and maybe this is where we are going with drug addiction also. We clearly don't want people discriminated against for any reason, but we also want to be able to have holistic medical care that includes knowledge of a patient's addiction history. I yield back.

Mr. CARTER [presiding]. The gentleman yields. The chair recognizes the gentlelady from California, Representative Eshoo.

Ms. ESHOO. Thank you very much, Mr. Chairman, and thank you to all of the witnesses. It is good to have you here on a subject that is really wrecking communities and wrecking people's lives and there is enormous loss of life surrounding this issue. Over the last at least month or 5 weeks, I have had five friends and my sister, so six individuals that have shared with me the following:

They had hip replacement surgery. And I am directing this to Dr. Strain. They were sent home with a bottle of 100 tablets of either Oxycontin or Percocet. Now a hundred tablets of either is, I think, over the top. I am not a physician but that is a lot of pills. Why is that the case? Why is so much being prescribed?

Dr. STRAIN. So——

Ms. ESHOO. I would think, excuse me, that if you are not an addict you may have a new hip, but by the time you are finished with your recovery you will be an addict. So is there a kickback on these drugs? Can you enlighten us as to why so much is being prescribed? And this is the second most common surgery in the country. Number one is cataract surgery; number two, hip surgery.

Dr. STRAIN. So certainly if we were having this conversation even 5 years ago I would have said the reason that there is large numbers of pain pills being prescribed is because the medical profession has had it drummed into its head that we need to be more aggressive about treating pain. And that is something that goes back 15 years and 20 years.

Ms. ESHOO. Well, I think it is important to stay ahead of pain, but a hundred?

Dr. STRAIN. I agree. I think that that——

Ms. ESHOO. And these were all, they were different hospitals that they were discharged from.

Dr. STRAIN. The current CDC guidelines do not recommend doing that. The current thinking by other professional organizations is not to be prescribing those sorts of amounts of pain medications. I don't know the particulars of these situations, but it is alarming to hear. And I think that the medical profession hopefully is——

Ms. ESHOO. But what would you suggest? What would you prescribe?

Dr. STRAIN. Well, first of all——

Ms. ESHOO. I am not asking you what prescription you would write and how many pills you would prescribe, I am speaking in terms of policy.

Dr. STRAIN. In terms of policy I would say that there should be a much lower of medicines prescribed whether it is oxycodone or whatever. I would follow things like the CDC guidelines for a week, reevaluating the patient, using non-opioid medications for the treatment of pain. I should parenthetically note I am not a pain treatment doctor. I am a psychiatrist by training. But I think a lot about this because of this issue and my recommendations would be along those lines. Did I answer your question?

Ms. ESHOO. Well, does CDC have guidelines now on this?

Dr. STRAIN. Yes.

Ms. ESHOO. They do.

Dr. STRAIN. Yes. They issued guidelines about a year ago.

Ms. ESHOO. It seems to me they are not being, they either don't know about it or that they are just not paying any attention to it.

Dr. STRAIN. Well, I think that——

Ms. ESHOO. Do you have any suggestions that have, excuse the expression, more teeth in it?

Dr. STRAIN. Well, I think that from a systems level what we could do, I think that we need to continue to be aggressive in our education of all healthcare providers about this, but I don't——

Ms. ESHOO. We really have a crisis obviously on our hands, but it seems to me that in the system itself, professionally, we are creating a whole other wave of it.

Dr. STRAIN. I think though I like to hope that we are turning the corner on that and not doing that.

Ms. ESHOO. Well, let me just switch gears because I don't have very much time left. I am an original cosponsor of Congressman Lance and Kennedy's bill which makes investments in CDC's surveillance of injection drug related infections. What barriers currently exist to states implementing drug related infection surveillance systems today?

Dr. STRAIN. Are you asking me that question or——

Ms. ESHOO. Well, whomever wants to answer.

Dr. STRAIN. I think you were commenting on this bill.

Dr. KILKENNY. Thank you. I think I can speak to that. The barriers are probably mostly manpower. We need more people to do the adequate case tracking and we need more communication amongst the agencies to not the same level of communication that this end of the table is talking about, but communication in the public health sectors to basically identify the risk, the risky individuals, and case-track them and work that epidemic with the methods that we use. It is a labor-intensive method.

Ms. ESHOO. I am not so sure I understand the answer, but I know we are going to have the opportunity, Mr. Chairman, to submit questions to the witnesses and I will do that.

Mr. CARTER. Sure. Thank you.

Ms. ESHOO. I will yield back. Thank you everyone.

Mr. CARTER. The gentlelady yields. The chair recognizes the gentleman from Florida, Mr. Bilirakis.

Mr. BILIRAKIS. Thank you. Thank you, Mr. Chairman, I appreciate it. I thank the panel for their testimony.

Mr. Bauer, Florida law as of January 1st, 2018 requires that all controlled substances dispensed to an individual be reported as soon as possible, but no later than the close of the next business day to afford its PDMP the electronic Florida online reporting of controlled substances evaluation. If the controlled substance is dispensed on a Saturday and the pharmacy is closed on Sundays it could result in a 48-hour latency. Does typical notification latency range from 2 hours to 7 days depending on the State?

Mr. BAUER. Thank you for that question. Today there are 43 States that require submission of controlled substance prescriptions no later than 24 hours. There is one State that is real time, Oklahoma, and there are, the remaining States are either on a 7-day to 8-day cycle.

Mr. BILIRAKIS. OK, thank you. And yes, elaborate a little bit, as far as how important that is.

Mr. BAUER. Absolutely. The timely submission of information is extremely important. The 43 States that do submit the information no later than 24 hours, there are typically multiple submissions that are made of the dispensation when it leaves the pharmacy. For example, when it comes into our system we append that information. We provide our logic as far as appending that to the right patient and make that information available within about 5 minutes' time. So it is very much near real time that once that information is received by the PDMP, in the case of Florida that information is made readily available within about 5 minutes' time.

Mr. BILIRAKIS. Very good. I know it is critical. I understood that many States are able to share PDMP data across State lines. However, even if States are connected to an information hub, isn't it true that those States do not necessarily have across State line information for all other States connected to the hub? Is that true?

Mr. BAUER. Yes. Today the 45 States that do participate in PMP Interconnect, for example, can share with all 45 States should they wish. It is up to the discretion of the actual state as to what States they wish to share information with. Again most States, in fact all States share data with at least their border states. Most draw another concentric circle and others look at different migration paths as far as the I-95 corridor or the I-65 corridor or the Northeast states as far as sharing information.

Mr. BILIRAKIS. OK. I think I know the answer to this question but I am going to ask it. Can any State PDMP actually stop the fraudulent prescriptions from leaving the pharmacy if the patient obtained multiple prescriptions within the same day, potentially, across State lines?

Mr. BAUER. Yes. That is a great question. Built into today's PDMPs there are very efficient and effective ways where the States

are actually proactively sending alerts based on various thresholds of the data both within their State and combined with multi-state data.

So, for example, understanding if a patient is traveling from State to State to State accumulating prescriptions from multiple providers or multiple dispensers, that information can be made available via an alert is what we call based on specific thresholds that states set so those alerts are sent out proactively to the actual prescriber or pharmacist that is checking on that patient.

Mr. BILIRAKIS. What are we doing to call out those five States that aren't participating?

Mr. BAUER. Yes. That is a great question. Again it is more of a policy issue. California and Florida are addressing those issues as we speak. Florida will be online hopefully by July 1st, California later this year. The remaining States actually are in process, meaning the actual MOU, the memorandum of understanding that is required to share data among States is in review. The only States that are an exception to that are Nebraska and Hawaii. Those States have not yet engaged on the MOU process. But Washington State and Wyoming have.

Mr. BILIRAKIS. Very good, thank you. I yield back, Mr. Chairman, appreciate it.

Mr. BURGESS. Will the gentleman yield to the chair for just a second?

Mr. BILIRAKIS. Yes, I will. Yes, I yield.

Mr. BURGESS. I wanted to make the gentleman aware that in the appropriations bill that will be on the floor of the House, the NASPER language in the fiscal year 2018 omnibus bill, just to draw attention to the fact that it will promote these Prescription Drug Monitoring Programs including implementation of activities described in the National All Schedules Prescription Electronic Reporting Act of 2005 that was this committee's product, and include, as amended, by the Comprehensive Addiction and Recovery Act of 2016 and this shall include efforts continuing to expand and enhance the utility of PDMPs in States and communities making them more interconnected real time and usable for public health surveillance and clinical decision making. The CDC shall use $10 million of the funds provided to conduct an opioid nationwide awareness and education campaign.

So that is a little bit different now we have actually got NASPER, which we have worked on in this committee as long as I have been on this subcommittee, is actually receiving funding in this appropriations bill should it pass in a little while.

So I now recognize the gentleman from New Mexico for 5 minutes for questions.

Mr. LUJÁN. Thank you, Mr. Chairman.

Mr. Martz, I would like to thank you for being here today, sir, all the witnesses who are with us today. My questions today will specifically be for Dr. Martz.

Yesterday I was taken aback by the conversation about how providing individuals who continue to face stigma and discrimination with heightened Part 2 protections, which include the right to decide with whom to share their substance abuse treatment records, stigmatizes individuals with substance use disorder. I was sur-

prised to hear SAMHSA echo this accusation in the final rules modernizing Part 2 regulations. Those rules explicitly acknowledge the stigma and discrimination faced by individuals with substance use disorder.

All of America's antidiscrimination laws from Civil Rights Act to Americans with Disabilities Act to the Fair Housing Act provide heightened protections for populations like individuals with substance use disorder who face stigma and/or discrimination because of who they are. And, frankly, I am having a hard time understanding the argument that these protections stigmatize these individuals.

So, Dr. Martz, please describe the stigma and discrimination that individuals with opioid use disorder face.

Mr. MARTZ. Thank you. It is an excellent question and a critical area because and to the points earlier this is not limited to the ERs. This is stigma that goes across the way. One in four families has someone in the family now with substance use disorder, and so very often my experience of substance use disorder is cousin Joey who has been stealing from us. And so stigma runs deep and it is very different from the aspects of other medical conditions which are very unique to the substance use disorder which, for example, there are still crimes associated.

So you don't get thrown in jail for having depression. You don't have your kids taken away for your acne. You don't have a loss of your job because you have a heart attack. So, medical conditions are not all the same and so there are reasons why there may be some segregation even though there are ways to coordinate that care effectively. These stigma issues are critical and to suggest that the stigma is caused by these laws is a little bit of a misunderstanding.

For example, we don't have laws protecting antidiscrimination in the workforce because we are creating stigma in the workforce, we have laws protecting things like gender and race and ethnicity and religion because these things have been discriminated against in the past. And so even if we have come a long way as we have with HIV, we have not yet come that far with substance use disorder and so it still maintains a critical protection.

Hopefully some day in the future we will understand that these are brothers and mothers and sisters and children that we are talking about here and can move beyond that discrimination, but we are just not there yet. We need that protection desperately.

Mr. LUJÁN. So a yes or no question, is that stigma and discrimination the result of heightened protections provided by the Part 2 protections?

Mr. MARTZ. No.

Mr. LUJÁN. I was also taken aback by something in Dr. Strain's testimony. In his discussion of rolling back Part 2 for payment purposes he states that, "patients could retain the ability to keep their substance use disorder treatment from their health plans by choosing to pay out-of-pocket for services which is a right guaranteed under HIPAA." To me this means that a person's ability to protect the privacy of their substance abuse treatment record would be based on their income, their ability to pay out-of-pocket for treatment. If you are rich you can keep it private.

Dr. Martz, is it appropriate to make a person's ability to keep their substance use information private based on a person's ability to pay cash for treatment?

Mr. MARTZ. Thank you. My gosh, that is such a fundamental civil right to be able to be private, have my own and disclose at my own pace when I am ready and when I am able. That shouldn't be something that is only available to the rich who can afford it. Many folks that we deal with are police officers and teachers and students and all walks of life so should have these opportunities should they choose to use that option.

Mr. LUJÁN. One thing that I was struck with as well is I learned that it was estimated that 20 million people in the U.S. have some form of substance use disorder. Currently, four million people are seeking treatment as has been reported, but the fear of not being provided confidentiality is one of the primary reasons people do not seek treatment.

So, Mr. Chairman, I know that this is an important part of the legislative package that we have, and I certainly hope that we take this into consideration as we try to make things better versus taking protections away from individuals. And I yield back.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back. I am sure ICD-10 has not one but fifteen different codes. The chair now recognizes the gentleman from Illinois, Mr. Shimkus, 5 minutes for questions.

Mr. SHIMKUS. Thank you, Mr. Chairman. And it is great to have you here. We have had 2 days of hearings and as I mentioned yesterday it is just not, I mean we are focused on opioids but there are a lot of other addictive drugs out there and challenges.

So I am going to be brief because I want to focus on what Gus Bilirakis was saying and to, really, Mr. Bauer on the Prescription Drug Monitoring Programs. One way we can shame the five States is to call them out, and we can do it ourselves and we use the bully pulpit to say, you guys need to start sharing information. We have got to stop the easy access especially across State lines or in other areas.

A good example, so I really live in the St. Louis metropolitan area, I am from Illinois. Illinois has one, Missouri does not. St. Louis County has one which really makes it very difficult to make sure we have the procedures in place to be able to access them when a State doesn't allow the States to have the memorandum of understanding and work through those processes.

We have seen these type of things when they can communicate in the meth challenges. We have seen that be successful. We need your help in figuring out how to really force this national communication across state lines to address this. I am curious if you can expand on ways we can help ensure that these multiple systems are working together as opposed to creating new burdens and confusions.

Mr. BAUER. Sure, another excellent question around interoperability and states being able to share data among themselves. I think today with the current PMP Interconnect system, for example, that is facilitating about 18 million transactions a month with 45 sStates, again I stated earlier it is more a matter of policy and I think we are making some significant progress with Florida com-

ing on board and the remaining States are making, I think, measurable progress towards that.

So I think it is not out of the question that all remaining States that are not currently sharing data can share data. There is a very effective means to do that today with a single MOU in place to accommodate for different state laws and security concerns as well.

Mr. SHIMKUS. When someone has been prescribed legally and they go to the pharmacist, they should be able to get that dispensed but they shouldn't be able to go across the state lines and there should be a red flag saying, hey, it has already been filled. And that is what we need to work on and that would be helpful.

Mr. Chairman, in lieu of time and other colleagues, I am going to yield back so you can give them a chance to ask.

Mr. BURGESS. The chair appreciates the gentleman. The chair recognizes the gentlelady from Indiana for 5 minutes for your questions, please.

Mrs. BROOKS. Thank you, Mr. Chairman. And thank you to our colleague from Illinois for yielding.

I want to ask you, Dr. Banner, I am the lead sponsor on H.R. 5329, a bipartisan bill to enhance our poison control centers in the country of which there are 55, I understand, across the country. But most people probably don't realize that the poison control centers field about three million calls, but more recently about 192 calls a day on average on the opioid misuse and abuse, and I really want to talk about the importance of not only the hotline but what the service that poison control centers provide.

How can poison control centers work with the educators, caregivers, people who call, children, others, what is poison control center's role? I think it is one of those you know the number and you rush there, and I have had to use it once or twice when my kids were young as well. I hate to admit it, but we all do at some point. And, but what is the role of the poison control centers with education?

Dr. BANNER. We so very much appreciate your sponsorship and involvement in this. If we have a couple of hours I could really explain this to you. We have a very multifaceted approach to education. Personally, I have emergency medicine residents rotating with me at all times in the poison center and in the ICU and we are educating them. I am teaching in the College of Pharmacy as part of my responsibilities at the poison center and I think the other 54 centers are similar. We are actively engaged in that level of education.

The certification requirements for a center is to have an educator who is principally pointed at the public and, too, the National Poison Prevention Week is one of their big times, but they are engaging kids at the elementary and early-on levels about the dangers of things. And as we have evolved, they have incorporated more about substance abuse into those educational packages and teaching teachers, et cetera.

Did you have something else to add?

Mrs. BROOKS. Well, I want to just, in your written testimony you actually mention that actually a quarter of calls to our poison control centers come from healthcare facilities. And so, and just your testimony now about rotating residents in and so forth, there is a

significant need, is there not, to continue to increase the education of poison issues leading injury cause, by the CDC in this country, of death with our medical professionals?

Dr. BANNER. This was a simple job back in the '90s. The explosion that has occurred with bath salt drugs, synthetic cannabinoids, synthetic opioids has just changed the landscape. And I would agree with you, the reason we get about 25 percent of our calls from other healthcare professionals is because the level of training of the medical toxicologists and the people working in the poison centers is very, very unique.

And the other issue is Oklahoma has a lot of rural hospitals as do many of the poison centers, and my ability to reach out to a physician in a very rural hospital who has never seen this before, and I have, is very helpful. Plus, I am a critical care doctor. The vast majority of the doctors that are medical toxicologists are trained in emergency medicine or critical care and we are reaching out to rural areas with high level, intensive care, emergency medicine, and toxicology all at the same time and providing that and educating them at the same time.

Mrs. BROOKS. In fact, in our bill we are directing HHS to implement call routing based on a caller's actual location because that is not necessarily how you receive that information now. Is that correct?

Dr. BANNER. That is correct. When this was initially funded back in 2000 it was reasonable to have where your area code. And since then, area codes, now people are taking their phones, particularly the military they are moving all over the country. And one of the benefits of a regional poison center is I am speaking to a doctor that I know in that area and if I am suddenly faced with a caller who happens to have the Oklahoma area code and they are in California, I can't really say you need to go down to Dr. Such-and-Such at this hospital, because I don't know them.

So the geo-routing, it sounds fairly simple. It is a little more technically complicated, but it is something we really need because we have got to, we have the regional resources to help people and it is where they are at right now, not where they used to live.

Mrs. BROOKS. Thank you for your leadership in this area. And on behalf of citizens in Indiana and across the country and my colleague from Oklahoma, we really appreciate your advocacy for poison control centers.

Dr. BANNER. Thank you.

Mrs. BROOKS. I yield back.

Mr. BURGESS. The chair thanks the gentlelady. The gentlelady yields back. The chair recognizes the gentleman from Texas for a unanimous consent request.

Mr. GREEN. Thank you, Mr. Chairman. I would like to ask unanimous consent to enter in the following letters from NAMA Recovery-the Campaign to Protect Patient Privacy Rights and the Pennsylvania Recovery Organizations Alliance, into the official record.

Mr. BURGESS. Without objection, so ordered.

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

Mr. BURGESS. The chair recognizes the gentleman from Oklahoma, 5 minutes for your questions, please.

Mr. MULLIN. Thank you, Mr. Chairman.

Dr. Banner, good to see you here. We were taking little friendly wagers up here to see if you had your boots on or not. I said yes and you probably got your cowboy hat outside too. So I do appreciate the knowledge that you bring and thank you so much for coming up here. I know it is hard to leave our beautiful state especially where we live, right?

Dr. BANNER. That is right.

Mr. MULLIN. Dr. Martz, I want to dig in a little bit on some stuff that you have been saying. And I respect your opinion, but I have a problem with the fact that you are trying to push it off as facts. When we start talking about privacy—I just want a yes or no here because you kept referring back to this—is it legal for treatment to be shared with an employer right now? The answer to that is no, so is it legal? Yes or no.

Mr. MARTZ. There are conditions with which you can really make a release.

Mr. MULLIN. Only if the individual has consent. Don't mix words with me, yes or no. Is it legal or no?

Mr. MARTZ. In that condition, no.

Mr. MULLIN. Right. I am an employer. I have several hundred employees. It is completely illegal. Second, I am also a landlord. Is it legal for treatment information to be shared with a landlord? Yes or no.

Mr. MARTZ. No.

Mr. MULLIN. No. It is absolutely not. Is it legal for information to be shared in a criminal case or a divorce hearing?

Mr. MARTZ. No.

Mr. MULLIN. No. So what you are saying about privacy is completely irrelevant to what we are trying to do here. This is about patients. It is not about opinion or maybes. It already is illegal and under this legislation it stays illegal.

So when you are testifying with us, please be a little bit more factual on what you are saying instead of making a broad statement like that and drawing fears into people. We bring you here because you are considered an expert. Please be that expert. I know you have a wealth of knowledge up here, but you are misleading us and the panel when you don't put facts with it.

Second of all, you start talking about the stigma that is put in place and you referred back to SAMHSA several times. I sent out a letter to the assistant secretary asking for their information on our bill and what their thoughts were. Let me read you a quote that came out of it. This is my favorite letter that when they sent it back they said, "The practice of requiring substance use disorder information to be any more private than information regarding chronic illness such as cancer or heart disease may itself be stigmatizing." That is from SAMHSA. Pretty plain and simple there that they think, itself, it shouldn't be treated any differently.

Now let's talk about the fines, because you brought up fines about this. How many, underneath Part 2, how many penalties have been issued underneath Part 2 for violation of Part 2?

Mr. MARTZ. On Federal or State level, because there will be sanctions against licenses on the local level.

Mr. MULLIN. Federal.

Mr. MARTZ. Federal, not that I am aware of.

Mr. MULLIN. Two. How many has been brought up underneath HIPAA?

Mr. MARTZ. That is outside of my scope.

Mr. MULLIN. Let me just kind of put this out there, 173,426 since 2003. Now why is that?

Mr. MARTZ. There are——

Mr. MULLIN. Because you talked about this in your opening testimony and I just want to make sure that we are factual here so you understand what we are talking about. A lot of people want to talk about privacy and about not providing or not separating or why Part 2 and HIPAA needs to be separated, but underneath Part 2 the penalty is $50 if that information is mishandled with the patient, $50. It is not worth the court's time to deal with it. It is only two cases. Underneath HIPAA it ranges between $150,000 per violation and a maximum of $1.5 million per year.

This is about patients. What we are trying to do here is treat the patient. But how can he treat the patient when the doctor can't see all the medical information? How can he do it? And the reason why I am so passionate about it because it touches my family, we are currently dealing with it. I currently dealt with this situation yesterday over the phone because we have a family member that has a disorder of being addicted to drugs because it started with an elective surgery and now her life is completely ruined and she keeps going to doctors and they keep prescribing her stuff.

And they can't see her complete record and how many times she has been in treatment, so every time she goes in they start diagnosing, or prescribing her more pain medicine because she is in pain. Well, what is the difference between pain and a withdrawal? Because at some point you start coming off of it and you start having withdrawals and guess what, that is painful too and so we are talking about combining those two.

Are you following me on this? So what is wrong with my legislation that allows a patient to be treated completely? And don't tell me about the stigma because it is not about stigma. It is about treatment. It is about getting the patient back to who the person they were before.

Mr. MARTZ. Thank you for your passion and information. I fully agree with the points that you are making. I would add respectfully a couple of points in addition to that. In good clinical care and for the treatment of the use disorder, OK, for the——

Mr. MULLIN. Make it short because I didn't know I was already over time.

Mr. MARTZ. Sorry. Thank you, that it is critical to have that patient be involved in that collaboration so that there can be the best collaborations. And even in——

Mr. MULLIN. They are seeking more treatments because they are addicted to drugs.

Mr. MARTZ. Which will all be noted in the PDMP where they will all have access to that already, information.

Mr. MULLIN. Which is important for the doctor to have the same information. That is why we are trying to see, or trying to compare the two and make sure that both of them are combined so the doctor can give the patient the treatment they need. That they need, they are professionals just like you are a professional. I yield back.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back. The chair recognizes the gentleman from Georgia, Mr. Carter, 5 minutes for your questions, please.

Mr. CARTER. Thank you, Mr. Chairman, and thank all of you for being here. And this is a great panel and I appreciate your participation here.

Mr. Bauer, in 2009, as a member of the Georgia State Senate I sponsored the legislation creating the Prescription Drug Monitoring Program in the State of Georgia, so I am very interested in it. I appreciate you throughout your testimony clearing up the fact that when States are sharing information they are not sharing it with all States, they are only sharing it with certain states. And initially that was a little confusing, so I hope my colleagues understand that just because you are sharing information you are not sharing it with all States. You are only sharing it with States that you choose to share it with and I just wanted to make sure we got that straight.

Mr. Guthrie asked you a question, Mr. Bauer, about who is mandated to see this information that is on the PDMPs and you answered him and said 40 states mandate. Mandate who to see it, pharmacists or doctors?

Mr. BAUER. Predominantly prescribers. So the 40 States that have a mandated use law or statute, typically that is a prescriber. In a handful of states it also includes the dispenser which would include the pharmacist.

Mr. CARTER. I am not sure I agree with that but I will take your word on that. In fact, in the State of Georgia when we created it, it was the pharmacist who had to look at it. Starting July 1st, the doctors will have to look at it and I think in most cases it is for the pharmacists and not for the doctors. But anyway will you clarify that for me and follow up in my office on that?

Mr. BAUER. Yes, sir.

Mr. CARTER. I appreciate that very much. Also I wanted to ask you, I have had a number of companies come into my office who are showing me how they can incorporate the PDMPs with the electronic health records so that we are not disrupting workflow, and that is certainly something that is important and certainly something that we have experienced in the pharmacies when we are trying to incorporate the PDMPs with our workflow. It is a disruption and the more we can incorporate it into our workflow the better the program will work, and I am sure that is the case with physicians as well and I know it is the case with pharmacists.

Also I wanted to ask you, cash prescriptions, are they being included in your PDMPs?

Mr. BAUER. Yes sir, all prescriptions, controlled substances, typically Schedules II through V, including cash, are required.

Mr. CARTER. OK. And let's talk about Schedule V prescriptions because sometimes that can cause a problem particularly with patients who are getting medications that are Schedule V and not necessarily medications of abuse. For instance, epilepsy patients may get some Schedule V prescriptions and sometimes this can cause a disruption in their therapy as well.

Have you experienced anything with that? Is that something that you are looking at to make sure that we don't disrupt that therapy?

Mr. BAUER. That is a great question. From a PDMP perspective that is not something that we weigh in on. That is typically a state policy decision that is made. Our responsibility is to collect the information.

Mr. CARTER. OK. All right, one last question, you talked about methadone with I believe it was Representative Guthrie again. You said the methadone clinics were not required to report to the PDMPs?

Mr. BAUER. Any methadone administered in a clinic.

Mr. CARTER. What about in pharmacies? I am required in Georgia to——

Mr. BAUER. If it is filled by a pharmacy that is reported to the PDMP.

Mr. CARTER. If it is filled by a pharmacy, but if it is filled by a clinic it is not?

Mr. BAUER. Correct.

Mr. CARTER. There we have it. For a while we didn't have the VA reporting and that was a problem, now hopefully they are online as well.

I want to go to you, Mr. Banner, because one thing that has concerned me and I just wanted to get your opinion on it was the use of naloxone and the dependency that it seems to be getting. I know we have had some situations where some of the ambulances have been carrying so much of it and actually had to administer so much that it is bankrupting, literally, some of their budgets and that they have had to stop and only carry a certain amount on that. Do you see that sometimes happening?

Dr. BANNER. We definitely have areas where there are spikes that are concentrated activities and that is concerning in and of itself. But yes, for a lot of reasons there are a lot of shortages of a lot of drugs and that pushes prices up and that is a problem. I think it is going through a this-should-work-for-everything phase and we know it only works for the opiate receptor interaction drugs.

Mr. CARTER. Right. But I think one of the problems too is that users are getting dependent on it knowing that oh, if I OD, they are going to come rescue me and I will be OK.

Dr. BANNER. Yes. I think it does encourage people in some ways to push the envelope.

Mr. CARTER. Exactly, exactly. Thank you. And also thank you, you mentioned something that throughout these hearings I have not heard anyone mention: synthetic marijuana. That has been a big problem in Georgia. Thank you for mentioning that because we want to continue that as well. And I know I am out of time and I yield back.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back. The chair recognizes the gentleman from New Jersey, Mr. Lance, 5 minutes for your questions, please.

Mr. LANCE. Thank you very much, Mr. Chairman, and my thanks to the distinguished panel. We have been back and forth in several hearings today, several of the subcommittees and of course votes on the floor. I want you to know this is an incredibly important topic to the entire nation and you are among the great experts on it.

Dr. Kilkenny, could you speak briefly about the opioid crisis and the rise of infectious disease rates and how the two issues are linked?

Dr. KILKENNY. Yes sir. Blood-borne pathogens are spread by sharing blood and injection drug use. When people who are engaged in injection drug use are sharing syringes or other materials of injection they are often sharing blood. So there is a clear correlation between those blood-borne pathogens that would be Hepatitis B, Hepatitis C, and HIV, and injection drug use.

Mr. LANCE. How have your efforts been successful in bringing together community partners in Huntington to address infectious diseases associated with the opiate epidemic?

Dr. KILKENNY. The city of Huntington has a remarkable history of working together against common threats. And with the opioid epidemic reaching a level that it impacts every family, we have no problem getting every entity aligned in a strategy against it. So we have brought in virtually every other entity in the community into the strategic plan.

Mr. LANCE. Thank you. I have introduced legislation regarding the opiate issue and infectious diseases and my cosponsors are Congressman Kennedy on the other side of the dais. This is completely bipartisan and I hope that you as the experts might have the opportunity to review the legislation.

I think there is a growing awareness among the various avenues we have to pursue that there is a significant correlation between the opiate crisis and infectious disease rates. And we are in this battle together and I am sure we will overcome and conquer based upon our joint efforts both bipartisan and bicameral in nature here on Capitol Hill, but also with leading experts across the country including this distinguished panel.

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

Mr. BURGESS. The gentleman yields back. The chair thanks the gentleman. The chair would recognize Mr. Walberg of Michigan, not a member of the subcommittee but my understanding is you want to waive on for questions. Is that correct?

Mr. WALBERG. That is correct.

Mr. BURGESS. The gentleman is recognized for 5 minutes for questions.

Mr. WALBERG. I appreciate, Mr. Chairman, the opportunity to join the August subcommittee. I have a great interest in this and a personal interest and I appreciated hearing what I have been able to listen to today about the fuller subject that we are addressing. And of course there has to be compassion. There has to be a willingness of a patient to seek help, first and foremost, but there also has to be certainly a willingness of the medical profession and society in general to reach out and solve the problem as well.

Earlier this Congress, I introduced Jessie's Law with Congresswoman Debbie Dingell in an effort to try to find a solution to something that tragically took place in Michigan with Jessie Grubb, a resident who had been doing very well in beating her addiction and growing was involved in a sports accident injury in preparation for a marathon and had a surgery. Her family as well as Jessie herself notified the attending physician, the surgeon, of her problem with addiction, but it didn't reach the attention for some reason of the

discharging physician and so she was sent home from the hospital with a prescription of oxycodone which she ultimately overdosed on the next day and lost her life.

So we want to find a solution to that. And, Dr. Strain, we are currently examining both Jessie's Law and H.R. 3545, the Overdose Prevention and Patient Safety Act. Can you elaborate on the major differences between the bills and, if so, why it would be helpful to have both?

Dr. STRAIN. First, I am sorry for that loss and for the family, for you and how you have had it impact you as well. It is a tragedy. I think both bills have value. I want to just be clear, I think that both have great value. I think that both illustrate the fact that as a physician I teach my residents and interns when in doubt get more data, and that is something that we are in a situation now where we may not know about how to get more data.

So I could, for example, have seen Jessie and not known about her addiction history if she didn't tell me about that. I think that as I understand Jessie's bill, I think bringing together stakeholders who can look at how could something like this not happen in a medical record again is a worthwhile thing to do and to see if there is some way that that can be codified. I don't think it is enough. I think that we have a situation right now where we have got a whole treatment system, substance abuse programs that could be taking care of somebody and I may not know about that.

And it is artificial at this point if I could say, if I could take a moment to say it is artificial. I could know somebody has got a substance abuse treatment, substance abuse problem documented in the record, but it is only if they are in a particular program that I may not know about what is going on in that program.

So I have plenty of patients with substance abuse problems. I have asked them, they have told me. I have it documented in my records. Those records can be accessed by obstetricians, by orthopedic surgeons, by whoever. They can get access to that information in my record but they can't get access to the treatment records, which is artificial.

Mr. WALBERG. So what will give that access? What are the additional things we need to do?

Dr. STRAIN. I think the Mullin amendment does that. I think the Mullin amendment, 3545, does that.

Mr. WALBERG. It is mandatory and automatically shared with any and all who need to know that?

Dr. STRAIN. Well, with the proper protections in place as they are required, yes, which Representative Mullin pointed out in his questions, I think.

Mr. WALBERG. OK. Thanks for the opportunity to ask those questions. I see my time is about expired. I will yield back.

Mr. BURGESS. The gentleman yields back. The chair thanks the gentleman. The chair recognizes the gentleman from New York, Mr. Engel, 5 minutes for your questions, please. And the chair would observe that was the vote being called. So we will, after Mr. Engel we will recess and reconvene with the next panel.

But, Mr. Engel, you are recognized.

Mr. ENGEL. Thank you. Thank you, Mr. Chairman. This week, Congresswoman Brooks and I introduced the Poison Center Net-

work Enhancement Act, a bill that will reauthorize the Nation's poison center programs for an additional 5 years. Speedy access to poison centers through the national toll-free number, again 800-222-1222, is an essential resource for all Americans, especially parents who can take solace in the fact that there are 55 poison centers across the U.S. available 24 hours a day, 7 days a week, 365 days a year.

These centers are a smart public health investment. They offer real time, lifesaving assistance while at the same time saving hundreds of millions in federal dollars by helping to avoid the unnecessary use of medical services and shortening the amount of time a person spends in the hospital if hospitalization due to poisoning is necessary. Most of us already know about much of the work poison centers do thanks to a magnet on the refrigerator displaying the poison center phone number. But many may not know about the critical role poison centers are playing in the fight to end the opioid crisis.

Since 2011, our Nation's poison centers have handled nearly 200 cases per day involving opioid misuse. Data from poison centers has helped detect trends in the epidemic and experts have helped educate Americans about the crisis in ways they could potentially save the lives of their loved ones. For example, the Upstate New York poison center used the New York State Fair to educate New Yorkers about proper use of naloxone, the overdose reversal drug. This bill would ensure that these important activities continue.

I was proud to co-author the last poison center reauthorization in 2014 and I am proud to be part of this legislation. I want to thank Congresswoman Brooks for working with me for this important bill as well as Congresswoman DeGette and Congressman Barton for being the original cosponsors.

Dr. Banner, let me ask you this in light of what I have said. Thank you for your being here and for sharing your expertise. This bill would authorize additional funding for the poison control center grant program. Would you talk about how this funding will help build capacity at poison centers and enhance their ability to respond to the opioid crisis?

Dr. BANNER. I appreciate everything that you have done, Congressman, and you know on behalf of the poison centers I really appreciate you. We hope to continue this fight. We hope to expand our educational activities as we go forward. We have a big state, so do you, and getting reaching out, particularly rural areas where education is critical, is difficult and expensive and so having extra funding and improving our funding base helps us in those outreach activities.

We are also actively seeking the first responders to get a hold of the poison control center as part of naloxone administration. As the good gentleman from Georgia pointed out, it could be misused or overused and we want to actively supervise and help in that program and our ability to continue that activity is very critical. So we see a lot of opportunities reaching out to minority communities where these are problems as well is an important issue for us. So we thank you.

Mr. ENGEL. Well, thank you, Dr. Banner. You mentioned in your testimony that poison centers have helped identify trends in the

opioid epidemic. How do you think that this information in poison centers could help us as policymakers respond to the crisis more effectively?

Dr. BANNER. Well, I think it already has in a lot of ways. This is the kind of data when you see it, it may be coming from the CDC and we work closely with them. Every 8 minutes we upload from all 55 centers into a central database. Plus, conversations, we have our listservs and there is a lot of human intelligence going on where we are identifying things very early.

The increasing Oxycontin, a lot of our recognition of those came from the NPDS database which is that contributory public health surveillance activity that we do. So we are constantly updating that database so that the FDA, the CDC, can be monitoring activities. We do that in real time for some acute events, but we also are looking over long terms. Every year we publish and people rely upon it heavily to look at trends in what drugs are becoming more prevalent and identifying new substances.

So I think you do rely upon us. You might not know it came from a poison center, but our data is there and it is I hope really helpful in guiding you to see where the future lies.

Mr. ENGEL. Well, thank you very much and thank you for your good work. And thank you, Mr. Chairman. I yield back.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back. The chair recognizes the gentleman from Virginia for a unanimous consent request.

Mr. GRIFFITH. Mr. Chairman, I would request that we introduce into the record a letter from the President and CEO of Titan Pharmaceuticals, Inc., related to the therapeutics for select chronic diseases and related to opioids.

Mr. BURGESS. Without objection, so ordered.

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

Mr. BURGESS. And the chair wishes to thank this panel. You have been very informative. It has been a lively morning and that is what we wanted and so we appreciate your expertise and your sharing it with us. We are going to take a recess. This panel may be excused and we will reconvene 10 minutes after the vote series on the floor with our fourth and final panel. So the subcommittee stands in recess.

[Whereupon, at 12:44 p.m., the subcommittee recessed, to reconvene at 1:24 p.m., the same day.]

Mr. BURGESS. We do want to thank all of our witnesses for being here this afternoon and for taking the time to testify before the subcommittee. Each witness will have the opportunity to summarize their opening statement followed by rounds of questions from the members.

And this afternoon, for our fourth and final panel of this 2-day hearing, we are going to hear from Ms. Jessica Hulsey Nickel, Founder, President, and CEO, Addiction Policy Forum; Ms. Carlene Deal-Smith, Peer Support Specialist at Presbyterian Medical Services; Mr. Ryan Hampton, Recovery Advocate, Facing Addiction; Dr. Mark Rosenberg, Chairman of Emergency Medicine and Chief Innovation Officer, St. Joseph's Healthcare System, Board of Directors in the American College of Emergency Physicians; Ms. Stacy Bohlen, CEO of the National Indian Health Board; and Ms. Alexis

Horan, Vice President of Government Relations, CleanSlate Centers.

Again thank you all for being with us today. Ms. Hulsey Nickel you are recognized for 5 minutes.

STATEMENTS OF JESSICA HULSEY NICKEL, FOUNDER, PRESIDENT AND CEO, ADDICTION POLICY FORUM; RYAN HAMPTON, RECOVERY ADVOCATE, FACING ADDICTION; CARLENE DEAL-SMITH, PEER SUPPORT SPECIALIST, PRESBYTERIAN MEDICAL SERVICES; MARK ROSENBERG, DO, MBA, FACEP, FAAHPM, CHAIRMAN OF EMERGENCY MEDICINE AND CHIEF INNOVATION OFFICER, ST. JOSEPH'S HEALTHCARE SYSTEM AND BOARD OF DIRECTORS, AMERICAN COLLEGE OF EMERGENCY PHYSICIANS; STACY BOHLEN, CEO, NATIONAL INDIAN HEALTH BOARD; AND, ALEXIS HORAN, VICE PRESIDENT OF GOVERNMENT RELATIONS, CLEANSLATE CENTERS

STATEMENT OF JESSICA HULSEY NICKEL

Ms. HULSEY NICKEL. Thank you so much, Chairman Burgess and Ranking Member Green.

[Disturbance in hearing room.]

Mr. BURGESS. Ms. Hulsey Nickel, you are recognized for 5 minutes, please.

Ms. HULSEY NICKEL. Thank you so much, Mr. Chairman, for your leadership on this important issue that is facing so many families and communities nationwide. My name is Jessica Hulsey Nickel and I am the President of the Addiction Policy Forum. I started the Addiction Policy Forum to bring patients, families, stakeholders across the country together to advocate for a comprehensive response to addiction including prevention, treatment, recovery support, overdose reversal, criminal justice reform and law enforcement, and also bring a voice for families. We have one goal, to help create a world where fewer lives are lost to addiction and help exists for the millions of Americans who need it.

I am grateful to be with you today to discuss key legislation and how it will help address the addiction crisis. I know firsthand the devastating impact that substance use disorders has on families and communities. I lost both of my parents to addiction, and their substance use disorders meant for me and my little sister homelessness and foster care and being wards of the state until I was 10, and then being placed with our grandparents, and I lost both of my parents far, far too young.

Every day we lose 174 people to drug overdoses in our country. One hundred seventy four—that is like a plane crash every day. It is important to put real faces to the scope of this crisis and the real families and communities that are at the epicenter, so we wanted to share with you some of the stories from our families.

First up is Doug and Pam who lost their daughter Courtney when she was just 20 years old. He describes Courtney as a shining star. The room lit up when she walked in and everyone loved her. Doug writes, we were told that because it is not a matter of life or death there would be no coverage for treatment. On the advice of our local authorities we asked her to leave our home and canceled her insurance. By doing this she would be homeless and

then could be eligible to receive treatment. Courtney died alone, away from our home, and the day before she was scheduled to go into a treatment facility.

Lorraine describes her twin brother Larry as amazing, charming, funny, popular, and the most talented drummer you have ever heard. Larry died from a drug overdose leaving behind his 1-year-old son and Lorraine became a single parent overnight.

Jennifer lost her son Dylan when he was just 19 years old. She says to us, every day when I walk into my house I see Dylan's shoes sitting on the floor where he kicked them off and his jacket draped over the bannister where he left it. He will never have the chance to get married, to have kids, to travel, to do all the things that a 19 year old should have experiences.

And then Amy who runs our Massachusetts chapter, she lost her son Emmett when he was just 20 years old. In college studying computer science, Emmett had six overdoses reversed at his local hospital, but treatment was not initiated and the family was not notified. Each of these overdoses was an opportunity to engage him in the help that he needed.

As a community of families, patients, and key stakeholders, we are so pleased to see the comprehensive approach that this committee is pursuing with the legislative proposals that are being considered. I would like to address three pieces of legislation in particular that will help us respond to this crisis.

First off, the Comprehensive Opioid Recovery Centers Act of 2018, we have an enormous treatment gap in this country. Of the 21 million people that need treatment for a substance use disorder, only about ten percent will receive it. Can you imagine if ten percent of Alzheimer's or ten percent of cancer or ten percent of diabetes patients received treatment?

Our current healthcare system has many systemic issues that continue to limit the effective and sustainable implementation of evidence-based practices to treat substance use disorders. For example, there is a lack of integration between general and specialty care. There is a lack of screening for substance use disorder in health care. There is inconsistency providing all three FDA-approved medications for opioid use disorder.

The Comprehensive Opioid Recovery Centers Act will help address these barriers through the development and promotion of integrated care models based on best practices which will build a pathway toward a comprehensive healthcare infrastructure that must be achieved to ensure that everyone suffering with a substance use disorder has access to quality treatment. This is a preventable and a treatable illness.

The Addiction Policy Forum supports the quick enactment of CORC, the Comprehensive Opioid Recovery Centers Act which will help fill the need for coordinated, comprehensive care for patients. Many thanks to Congressman Guthrie and Congressman Green, for their leadership on this bill.

I would also like to address the TEACH Act—Treatment, Education, and Community Help Act to Combat Addiction. There is an alarming lack of substance use disorder education in medical school curriculums and among current physicians. According to the 2016 Surgeon General's report, only eight percent of U.S. medical schools

have a separate required course on addiction and only a handful of medical schools have robust curriculum on the diagnosis and treatment of substance use disorders.

Often, healthcare providers do not feel prepared to deal with what is commonly perceived as a difficult patient population, and because of the lack of education for students and experienced practitioners patients can be denied access to a large portion of evidence-based treatment options. Physicians around the country also report not having enough training on the prescribing of pain medications and alternative treatments for chronic pain. This particular gap in physician education in the midst of a worsening opioid epidemic must be addressed.

The TEACH Act incentivizes the development of evidence-based education and curricula. The legislation would fund educational institutions be centers of excellence and substance use disorder education and require such institutions to collaborate with the stakeholders in their community who are really on the front lines of this crisis. We are supportive of the TEACH Act and I thank Congressman Bill Johnson and Paul Tonko for their work on this legislation.

And, finally, just very briefly, we are also very pleased to see the Preventing Overdoses While in Emergency Rooms, the POWER Act. This makes me think of Emmett and his mom, Amy, and how we can do a better job of equipping our emergency room physicians and all of our providers and emergency room departments to address nonfatal overdoses and to use this as an intervening moment. This is a high priority for the Addiction Policy Forum and we are in support of the POWER Act and grateful for this committee and your commitment to these issues.

And I just wanted to express on behalf of all of the families that your focus on this issue in such a comprehensive manner that includes all six of the key components—prevention, treatment, recovery, support, overdose, reversal—the focus means the world to us. We have millions of families that are struggling, some alone, some trying to come together and really fight for better responses. And so I am here to also transmit that heartfelt thank you for your leadership and focus on these issues.

So thank you so much for having me today.

[The prepared statement of Ms. Hulsey Nickel follows:]

Statement by
Jessica Hulsey Nickel
President and CEO of the Addiction Policy Forum
Before the House Committee on Energy and Commerce, Subcommittee on Health

March 22, 2018

I would first like to thank Energy and Commerce Subcommittee Chairman Michael Burgess (R-TX), Ranking Member Gene Greene (D-TX), and the members of the subcommittee for hosting this series of hearings and for inviting me to testify on behalf of important legislation that can help address our nation's addiction crisis.

My name is Jessica Hulsey Nickel, and I am the President of the Addiction Policy Forum. I started the non-profit to help patients, families and stakeholders across the country advocate for a comprehensive response to addiction -- including prevention, treatment, recovery, overdose reversal, criminal justice reform and law enforcement. We convene key partners from throughout the field around one table with a shared goal: to help create a world where fewer lives are lost to addiction and help exists for the millions of Americans who need it.

I am grateful to be with you today to discuss the proposed pieces of legislation and how they will help address this crisis. I know firsthand the devastating impact that addiction can have on families. Both of my parents struggled with heroin addiction and ultimately lost their lives to this preventable, treatable disease. My story is just one of the millions repeated daily across our nation - and I have heard these stories from the thousands of mothers, fathers, sisters, brothers

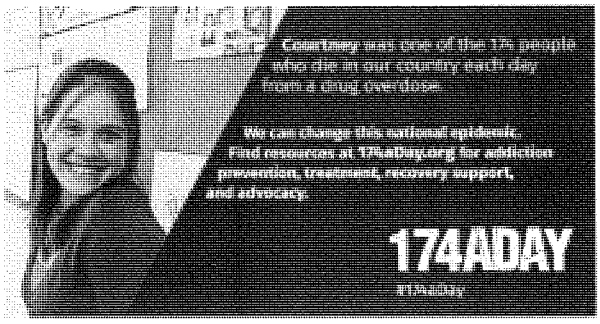
and other loved ones who have reached out to the Addiction Policy Forum in need, in grief, in hope and wanting to be a part of the solution to this crisis.

Last December the Centers for Disease Control (CDC) released a haunting report stating that over 63,300 people died from a drug overdose in 2016 -- a 21 percent increase from the previous year, largely due to an increase in opioid overdose deaths.

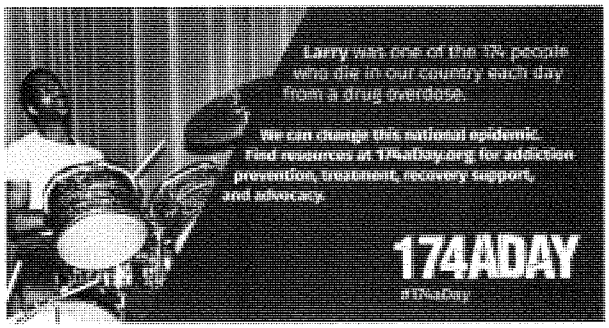
In 2016, 174 people died every day from a drug overdose in our country. 174. That's equivalent to more than two commuter planes crashing every day for an entire year. But you can bet that if those planes were actually going down the FAA would stop operations until they found out exactly what was going on. Addiction is a more muted killer. In 2016, the Addiction Policy Forum launched the 129aDay campaign to honor those we have lost and their families, who sit at the epicenter of this crisis. Each year, we update the campaign to reflect the increasing number of lives that are lost each year. The latest data available show 174aDay and all indications suggest that this number is continuing to rise.

Amidst the horrific numbers, it's important to put real faces to the scope of this crisis and I'd like to take a moment to share letters written by some of our families.

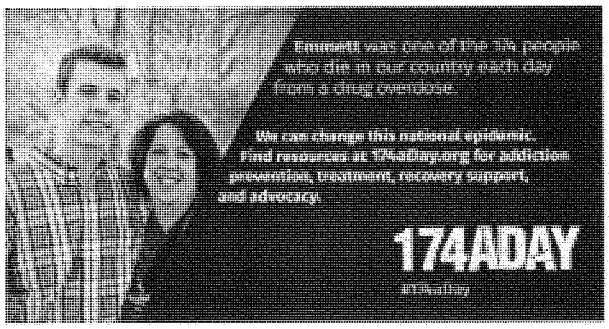
Doug lost his daughter, Courtney, when she was just 20 years old. He describes Courtney as "a shining star. The room lit up when she walked in and everyone loved her." Doug writes: "We were told that because 'it is not a matter of life or death' there would be no coverage for treatment. On the advice of our local authorities, we asked her to leave our home and canceled her insurance. By doing this, she would be homeless and then could be eligible to receive treatment. Courtney died alone, away from our home and the day before she was scheduled to enter a treatment facility."



Lorraine describes her twin brother, Larry, as "amazing, charming, funny, popular and the most talented drummer you've ever heard." Larry died from a drug overdose almost 30 years ago, leaving behind his one-year old son, who Lorraine raised - making her a single parent overnight.



Emmett's mom, Aimee describes him as "the average American teen; he loved video games and BMX biking. He was a caring, funny, smart young man with the potential for greatness. He was the adored older brother to Zachary (age 18) and Alice (age 9). He had a smile and charm that could light up a room – but heroin stole that from him, and from us"



Dylan's mom, Jennifer, describes the day of his death: "I don't remember much about that day, but I do know that my life will never be the same. Every day when I walk into my house, I see Dylan's shoes sitting on the floor where he kicked them off and his jacket draped across the banister where he left it. We will never have another one of our midnight snacks. He will never have the chance to get married, have kids, travel and do all of the things that a 19-year-old should have the chance to experience."

Of the 21 million people that need treatment for a substance use disorder, only about 10 percent will receive it. Ten percent. Can you imagine a world where only 10 percent of cancer or Alzheimer's or diabetes patients got the treatment they needed? 174 sisters, sons, husbands, daughters, mothers are lost each day.

A Comprehensive Response to Addiction

As a community of families, patients and key stakeholders, we are pleased to see the comprehensive approach of this Committee reflected in the numerous legislative proposals that are being considered.

Our community has outlined eight key priorities for addressing addiction in this country and we are grateful to this Committee and its members for foeusing on so many of the following crucial components.

1. **Help Families in Crisis:** Provide new, effective resources and support for patients and families in crisis.
2. **Expand Treatment Access and Integration into Healthcare:** Through partnerships and research, develop resources, protocols and tools for physicians, healthcare systems and the workforce to integrate treatment of substance use disorders into healthcare.
3. **Drive Discovery:** Invest in research on how to treat, prevent and cure addiction and its related disorders.
4. **Expand Recovery Support:** Properly prioritize and secure resources for the recovery support programs that individuals need in their communities.
5. **Prevention:** Increase funding for and the number of evidence-based prevention programs nationwide.
6. **Protect Children Impacted by Parental Substance Use Disorder:** Expand resources to support children who have a family member with a substance use disorder.
7. **Reframe the Criminal Justice System:** Partner with key stakeholders to re-envision how the criminal justice system responds to addiction.

8. **Educate and Raise Awareness:** Intensify the urgency around addiction and raise awareness.

Support for Innovative Legislative Proposals

I am here today to specifically address three pieces of legislation that will help us respond to and address this crisis, the Comprehensive Opioid Recovery Centers Act of 2018; the Training, Education, and Community Help (TEACH) to Combat Addiction Act of 2018; and Preventing Overdoses While in Emergency Rooms Act of 2018 (POWER).

COMPREHENSIVE OPIOID RECOVERY CENTERS ACT OF 2018

Our country has come a long way in a short period of time in our understanding of addiction and evidence-based services required to properly address this chronic disease. Many in the treatment and recovery fields are doing tremendous work that is both saving and restoring lives and the Addiction Policy Forum has the privilege of working alongside so many of them. Unfortunately, in many parts of the country, treatment and recovery services are either fragmented or non-existent. For many patients, the process of trying to find quality treatment is difficult and confusing.

We have an enormous addiction treatment gap in this country. In 2015, the Substance Abuse and Mental Health Services Administration (SAMHSA) reported that an estimated 21.7 million people aged 12 or older (8.1 percent of that population) needed substance use disorder treatment, but only an estimated 2.3 million of that population received treatment at a specialty facility. Stated plainly, only 10.8 percent of adolescents and adults who needed treatment received it.

For years, the addiction treatment field has been struggling to address a myriad of daunting issues due to insufficient resources, inadequate treatment infrastructure, and a cultural understanding of the disease defined by prejudice and inclined toward punishment. Today, the field is undergoing a major transformation as our societal understanding of addiction hurries to catch up with the science and vital advancements in treatment. However, the current healthcare system has many systemic issues that continue to limit the effective and sustainable implementation of evidence--based practices to treat substance use disorders. These limitations include:

- Lack of integration between general and specialty care.
- Lack of screening for substance use and SUD in general healthcare.
- Workforce shortages, with high staff turnover due to low reimbursement rates and salaries leading to high training costs, poor fidelity and insufficient training.
- Insufficient oversight and quality control of specialty addiction treatment programs that often do not deliver evidence-based care (e.g. detoxification should always be followed by treatment).
- Lack of incentives for program evaluation and quality improvement activities.
- Lack of standard credentialing, core certification criteria and standardized curricula are needed and should incorporate training related to pharmacotherapy.
- Resource limitations hamper the implementation of evidence-based practices with fidelity, particularly in poor states that lack investment in healthcare infrastructure.
- Lack of support for technical assistance, which tends to be provided reactively, when there is a problem.

The Comprehensive Opioid Recovery Centers Act (CORC) of 2018 will help address these barriers through the development and promotion of integrated care models based on best practices, which will build a pathway toward the comprehensive healthcare infrastructure that must be achieved to ensure that everyone suffering with a substance use disorder has access to quality treatment. Specifically, the legislation will provide resources to operate these centers, which will provide the full spectrum of evidence-based treatment services including intake evaluations and regular assessments, all Food and Drug Administration (FDA)-approved treatments for substance use disorders, detoxification, counseling, residential rehabilitation, recovery support services, pharmacy and toxicology services, and interoperable electronic health information systems.

The Addiction Policy Forum supports the quick enactment of CORC, which will help fill the need for coordinated, comprehensive care for patients with opioid use disorder. In so doing, these Centers will also address those at risk for overdose, arrest or other criminal-justice involvement receive the healthcare they need to return to their families, work and a healthy life.

I thank Committee's Vice-Chairman Brett Guthrie (R-KY) and Ranking Member Gene Green (D-TX) for their leadership on this bill.

TRAINING, EDUCATION, AND COMMUNITY HELP (TEACH) TO COMBAT ADDICTION ACT OF 2018

Medical education about the identification and treatment of substance use disorders needs to be improved for practicing healthcare professionals as well as those in training. There is an alarming lack of substance use disorder education in medical school curriculums. According to a 2016 Surgeon General report, only eight percent of US medical schools have a separate required

course on addiction and only a handful of medical schools have robust curriculum on the diagnosis and treatment of substance use disorders.

Every medical, nursing and dental school in the nation should train clinicians to identify and treat addiction and substance use disorder screenings should be required as part of routine health exams by general practitioners. Introducing the Screening Brief Intervention and Referral to Treatment (SBIRT) approach, for example, during residency programs will help to embed awareness and competency concerning substance use disorders in the expectations set for general practitioners and will ensure earlier and more comprehensive patient identification.

For a variety of reasons, most patients do not tend to seek help for a substance use disorder, but often suffer from associated and unrelated health issues for which they seek care. Thus, ensuring substance use disorder literacy among care practitioners and encouraging regular screenings is the first step. Assessments are more detailed and are applied to patients who screen positive, which will help doctors identify at-risk patients before the disorder progresses. In addition to professional education and screenings, more has to be done to decrease the stigma surrounding addiction and to improve confidentiality assurance in the doctor--patient relationship so that patients feel comfortable being honest with their providers about their struggles with substance use.

While there is certainly good work going on to improve medical professional education related to substance use and addiction, we must ensure speedy dissemination of the most current research and best practices. Unless a medical school student has chosen to specialize in addiction treatment, providers typically enter the workforce unprepared and ill-equipped to address the needs of the increasing number of patients with substance use disorder. In addition, practicing healthcare providers who were not required to take addiction treatment courses in medical

school, may avoid engaging with patients about substance misuse due to their own unfamiliarity with the disease. Often, healthcare providers do not feel prepared to deal with what is commonly perceived as a difficult patient population. Because of the lack of education for students and experienced practitioners, patients are denied access to a large portion of evidence-based treatment options that are only available in medical settings.

Physicians around the country also report not having had enough training on the prescribing of pain medication and alternative treatments for chronic pain. This particular gap in physician education in the midst of a worsening opioid epidemic must be addressed.

According to a 2017 systematic review published by the The Journal of the American Medical Association, more than two-thirds of patients reported unused prescription opioids following surgery. In 2016, 11.5 million people misused prescription pain relievers compared with 948,000 people who used heroin, and an estimated 239,000 adolescents aged 12 to 17 were currently misusing pain relievers. The most common source for the last pain reliever that was misused was from a friend or relative. Every day, over 1,000 people are treated in emergency departments for misusing prescription opioids, and from 1999 to 2016 more than 200,000 people have died in the US from overdoses related to prescription opioids.

The Training, Education, and Community Help (TEACH) to Combat Addiction Act of 2018 incentivizes the development of evidence-based education and curricula. The legislation would fund educational institutions to be "Centers of Excellence in Substance Use Disorder Education" and require such institutions to collaborate with stakeholders in their community who are working on the front lines of the opioid crisis. In addition, the bill would codify NIH Centers of Excellence in Pain Education that act as hubs for the development, evaluation, and distribution

of pain management curriculum resources for medical, dental, nursing, pharmacy and other schools to improve how health care professionals are taught about pain and its treatment.

The TEACH Act would help expand the curricula and training resources that are so needed for our physicians and other key healthcare providers to better address addiction, pain, and the opioid crisis.

I thank Congressman Bill Johnson (R-OH) and Congressman Paul Tonko (D-NY) for their work on this legislation.

PREVENTING OVERDOSES WHILE IN EMERGENCY ROOMS (POWER) ACT

We know that those who have experienced a non-fatal overdose are at great risk of repeated overdose and often need treatment for substance use disorder. However, most hospitals nationwide do not provide the linkage to addiction treatment and care needed at that key intervention point. Currently, too many emergency departments in the United States do not have standard protocols in place to assist patients presenting with an overdose. The Addiction Policy Forum, in partnership with the Berger and Mercy Healthcare systems in Ohio, has established pilot programs to direct patients who have recently been admitted to an emergency department for an opioid-related overdose to treatment.

The rate of opioid-related emergency department visits increased in almost all States between 2009 and 2014, with the greatest increases in Ohio (106.4 percent), South Dakota (94.7 percent), and Georgia (85.2 percent). And recently released data from the CDC showed that emergency department visits for suspected opioid overdoses increased nearly 30 percent in the US from July 2016 to September 2017. Two of the sixteen states, Wisconsin and Delaware, experienced increases of more than 100 percent.

To improve how hospitals respond to overdose and addiction, the Addiction Policy Forum is implementing the Emergency Medicine Initiative to help hospitals develop and implement post-overdose interventions in Emergency Departments.

Through the initiative, we will develop open-source protocols and tools that can be used by emergency departments across the nation. These will include model workflows, education videos for practitioners, model post-overdose discharge instructions, and other tools to empower practitioners to deliver evidence-based care.

The POWER Act is a key piece of legislation that will bolster current policies nationwide in order to better connect patients that have presented with an overdose with the treatment they need. POWER will provide emergency departments with the resources and information needed to develop evidence-based protocols for screening overdose patients for substance use disorder, initiating treatment with FDA-approved medications in emergency departments, providing effective referrals to evidence-based treatment upon discharge, and implementing best practices for care coordination and integrated care models for long-term treatment and recovery services.

The Addiction Policy Forum endorses the McKinley/Doyle POWER Act and urges this Committee to push for enactment to provide these resources to communities as quickly as possible.

We are grateful to Congressman David McKinley (R-WV) and Michael Doyle (D-PA) for their leadership on this legislation and for bringing attention to how we can advance evidence-based practices and reduce overdoses and fatalities from opioid use disorder.

Conclusion

I look forward to working with you and the Members on this Committee to advance meaningful legislation built on a comprehensive response that includes prevention, treatment, recovery, overdose reversal, law enforcement, and criminal justice reform.

Thank you for the opportunity to testify today and for your commitment to addressing such an important issue that impacts millions of American families every single day.

Mr. BURGESS. We appreciate your testimony. Of course we also focused on enforcement during one of our first panels and as well as scientific discoveries to try to expand the universe of medications to treat pain.

Ms. Deal-Smith, you are recognized for 5 minutes, please.

STATEMENT OF CARLENE DEAL-SMITH

Ms. DEAL-SMITH. Good afternoon, ladies and gentlemen. My name is Carlene Deal-Smith. I am a Native American of the Navajo tribe from Farmington, New Mexico. I am employed with Presbyterian Medical Services Totah Behavioral Health Authority. I work with homeless individuals who have substance abuse problems.

Due to my own struggles with alcoholism I am able to assist with what they are struggling with. I understand the impact substance abuse has on their lives, understand them when they say nobody cares, the low self-esteem, and the unemployment they suffer with. The relatives, we call our clients relatives because that is how we relate to them, totah has a program that helps them get their life back.

It takes months, maybe sometimes years for them to achieve sobriety, and being their peer support you have to be consistent with being available to them. Each day is a new day. It doesn't matter if they had a bad day yesterday. Being a peer support you have to model being healthy by your own recovery. A hard day in sobriety can be achieved when you model you are taking care of yourself. Being healthy is the key to help the relatives that still suffer.

I come to you today to show my support for peer support programs. These programs offer more than just support, they offer jobs and independence. Thank you.

[The prepared statement of Ms. Deal-Smith follows:]

My name is Carlene Deal-Smith. I am a Native American Woman of the Navajo Tribe, Master Weaver, and also a recovering alcoholic. I have struggled with my addiction for 20 years and I am 17 years sober. This would not be possible if it weren't for the places I have worked.

I have worked with Substance Abuse Programs for 25 years and I have been employed with Presbyterian Medical Services through their Totah Behavioral Health Authority program for 14 years, 9 months. This program provides services to homeless addicted individuals seeking a better life. Services provided include counseling, Traditional Dine' (Navajo) healing practices, sobering house services, and dormitory housing. I have experienced similar struggles with addiction and homelessness. My past gives me a better understanding of how to approach the specific needs of this population. Not only am I gratified by the services I am able to provide to my relatives (clients) that have substance abuse problems, working as a peer supporter is my way of staying sober myself. I am humbled by their struggles and I see hope for a better tomorrow for them.

Every day on my way to work, I pray to my Creator to give me guidance and ask for the right thing to say to the Joint Intervention Program (JIP) relatives that I work with who suffer from substance abuse orders. Once I get to work, my relatives and I talk about how they can use what they are learning in JIP to get through another day clean and sober. Because I am clean and sober, my experience helps show them it is possible. The relatives in JIP do not know how to cope without their substances. Every day is a struggle for them. I have to listen to them and be present with them in their struggle to hear their pain. I am with the relatives 40 hours a week. Another valuable service I provide at Totah is communicating with staff who do not have a lived experience of substance use disorder to help explain the relatives' struggles on that particular day. In this way I serve as an important intermediary for the relatives and the other behavioral health providers to improve services and outcomes.

I believe Peer Support works because I see the miracles happening each day that I am working with the relatives. Some days are harder than others. For so many people in recovery, simply getting through another day is a big accomplishment. For me, being present with them during this process is a big plus. Being their voice is a big part of their accomplishment, because their addiction has beaten them down so much, they don't like themselves anymore. Every day the JIP relatives are given a daily affirmation and use that throughout the day, to give them something positive to hang on to all day. The longer they are in the program, the more you hear them start to write their own positive affirmations. You can see their self-esteem and self-worth come back. You hear it in their voice; they start to matter again. You see by their appearance that they are taking care of themselves. They want to see how they are doing physically; they want to get an annual physical to see what alcohol has done to them. And most times, they can do something about their wellbeing and they start working on getting healthy.

I'd like to also point out that peer support programs offer more than just support to people in recovery – they offer jobs to people in recovery. When you are in your addiction, and even into recovery, you find yourself feeling "less than". Employment and independence help you feel like you are a part of the world and that you matter. Trying to find a job and transportation are extremely difficult, especially for those of us who have a history of substance use disorder. However, peer support programs make employment possible. I earned my relevant job experience with a lot of struggle and hard work. It makes me proud to be able to turn that struggle into a career that allows me to support myself and help other people recover.

Most of the relatives that we work with are people who are hurt and lost. We give them a safe place to be whole again, mentally, physically, emotionally, financially and spiritually. Like it has for me, peer

support also provides them a career choice to aspire to and give back. I am thankful for Presbyterian Medical Services and the opportunities they have provided to me and to our peers.

In my opinion, increased funding for Peer Support is essential to help overcome barriers that prevent addicted individuals from accessing peer support services as well as those in recovery from obtaining peer support status. I completely support the bill introduced by Congressmen Luján and Johnson.

Mr. BURGESS. The chair thanks the gentlelady for her testimony. Mr. Hampton, you are recognized for 5 minutes, please.

STATEMENT OF RYAN HAMPTON

Mr. HAMPTON. Thank you, Mr. Chairman. Mr. Chairman, Ranking Member Green, and members of the committee, my name is Ryan Hampton. I would like to thank the committee for inviting me to speak on the Ensuring Access to Quality Sober Living Act on behalf of Facing Addiction with NCADD, which represents over 800 community organizations and 75 regional affiliates across the United States, a network now reaching over 35 million Americans.

As a person in sustained recovery and a member of the recovery community, it is an honor to speak about the impact that H.R. 4684 will have on Americans with substance use disorder. I spent a decade struggling with an addiction to heroin. Addiction is not the result of bad decisions, but rather a health condition that is exacerbated by drug use. I am one of millions of Americans affected by it.

Addiction affects people from all backgrounds, constituencies, races, classes, religions, and party affiliations. It does not discriminate. However, unlike other chronic illnesses like cancer and diabetes, we do have a solution. We are not struggling to find a cure. This issue is one that we can address together and prevent further loss of life. One of the ways we can do this is by supporting ethical guidelines for recovery housing.

The person you see sitting in front of you today is in remission from the potentially fatal illness of addiction in spite of the broken system that we have in place. Long waiting lists, abstinence requirements for housing, unscrupulous operators, and unethical treatment practices all undermined my recovery. Some facilities discriminate against harm reduction measures and medication assisted treatment. That is a barrier to access and it kills.

I went through multiple treatment centers, detoxes, and sober living homes before I was finally able to sustain my recovery. Not everyone has been so lucky. I am here today because my friend Tyler died of a heroin overdose in a sober living home. Because there was no naloxone on site and because the home staff weren't trained to deal with overdoses, my friend lost his life.

Not having naloxone in a sober living home is like refusing to put lifeboats on an ocean liner. It doesn't mean that you are planning on a shipwreck. It means that in case of a disaster the passengers will make it safely to land. When I heard how Tyler had died I was outraged and I approached my congresswoman, Judy Chu. Thanks to her help, the support of Facing Addiction and the National Alliance of Recovery Residences, I stand before you today asking for bipartisan support of H.R. 4684 as a solution. I know it is not a silver bullet, but it will help get best practices in recovery housing implemented across the country.

Tyler's death was 100 percent preventable and H.R. 4684 addresses the changes we need in order to ensure that recovery homes are doing what they are supposed to do, saving lives and not endangering Americans. Recovery should never be about luck and it shouldn't be a guessing game for people who are in desperate need of help. H.R. 4684 is a step in the right direction that will for

the first time allow SAMHSA to develop best practices that can be disseminated to states and help people and prevent more tragic overdoses like the one that killed my friend.

Quality, access, care, and choice are key parts of the existing NARR standards for recovery residences. Quality means defining the essential elements of a properly operated recovery residence. Access means providing a road map for developing the full spectrum of recovery housing to better match needs and a blueprint for housing providers to rise to the occasion. Care means evaluating the peer support components of a residences recovery environment. Choice means empowering informed recovery housing choices with regard to placement and resource allocation.

Everyone should have equal access to recovery support services. Not just prevention and treatment, but continuing care that includes peer support and housing. The 2016 Surgeon General's Report on Alcohol, Drugs, and Health, and the White House Commission on Opioids final report both recommend the use of peer recovery supports and recovery housing. Providing ethical and safe housing and support post clinical services is linked to higher rates of recovery.

Without these measures in place we will continue to lose people like Tyler. Millions of Americans who access treatment and continuing care ask for help in good faith. We must ensure that their safety net is strong, safe, and ready to catch them.

And, Mr. Chairman, on a personal note, to close I would like to say that not a single day goes by where I do not think about the friends that I have lost and the people that I have loved that are gone from this crisis, and I showed up to testify today for them, because of them, and in memory of them. Thank you.

[The prepared statement of Mr. Hampton follows:]

TESTIMONY

OF

RYAN HAMPTON

PERSON IN SUSTAINED RECOVERY FROM AN OPIOID USE DISORDER

RECOVERY ADVOCATE, FACING ADDICTION WITH NCADD

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

"Combatting the Opioid Crisis: Prevention and Public Health Solutions."

MARCH 22, 2018

Testimony of Ryan Hampton, Facing Addiction with NCADD

in Support of H.R. 4684:

"Ensuring Access to Quality Sober Living Act"

U.S. House Energy and Commerce Subcommittee on Health

March 22, 2018

Mr. Chairman, Ranking Member Green, members of the committee: my name is Ryan Hampton and I'd like to thank the committee for inviting me to testify today on H.R. 4684 – the "Ensuring Access to Quality Sober Living Act." As a person in sustained recovery from an opioid use disorder, an advocate, and a member of the recovery community, it is an honor to speak about the impact that H.R. 4684 will have on Americans with substance use disorder. It's meaningful that you've included people in recovery at policymaking tables, so my testimony today feels empowering.

A little about me.

I first became addicted to opioids after a doctor gave me a prescription for painkillers following a hiking injury. I spent a decade struggling with an addiction to heroin. The person you see standing in front of you today is in remission in spite of the broken system we have in place. I have been sober for over three years, yet I tried for much longer to access the limited number of tools available to indigent people with substance use disorder.

For years, when I was in active addiction, I went to free support groups at treatment centers, ate soup and sandwiches at homeless shelters, and put my name on dozens of addiction treatment waiting lists. I had no money, no insurance. No matter where I turned, the answer was usually, "Sorry, we can't do anything for you." At one program, after I'd broken down in front of the director, begging for help, they finally said they could help me. The director took out a thick ringed binder and opened it: it was the treatment

center's waiting list. He said he could put my name on the list, last, after hundreds of other people. I remember realizing how hopeless my situation was. What if I died before my number came up? What if my phone was disconnected? What if I missed the call? I called addiction programs every day. There were no places for people like me, who lacked money, insurance, and family to fall back on.

I did get some help from the free recovery resources I could find. 12 Step meetings, free meals, and low-income or publicly funded facilities provided me with just enough support to keep trying. Few offered same-day services: most were assessment-only. I knew I was deeply sick, and that I would need medication and professional intervention. Surviving until I got the opportunity to get treatment was crucial for a heroin user like me. Then, after I got into a treatment center, I needed help re-entering everyday life. I needed a long term, safe, sober living situation that facilitated my recovery. I didn't need much to stay sober, but the things I needed were absolutely not negotiable.

I needed housing, medical care, and a supportive peer network, and a low barrier to access those things. I needed help, acceptance, and a path out of my addiction.

Along the way, I learned what *didn't* work. Long waiting lists, abstinence requirements for housing, unscrupulous house managers, and unethical treatment practices all undermined my recovery. Some facilities discriminate against harm reduction measures by refusing to stock naloxone. Others will not allow people who use medication assisted treatment. If you're on methadone, you may be unwelcome. That's a barrier to access, and it kills. I, and many of the people I knew, failed to find a safe place to live, or had a single relapse and were forced back into homelessness. The stigma of addiction was reinforced by the very people who were supposed to be helping us. Many of those people are dead now, because the help they needed was withheld.

Even someone as determined and desperate as me struggled to get help. I went through multiple treatment centers, detoxes, and sober living homes before I was able to finally find sustained recovery. My struggle was the result of trying to navigate a fractured system on my own, with no resources and no guide. I truly wanted to recover, and so did most of the people I knew. Yet, I am here today and many of the people I have met on my journey are still out using, or dead.

- Recovery should not be dependent on luck.

Once I knew I needed help, I faced a huge challenge.

High costs and long waiting lists shut me out of treatment for years. There was no clear path to recovery, that I was aware of. I thought I was supposed to go to treatment, where I would magically be cured of my addiction. I knew nothing about sustaining recovery, or what happened after the standard 28-day treatment.

Yet, those 28-day programs weren't available to me. I was forced to continue in my addiction while I sought help. This was a problem: first, I could have overdosed and died before I ever got the chance to get sober. Second, many places that offered support made it clear that if I couldn't pass a drug test, I wouldn't be welcome. Housing, treatment, and medical care were offered only to people who were "clean." Conditional support made recovery impossible for someone like me, who needed medical detox and inpatient treatment. I explained to more than one gatekeeper that if I'd been able to stop on my own, even for a day, I would have. However, my addiction was in control, and those doors were closed to me.

Third, there were more challenges beyond just stopping my heroin use. I was unemployable in early sobriety. I had some skills, but no idea how to find work or explain to an employer why I hadn't been able

to hold a steady job for the last decade. I had nowhere to live; no car, no bank account, and no credit history. Even when I was sober, I didn't have the tools I needed to re-enter society and contribute in a productive way. I wanted those things, but had no idea how to attain them. I may as well have been wishing for the moon. Again, because there was no clear path for me, I went in circles.

- Every day I spent seeking help could easily have been my last day alive.

Most importantly, I needed a place to live.

Finding recovery housing was even more difficult than finding treatment. After I'd gotten a bed in a residential treatment, with financial help plus a "scholarship" to offset the cost of treatment, I was homeless. Everything I owned fit into two garbage bags, which I lugged with me from place to place. The stress and anxiety that I felt from not knowing where I would live was incapacitating. One time, I was able to find sober living shortly after treatment, but the owner was not a trustworthy person. The "sober residence" was essentially a flophouse, with no recovery support, no oversight, and no peer network. At least one of my roommates was actively using heroin. That home's owner was arrested shortly after I moved in, and convicted of a crime. When I relapsed, I quickly went back to my old life. Without safe, sober housing, all my hard-won sobriety fell apart.

The 2016 Surgeon General's Report on Addiction Alcohol, Drugs and Health and the White House Commission on Opioids Final Report both recommend the use of peer recovery supports and recovery housing[1,2]. A recent study by Harvard's Recovery Research Institute (RRI) found that, "because it can

[1] U.S. Department of Health and Human Services (HHS), Office of the Surgeon General, Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health. Washington, DC: HHS, November 2016.

take some time after abstinence has been initiated for the brain systems to recalibrate and to adapt to the absence of drugs, services should be provided in an ongoing way after an acute residential or outpatient treatment."[3] Providing ethical, safe housing and peer recovery support post clinical services is linked to higher rates of recovery.

I realized, through painful trial and error, that my recovery relied on support that wasn't there. Guaranteed access to quality sober living would have made an immense difference in my recovery. Instead of facing stigma, rejection, and shame at every turn---instead of being told that I needed to cure myself of my own chronic illness before I could access shelter and medical care---I would have been able to focus on the difficult task of getting healthy again.

Even if you do not believe that access to addiction treatment and recovery supports like housing is the humane thing to do, the economic costs of *not* treating this illness are staggering. In November of 2017, the White House Council of Economic Advisors found that in 2015 alone, the cost of the opioid epidemic was over $500 billion. Increased costs to state Medicaid programs, emergency room visits, and hospital admissions and readmissions all drove this economic impact, not to mention criminal justice costs.

Some people may say that people with substance use disorder "brought it on themselves," and that *they* are the problem, not the system. To that, I say that science shows that the adolescent brain doesn't fully mature until after the age of 25. Many people use substances for the first time, prescription or otherwise, at a very young age. Holding an adult responsible for the uninformed decision they made with an immature adolescent brain doesn't make sense.

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[2] Office of National Drug Control Policy, President's Commission Final Report. Washington, DC. Retrieved March 16, 2018 from https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf

[3] Recovery Research Institute. Is Residential or Outpatient Treatment Alone Enough to Treat Substance Use Disorders? Retrieved March 16, 2018 from: https://www.recoveryanswers.org/research-post/is-residential-or-outpatient-treatment-alone-enough-to-treat-substance-use-disorders/

- Without a place to call home, it is nearly impossible to get sober.

I made it my mission to work day and night on this public health crisis.

As I grew in my recovery, I met other people who shared my beliefs about recovery access. Through Facebook, I connected with Greg Williams at Facing Addiction with NCADD. We talked about how people with substance use disorder were underrepresented in the media and in politics. Although the drug epidemic was already claiming 100+ lives every day, it seemed like nobody was talking about recovery, or the thousands of families, friends, and grassroots advocates who were on the front lines, saving lives.

Together, Greg and I made a plan: I'd take a cross-country road trip through America's heartland, talking to people affected by addiction. My best friend Garrett Hade, a small crew, and I piled into the vehicle and we set off. I didn't imagine we'd make history, but here we are. Over the next month, I filmed a series of short interviews. The documentary series, *AddictionXAmerica*, was viewed by over 1 million people and shared thousands of times. I was pleased: a national conversation was happening. People started talking about addiction like a disease, not a moral failing. The drug epidemic was a health crisis, a national emergency that political leaders and policymakers were choosing to ignore. When I came home to California, I felt energized and empowered.

- Raising awareness about addiction, and talking about recovery, is my mission.

Then my friend Tyler died – and no one was accountable.

Yet, all the awareness in the world is meaningless if we do not implement meaningful change. I'm here today because my friend Tyler died of a heroin overdose in a sober living home just a few blocks from my apartment. His body was found in the living room. Because there was no naloxone on site, and because the home staff weren't trained to deal with overdoses, my friend lost his life. Not having naloxone in a sober living home is like refusing to put lifeboats on an ocean liner. It doesn't mean that you're planning on a shipwreck: it means that, in case of a disaster, the passengers will make it safely to land.

When I contacted the residence's manager, I was brushed off. Nobody cared that my friend was dead. They didn't care that his death was preventable. They focused on his "choice" to use heroin, which anyone with experience with substance use disorder will tell you is a fallacy. There is no "choice" for people who are struggling with addiction. Our survival should not be conditional: we need help, not judgment and shame.

Tyler's tragic death was met with indifference. Nobody was held accountable. To my knowledge, the sober residence where he died has not changed their policy. A few weeks after Tyler's death, I contacted local sober livings in Pasadena and offered to do a free naloxone intervention training with clients. All but one told me they weren't interested: they said that naloxone encourages people to use.

- This ignorance and indifference places people in recovery housing at risk of death.

H.R. 4684 is the result of a community conversation with Congresswoman Judy Chu.

I was distraught, so I sought a solution in the only place I know to be effective: my Congresswoman's office. Congresswoman Chu agreed to meet with me, and listened to my story about my friend. Together, we discussed some possible solutions to this unaddressed problem. We are here today as a result of her willingness to help, and her support of the recovery community.

One way for policymakers to improve policy is to include people and families with lived experience in recovery from SUD at policymaking tables at the state and federal levels. Congresswoman Chu did that, and as a result, I'm able to give testimony on this meaningful and impactful piece of legislation. Including people from the recovery community could inject new proven successful policy prescriptions to this effort.

- Now, we have an opportunity to save lives by ensuring access to quality sober living.

H.R. 4684 is important. It's life or death.

As we are sitting here, someone will die in a sober home because the residence doesn't have naloxone on hand. Someone else will die because they were kicked out after a relapse. We can't let that happen. Individuals who relapse should be provided other recovery options, rather than being kicked out. They could be moved to another house or referred to treatment: that way, they won't endanger anyone else, and they'll still continue receiving help.

Without ethical measures in place, we'll continue to lose people like Tyler. Millions of people who access treatment and continuing care ask for help in good faith: we need to ensure that their safety net is strong, safe, and ready to catch them.

When a mother or father takes their child to sober living, they should be able to have confidence that they're leaving their child in good hands. Sober residences are a key part of continuing care.

- We should have a standard in place that ensures that these homes are what they say they are, and are equipped to do what they're supposed to do.

We need national standards for sober housing.

I'm here today because Congresswoman Chu listened to my concerns, and asked for my support of this critical bill. Thanks to her, the support of Facing Addiction with NCADD, which represents over 800 community organizations across the U.S. and 75 regional affiliates across the U.S., a network now reaching over 35 million Americans, as well as Students for Opioid Solutions (SOS) and the National Alliance of Recovery Residences (NARR), I ask for bipartisan support of H.R. 4684 as a solution. I know it's not a silver bullet, but it will help get best practices in recovery housing implemented across the country so those who don't implement them can be held accountable by their states.

My friend's death was 100% preventable, and H.R. 4684 addresses the changes we need in order to ensure that recovery homes are doing what they're supposed to: saving lives, not endangering Americans. Recovery should not be about luck, and it shouldn't be a guessing game for people who are in desperate need of help. The Betty Ford Institute Consensus Panel defined recovery as "a voluntarily maintained lifestyle characterized by sobriety, personal health, and citizenship." Similarly, the Substance Abuse and

Mental Health Services Administration (SAMHSA) defines recovery as "a process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential." Sober housing is a key part of the recovery process, and a vital stepping stone to helping people reach their potential. The NARR Standards for recovery emphasize dignity, choice, and safety.

Quality, access, care, and choice are key parts of the NARR Standards for recovery residences. H.R. 4684 is a step in the right direction that will for the first time develop a national standard that can be disseminated to states and help people---and prevent more tragic overdoses, like the one that killed my friend.

- Quality means defining the essential elements of a properly operated recovery residence that everyone in our communities should demand.
- Access means providing a roadmap for developing the full spectrum of recovery housing to better match needs and a blueprint for housing providers to rise to the occasion.
- Care means evaluating the peer support components of a residence's recovery environment.
- Choice means empowering informed recovery housing choices with regard to placement and resource allocation.

Recovery should be a peer-based system, and sober living helps build the peer network that is linked with greater success in recovery from substance use disorder. In addition to the cost savings, peer based environments are a model for later in life and teach you how to nurture your recovery. Their effectiveness is supported by evidence in the U.S. Surgeon General's Report on Alcohol, Drugs, and Health:

> *Recovery-oriented Systems of Care (ROSC) embrace the idea that severe substance use disorders are most effectively addressed through a chronic care management model that includes longer term, outpatient care; recovery housing; and recovery coaching and*

management checkups. Recovery oriented systems are designed to be easy to navigate for people seeking help, transparent in their operations, and responsive to the cultural diversity of the communities they serve.

Treatment in recovery-oriented systems is offered as one component in a range of other services, including recovery supports. Treatment professionals act in a partnership/consultation role, drawing upon each person's goals and strengths, family supports, and community resources.

On a systems level, outcomes from Connecticut's Department of Mental Health and Addiction Services (DMHAS) ROSC initiative have demonstrated a 46 percent increase in individuals served, with 40 percent using outpatient care at lower costs, resulting in a decrease of 25 percent annual cost per client and a 24 percent decrease in overall treatment expenses.

- Sober living standards mean lower costs, longer recovery, and healthier communities.

The NARR standards are crucial.

Requiring a standard of care is not an overreach. We must require sober homes to use evidence-based practices, without turning them into medical facilities. Recovery housing should feel like home: a safe place. It should be free of unlawful drug and alcohol use, a place to connect with community and learn new skills.

The period where someone would live in recovery housing is post-treatment. It may overlap with outpatient care, but it's not the same thing as medical care and shouldn't be put in the same category.

While there are some recovery residences that provide clinical services, they are more expensive and not affordable for most. That's why we should approach sober living as a separate aspect of recovery, not an extension of treatment.

Furthermore, it's important to keep costs low in order to remove barriers to recovery. Many people who need help are like I was: no insurance, no money, and no family to fall back on. To improve access, we need to keep sober living separate from healthcare.

- Evidence shows that, when we invest in recovery supports in the first five years, we are investing in future sobriety. Low costs correlate to long term success: there's no need to increase spending, just raise our standards.

I'm offering five guiding principles to Members of Congress and other leaders who want to support recovery.

These are non-partisan guiding principles to help end the greatest public health crisis of our time. There are ways that both parties can help end this health crisis, but I am optimistically looking at a bipartisan goal.

1. Humanizing Addiction for Both the Afflicted and the Affected

People with substance use disorder are smart, caring, compassionate, bright, creative, everyday Americans. We are your neighbors. Our kids go to school with your kids and sleep over at our houses. We live with a chronic disease, and we are responsible for its remission.

We need to be out, loud, and proud so the world sees who we are. We need leaders who sit with us and walk among us; speak with us in town halls; visit recovery night celebrations, and participate in our rallies.

2. Suffering From Addiction Is Not a Crime—Reforming Public Safety Responses

This means not locking up people who are addicted to illegal drugs. It does not mean legalizing dangerous drugs: rather, it means not turning people with substance use disorder into criminals. We need to stop locking people up without treatment, rendering them unemployable, and letting their addiction progress in prison. People who commit nonviolent crimes because of their addiction should have their charges and sentences commuted, once they have achieved successful recovery.

Criminal justice reform is an opportunity for every elected official to make a profound difference in ending the crisis by voting for measures that support recovery.

3. Dramatically Expanding Prevention, Screening, and Early Intervention Programs

So many lives could be saved and repaired if our government funded the evidence-based measures of the White House Opioid Commission. In proportion to the actual need, we need more funding. We may never meet the total need, but we require elected officials to allocate, earmark, designate, and pass deliberate budgetary support to combat addiction. We've got to make treatment universally available. We can't let Congress unanimously pass a parity law and then let it disappear by ignoring its enforcement.

4. Promoting Multiple Pathways of Recovery for Individuals and Their Families

Leaders must support the obvious clinical solutions and expand treatment. More importantly, they must support things like medication-assisted treatment on equal par with abstinence- based programs. Faith-based groups like Catholic Charities and Jewish Family Services that provide addiction care to everyone should receive government grants for their work. We're going to recognize faith as a pathway to recovery.

We're going to show that there isn't one definition of recovery and that there are no absolutes in treatment. Nobody is "less worthy" because of the way they reached remission.

5. Mainstreaming Addiction Health Services

We will treat addiction health services just like every other medical service: with parity and accountability. This means increasing the amount of credit hours about addiction a student is required to take in medical school about addiction. We need standardized screenings and other recovery support tactics, right in your primary care physician's office. We should require sick leave and other employer support for a worker battling addiction. Companies that employ those seeking recovery should receive tax credits. We need to ensure that communities build and nurture adequate treatment availability relative to their population, the same way we expect hospitals to.

After three years in sustained recovery, I am not only surviving. I'm thriving. I am employed, live in my own apartment, and have an incredible circle of friends and family who love and support one another.

In closing, my path to recovery was long, painful, and blocked by many barriers. Those obstacles, if removed, would create a better quality of life for people in recovery, lower costs for states and the federal government, and healthier communities.

Thank you for including my testimony today. As policymakers continue to make decisions about our nation's addiction crisis, it is meaningful to keep inviting people in recovery and families to the table. I know that, in partnership, we'll continue facing addiction together and end this public health crisis, once and for all.

Addendum 1: NARR and National Standards

An Overview From Internal NARR Documents

NARR Beginnings

NARR was founded in 2011 by a group of recovery leaders from across the country, all of whom shared a vision for creating a national unifying body dedicated to the support of, and advocacy for, ethical, quality recovery residences, unified in a commitment to best practices. Some leaders came from established state associations such as the Georgia Association of Recovery Residences (GARR), California Association of Addiction Recovery Resources (CAARR, now CCAPP), and Texas Recovery Oriented Housing Network (TROHN). Their initial goals were to codify recovery housing best practices, describe and categorize the many varieties of recovery housing existing across the country, and develop a standardized terminology bridging regional usage variations and permitting a national dialogue based on a shared framework. The group also sought to codify a framework for providing support services and quality assurance to statewide systems of recovery housing, based on the experience of a few long-established state-level organizations.

The founding group provided assistance to other individuals invested in developing new state and regional associations that would collaborate with the national entity, leading to the creation of the Florida Association of Recovery Residences (FARR), Ohio Recovery Housing and a few other organizations. Additionally and importantly, leaders from the Association of Halfway House and Alcoholism Programs (AHHAP) contributed wisdom, intelligence and ultimately merged with NARR to forward the goal of evolving best practices to create and implement a national Standard. [1, 2]

As of this writing NARR recognizes 28 state and regional affiliates, supporting approximately 2,300 recovery residences that provide homes for 25,000 recovering individuals. NARR has become more than an association – it is a movement raising the standard of operation for all recovery residences.

About the NARR Standard

It was clear from discussions leading to the formation of NARR that the most pressing national need was a set of standards that defined best practices for the various recovery housing modalities in existence. Work on the version 1 standard began in the year before NARR was formally incorporated. The effort drew on experts from around the country, including experienced providers, behavioral health professionals, state government officials and addiction researchers. Although starting with a blank canvas, the standard was developed with a few principles in mind:

- It needed to provide comprehensive guidance about the ethical operation of the full spectrum of recovery residences.
- The standard's primary purpose would be protection of the individual resident, and the individual seeking recovery in a standards-compliant residence.
- The basis of the standard would be the social model of recovery, emphasizing the peer-to-peer nature of the residential recovery experience.
- The standard needed to support a variety of abstinence-based paths to recovery.
- It would support a variety of operating models and recovery philosophies, and would not dictate the programmatic elements of operating a residence.
- The standard would provide comprehensive protection for residents, but would be achievable even by a low-cost residence.

The first version of the standard (2011) achieved those objectives, and was well received by operators, state recovery housing organizations and the professional community. Principal objections were that some

of the rules were more aspirational than concrete, and it was difficult to create rule-based systems for verifying compliance. Version 2 (2015) addressed those concerns with a new structure, and rules designed to be amenable to objective verification procedures. The new standard is also level-specific, since some essential rules are not applicable to all four of NARR's defined levels of recovery support. The new version also more formally incorporates social model principles and metrics. The standard covers these basic areas:

- Health and safety requirements; resident space requirements
- Operational rules including record keeping, financial integrity, staff training and supervision
- Resident rights, including rights to be fully informed about rules, fees and residence expectations affecting the resident; privacy, confidentiality; rights to file unresolved complaints with oversight organization
- Appearance and upkeep of the physical environment (dwelling, furnishings, grounds)
- Good neighbor policies and practices
- Maintenance of a peer-oriented recovery environment; respect for individual choice in recovery engagement; recovery activities and programming; abstinence verification

A Code of Ethics was released in 2016, designed to complement the standard, and applicable to all residence operators and staff.

The current version of the Standard for Recovery Residences and Code of Ethics are available on the NARR website, narronline.org.

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Addendum 2: The Role of Recovery Residences in Promoting

Long-term Addiction Recovery

A Policy Statement from The Society of Community Research and Action – Community Psychology, Division 27 of the American Psychological Association

Executive Summary

Addiction and the larger arena of alcohol and other drug (AOD) abuse and related problems exact an enormous toll on individuals, families, organizations, local neighborhoods, and whole communities in the United States. Although a great number of advances have been made in AOD treatment, far too few individuals who could benefit from treatment receive it, and many who do receive treatment will resume AOD use following their discharge from it. New recovery support institutions are emerging beyond the arenas of traditional addiction treatment to support individuals hoping to initiate and to sustain long term recovery from addiction. One promising mechanism is the recovery residence.

Recovery residences (e.g., sober living houses, recovery homes, and Oxford Houses) are sober, safe, and healthy living environments that promote recovery from AOD use and associated problems. At a minimum, recovery residences offer peer-to-peer recovery support with some providing professionally delivered clinical services all aimed at promoting abstinence based, long-term recovery. Recovery residences are sober living environments, meaning that residents are expected to abstain from alcohol and illegal drug use. Each credentialed recovery residence publishes policies on relapse sanctions and readmission criteria and other rules governing group living. Recovery residences may require abstinence from particular types of medications according to individual policy. Although the exact number is currently unknown, many thousands exist in the United States.

A small but growing body of research supports the effectiveness of recovery residences in sustaining abstinence and promoting gains in a variety of other domains, and the National Association of Recovery

Residences has developed guidelines to define levels of care and standards to ensure the quality of care received. Yet, despite these advances, recovery residences face innumerable challenges. Critical questions regarding the operations and effects of recovery residence participation remain unanswered, and research scientists wishing to study recovery residences face considerable funding challenges given the prevailing funding emphasis on the neuroscience of addiction. Efforts to establish or relocate recovery residences face challenges with start-up funding and often face considerable neighborhood and political opposition. Also of importance, many health and human professionals are unaware of recovery residences and their benefits on long-term recovery outcomes.

The Society of Community Research and Action (SCRA) has developed, with the executive, advocacy and research committees of the National Association of Recovery Residences (NARR), a policy statement on the value of recovery residences in the United States. This policy statement 1) describes the emergence and rapid growth of recovery residences as a new addiction recovery support institution, 2) highlights research to date on the positive effects of participation in a recovery residence on long-term addiction recovery and related outcomes, 3) champions a research agenda that would address many unanswered questions related to such participation, 4) advocates social policies (laws, regulations and funding guidelines) in which recovery residences can flourish, 5) supports programs of education and training to increase referrals to these new resources by health and human service professionals, and 6) promotes programs to educate local political leaders and the public about the value of recovery residences for individuals, families, and communities in the United States.

Background

Addiction and the larger arena of alcohol and other drug (AOD) and related problems exact an enormous toll on individuals, families, organizations, local neighborhoods and whole communities in the United States. Since the mid-twentieth century, an elaborate network of professionally-directed addiction treatment programs has been funded to respond to these problems, but more than half of individuals

treated in these institutions will resume AOD use following their discharge from treatment—most often in the first 90 days following discharge. Assertive continuing care and support is not a routine component of addiction treatment in the United States and only a small percentage of persons treated participate in post-treatment continuing care, which involves post-treatment monitoring and support. There are growing calls to shift acute care models of addiction treatment to models that emphasize sustained, post-treatment recovery management in order to elevate long-term recovery rates and enhance the quality of personal and family life in long-term recovery. Recovery management is a philosophical framework for organizing addiction treatment services to provide long-term recovery maintenance and quality-of-life enhancement for individuals and families affected by severe substance use disorders.

New recovery support institutions are emerging beyond the arenas of addiction treatment and recovery mutual aid societies to achieve these goals. By providing a physical and social world to recover within, these new institutions (e.g., recovery residences, recovery schools, recovery industries, recovery ministries, recovery community centers, recovery cafes, etc.), mark a major milestone in the history of recovery in the United States. One of the earliest to develop and one of the most important of these new institutions is the recovery residence.

Recovery residences (e.g., sober living houses, recovery homes, and Oxford Houses) are sober, safe, and healthy living environments that promote recovery from AOD use and associated problems. The number of recovery residences in the U.S. has grown dramatically in the past 25 years and have helped fill the void of community support between professionally directed addiction treatment and peer-led recovery mutual aid societies. The purpose of a recovery residence is to provide a safe and healthy living environment to initiate and sustain recovery—defined as abstinence from alcohol and other non-prescribed drug use and improvement in one's physical, mental, spiritual, and social wellbeing. Individuals build resources while living in a recovery residence that will continue to support their recovery as they transition to living independently and productively in the community. Although recovery is commonly believed to refer to abstinence and a general sense of quality of life, recovery is by no means

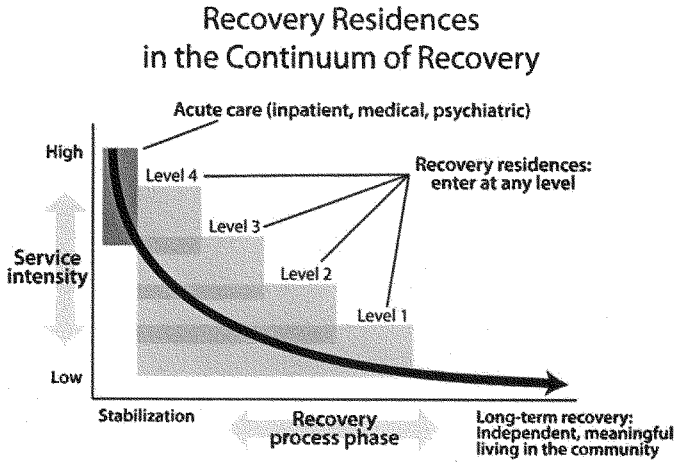
a simple construct that has uniform definition (i.e., some individuals define it as abstinence only from their primary drug; or as use of alcohol, but no drugs; or as no use of "hard drugs" but use of marijuana, or allow for use of "medical marijuana.")

There is growing consensus that recovery from severe substance use disorders involves three critical components: sobriety, improvement in global (physical, emotional, relational, spiritual) health, and citizenship (positive community reintegration). Recovery residences are abstinence-based environments that provide mutual support for these three elements of recovery -in contrast to "wet housing" that allows residents to use alcohol or other drugs or "damp housing" that discourages but does not exclude persons for using and that do not address these larger recovery processes.

A recent publication, *A Primer on Recovery Residences in the United States* (Jason, Mericle, Polcin, White, & the National Association of Recovery Residences, 2012), released by the National Association of Recovery Residences based on a review of all materials published on recovery residences to date found that:

• Although the exact number of recovery residences is currently unknown, there are many thousands of such residences operating in nearly every state across the nation;

• Recovery residences in the U.S. span from low to high service intensity and meet the needs of residents at various stages of recovery (see figure below):



• Most individuals in recovery residences have past or current involvement in addiction treatment and participate in 12-Step or other recovery mutual aid organizations during their time in the recovery residence.

• Participation in a recovery residence decreases in-treatment and post-treatment relapse rates and significantly increases recovery outcomes (using such recovery measures as sustained abstinence rates, improvements in global health and social functioning—e.g., high rates of employment) at up to two-years of follow-up. Longer-term (5-10 years) follow-up studies have not yet been conducted.

• These benefits extend to women, women with children, African-Americans, and persons with co-occurring psychiatric diagnoses.

• These benefits are contingent on adequate lengths of stay (more than 6 months in level I recovery residences) and a supportive community environment.

• The cost-effectiveness of recovery residences has not yet been rigorously investigated. However, some recovery residences, such as Oxford and California Sober Living Houses, are self-financed primarily through resident fees.

• Research to date generally finds that recovery residences do not negatively affect neighborhoods and may even provide benefits to the communities in which they are located.

Some recovery residences are designed specifically for individuals with certain needs (e.g., co-occurring addiction and severe mental illness, veterans, mothers with children); however, some recovery residences may not be equipped to adequately meet these residents' needs. Individuals with specific service needs seeking recovery residences should ask the provider about how these needs can (or cannot) be addressed within a particular residence. It is still unclear if outcomes differ for people with co-occurring disorders (mental health, process addictions, major medical issues such as Hepatitis C or HIV) living in recovery residences.

Recovery residences are divided into Levels of Support based on the type as well as the intensity and duration of support that they offer. Services provided span from peer-to-peer recovery support (all recovery residences) to medical and counseling services (recovery residences offering higher levels of support). The National Association of Recovery Residence Standards defines minimum services for each Level of Support, but additional services may be provided at each level. Section 5 of the National Association of Recovery Residences Standards, included in *A Primer on Recovery Residences in the United States*, details the minimum required service elements for each Level of Support. National Association of Recovery Residence-certified recovery residences meet standards addressing safety from an administrative, operational, property, and good neighbors' perspective. Recovery residences' internal governance varies across National Association of Recovery Residence Levels of Support. Forms of governance range from democratically run by the residents to oversight by licensed professionals. The regulation of recovery residences vary from state to state, local government to local government, and

model to model. In general, states regulate professional services and local governments regulate health and safety standards. Both state and local government regulation must adhere to federal laws and limits, such as the Americans with Disabilities Act and the Fair Housing Act.

The National Association of Recovery Residences, established in 2011, currently represents approximately 1,500 residences through its local organizational affiliates. The National Association of Recovery Residences advocates for recovery residences and their residents at the national and local levels. Members of the National Association of Recovery Residence maintain standards for recovery residences of all kinds across the four National Association of Recovery Residence Levels of Support, from Level 1 peer-operated residences to Level 4 residences offering a wide variety of treatment and recovery support services. Three additional recovery residence organizations exist with a national scope. The oldest is the Association of Halfway House Alcoholism Programs, founded in 1958, and all are now affiliated with the National Association of Recovery Residences. The members of the Association of Halfway House Alcoholism Program include all of the National Association of Recovery Residences Levels of Support. The Association of Halfway House Alcoholism Program's residences operate in accordance with social model recovery principles. Oxford House Inc. was established in 1975 and supports Oxford Houses internationally. Oxford Houses are National Association of Recovery Residence Level 1, with each residence operated solely by the residents in accordance with Oxford House guidelines. Oxford House Inc. supports and promotes its model for peer operated recovery residences through training, technical assistance, and access to startup financing. They also advocate for recovery housing rights and provide legal support to Oxford Houses involved in disputes with cities and towns over their right to exist. Treatment Communities of America (formerly Therapeutic Communities of America) represents more than 600 residential addiction treatment programs in the United States.

Recovery residences face innumerable challenges in spite of their rapid growth and positive findings on their effects on recovery outcomes. Critical questions regarding the operations and effects of recovery residence participation remain unanswered, and research scientists wishing to study recovery residences

face considerable funding challenges given the prevailing funding emphasis on the neuroscience of addiction. Efforts to establish or relocate recovery residences face challenges with start-up funding and often face considerable neighborhood and political opposition. Also of importance, many health and human professionals are unaware of recovery residences and their benefits on long-term recovery outcomes.

Recommendations

In light of these findings and circumstances, the Society of Community Research and Action (SCRA):

1) Recommends that national, state, and local agencies support local networks of recovery residences. Specially, the SCRA calls upon:

• The Substance Abuse and Mental Health Services Administration to develop funding mechanisms to support the development, sustainment, and expansion of recovery support services specific to housing.

• The Department of Housing and Urban Development to develop funding mechanisms to support the development, sustainment, and expansion of housing services specifically for individuals in recovery from behavioral health disorders.

• The National Association of Recovery Residences to disseminate national standards for recovery residences and to provide technical assistance for local organizations to meet these standards as a means of improving the quality of local recovery residences in the United States. This is of particular importance in order to deal with a perception by some that relapse is common among residents in recovery homes, they are often in unsafe neighborhoods, and many are disorganized and even exploitive of residents.

• Single State Authorities on alcohol and other drug problems to establish loan funds and other mechanisms that will support the development of recovery residences where the need for such resources has been established.

• The National Conference of State Legislatures, the United State Conference of Mayors, and the National League of Cities to develop policy documents and host webinars and conferences related to the issues surrounding the development of supportive housing for recovering individuals in local communities.

2) Recommends enhanced funding for critical research related to recovery residences. The SCRA calls upon:

• The National Institutes of Health (the National Institute on Alcohol Abuse and Alcoholism and the National Institute on Drug Abuse) to fund research related to recovery residences, including randomized clinical trials, long term outcome studies, cost-effectiveness studies, and studies that isolate the most potent ingredients of the recovery residence model of recovery support.

We need recovery outcome and cost savings data across the Levels of Support for various populations (including co-occurring, re-entry with criminal mindsets, etc.) recovering from a diversity of chemical substances in comparison to or in combination with alternative approaches. Without published research and evidence-based practice designations, licensed professionals and policymakers will continue to question the legitimacy of recovery residences and peer-based recovery.

• The Substance Abuse and Mental Health Administration's Center for Substance Abuse Treatment to fund evaluations studies related to the integration of recovery residences and related recovery support institutions (e.g., recovery community centers, recovery schools, recovery industries, recovery ministries) within the network of health care initiatives being launched by state and federal government.

Federal, state, and local funding sources to prioritize recovery residence research studies that address 1) the effects of participation in a recovery residence on treatment retention/completion and post-treatment relapse and recovery rates as well as measures of global health and social functioning—e.g., high rates of employment) at longer-term (5-10 years) intervals, 2) the degree of benefits living within recovery residences extends to women, women with children, African-Americans, and persons with co-occurring

psychiatric diagnoses, 3) the degree to which benefits are contingent on adequate lengths of stay (more than 6 months in level I recovery residences) and a supportive community environment, 4) the relative cost-effectiveness of recovery residences, and 5) the effects of recovery residences on neighborhoods and communities in which they are located. These are all high priority areas for research that is needed to develop a more solid basis for our understanding of recovery residences and their impacts on residents and communities.

• National Association of Recovery Residences to increase their presence at key national conferences (National Association of Addiction Treatment Providers, the American Society of Addiction Medicine, and the American Association for the Treatment of Opioid Dependence) to engage the research community on the need for research on recovery residences.

• Editors of addiction-related professional and trade journals to continue to publish studies and reviews and special issues on the effects of participation in a recovery residence on long-term recovery outcomes.

3) Recommends strategies to educate and train addiction treatment professionals and allied health and human services professionals on the value of recovery homes. The SCRA calls upon:

• The APA to disseminate this policy document to all APA members as well as to other major related professional associations (e.g., the American Psychiatric Association, the National Association of Social Workers) with the recommendation that the latter develop and disseminate policy statements on recovery residences and related recovery support institutions.

• College and university addiction studies programs, independent addiction counselor training programs, and educational and training programs for psychiatrists, psychologists, and social workers to integrate information on recovery residences within their respective curricula.

• The national network of Addiction Technology Transfer Centers to disseminate information on recovery residences, including assertive referral procedures that can be used to access such resources and how

recovery residences can be integrated into a continuum of care supporting long-term personal and family recovery from substance use disorders.

• The major addiction professional certification bodies [including NAADAC: The Association of Addiction Professionals, the International Certification & Reciprocity Consortium (IC&RC), the American Board of Addiction Medicine, and state addictions counselor certification boards] to integrate questions related to recovery residences into certification exams and their respective continuing education programs.

• The American Society of Addiction Medicine to formally recognize recovery residences as a level of care within its Patient Placement Criteria.

4) Recommends public education strategies that will address the stigma and misconceptions often attached to recovery homes and their residents. The SCRA calls upon:

• The National Association of Recovery Residences to develop a public edueation campaign on recovery residences aimed at state and local civic leaders and media representatives.

• The National Association of Recovery Residences' regional and state recovery residence consortia to collaborate with leading recovery advocacy organizations to incorporate issues related to recovery housing within larger recovery advocacy and anti-stigma campaigns.

• The Legal Action Center to develop a kit for local recovery residences on how to respond to NIMBY hysteria and discrimination related to recovery housing regulations and their enforcement.

• The Substance Abuse and Mental Health Services Administration (SAMHSA) and the National Association of Recovery Residences co-develop a recovery residence press kit and a webinar that could be incorporated into SAMSHA's 2013 Recovery Month activities.

Having reviewed the available scientific evidence on recovery residences, we believe these actions will play a significant role in elevating long-term addiction recovery outcomes in the United States and contribute to the quality of life of individuals, families and communities throughout the country.

The proposed policy statement was written by the National Association of Recovery Residences (NARR) research committee and approved by the NARR executive committee before submission to the SCRA. The NARR research members include Leonard A. Jason, PhD, Director, Center for Community Research, DePaul University; Amy A. Mericle, PhD, Research Scientist, Treatment Research Institute; Douglas L. Polcin, EdD, Senior Scientist, Alcohol Research Group; and William L. White, MA, Senior Research Consultant, Chestnut Health Systems.

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# # #

Mr. BURGESS. And the committee thanks you for your testimony. Dr. Rosenberg, you are recognized for 5 minutes, please.

STATEMENT OF MARK ROSENBERG

Dr. ROSENBERG. Thank you, Mr. Chairman. My name is Dr. Mark Rosenberg and I am the chairman of Emergency Medicine at St. Joseph's University Medical Center in Paterson, New Jersey. I serve on the board of directors of the American College of Emergency Physicians.

So on behalf of St. Joseph's University Medical Center and its 170,000 visits in the emergency department per year, the 38,000 members of the American College of Emergency Physicians, and the great State of New Jersey, I would like to thank the committee for this opportunity to provide testimony in support of two bills: ALTO, the Alternative to Opioids in the Emergency Department Act; and POWER, Preventing Overdose While in the Emergency Room Act.

There are two cornerstones to ending the opioid epidemic, prevention and treatment, and they are represented by these two bills that I am supporting today. The prevention program is Alternative to Opioids, or ALTO, and the treatment program is MAT or the POWER Act, and both are necessary to stop the continued opioid misuse, abuse, and overdose.

Prevention, H.R. 5197 ALTO, was developed by my team at St. Joseph's University Medical Center in New Jersey in 2016 to address the variation in prescribing habits and to decrease the reliance on opioids by emergency physicians. We started the program with a very simple premise, the best way to avoid opioid misuse and addiction is to never start a patient on opioids. The ALTO program is evidence-based protocols using nonaddicting and therapies that target receptor sites and enzymes that mediate the pain. An example is a patient with back pain. Instead of giving them opioids I give them a layered treatment of therapies that include nonaddicting medication and trigger point injections resulting in better pain management and improved patient experience of care.

I am proud to say that after 2 years of implementation at St. Joseph's, the ALTO program has witnessed tremendous success. In the first year there was a 57 percent reduction of opioid use and by the end of the second year there was over an 80 percent reduction of opioid use. These statistics reveal that education, evidence-based clinical treatment protocols, can have a dramatic impact on the fight against opioid addiction and overdose. More importantly, ALTO program can save lives and already there are emergency physician acceptance across the country to use ALTO protocols.

Emergency Department-initiated MAT, or medical assisted treatment, represents the treatment arm of the equation. Let me give you a moment to tell you about every single patient addicted or dependent on opioids or heroin fears going into withdrawal. Patient in withdrawal experiences a feeling of being sick with chills, sweats, GI symptoms, and agitations. These patients either have to do another dose of opioids to stop the withdrawal or they need medical assisted treatment to stop feeling sick and stop the withdrawal.

ED-initiated medical assisted treatment alone has shown positive results in getting patients with substance use disorders into addiction treatment. But MAT, plus a warm hand-off, yields the best opportunity for success in getting patients into addiction treatment as well as decreasing the need for inpatient addiction treatment services.

H.R. 5176 requires that healthcare sites have two essential ingredients that emergency physicians would like: Providers that are trained and licensed to provide MAT, and number two, agreements with community providers and facilities to continue services—the warm hand-off.

We appreciate what Congress has done to help the opioid epidemic. The $6 billion included in the Bipartisan Budget Act of 2018 will be very helpful in turning the tide against opioid misuse. We urge you and your colleagues to not only authorize H.R. 5197 and H.R. 5176, but to support full funding of these programs as well. This is one of the biggest healthcare challenges of our generation. It took many years to get to this crisis point and unfortunately it will take some time to resolve the epidemic.

But we are on the right track. Provide us with ALTO and MAT tools and funding and emergency physicians will be able to provide a better future for our patients as well as society. Thank you.

[The prepared statement of Dr. Rosenberg follows:]

Statement of

Mark S. Rosenberg, D.O., M.B.A., F.A.C.E.P., F.A.A.H.P.M.

Chairman, Emergency Medicine
Chief Innovation Officer
St. Joseph's University Medical Center
Paterson, New Jersey

Board of Directors
American College of Emergency Physicians (ACEP)

Before the
Energy and Commerce Health Subcommittee
U.S. House of Representatives

Hearing on

"Combatting the Opioid Crisis: Prevention and Public Health Solutions"

Presented
March 22, 2018

I. Introduction

Thank you, Mr. Chairman. My name is Mark Rosenberg, D.O., M.B.A., F.A.C.E.P., F.A.A.H.P.M., and I am the Chairman of Emergency Medicine at St. Joseph's University Medical Center in Paterson, New Jersey. In this role, I am responsible for overseeing the care of more than 170,000 adult and pediatric emergency visits annually – at the 4th busiest Emergency Department in the country. I currently serve on the Board of Directors of the American College of Emergency Physicians (ACEP).

On behalf of St. Joseph's University Medical Center, the 38,000 members of ACEP and the great state of New Jersey, I would like to thank the committee for this opportunity to provide testimony in support of HR 5197, The Alternatives to Opioids (ALTO) in the Emergency Department Act, and HR 5176, Preventing Overdoses While in Emergency Rooms (POWER) Act.

As you know, the United States faces a steadily growing crisis of opioid abuse and addiction that has reached epidemic proportions. According to data from Centers for Disease Control and Prevention, in 2016[1]:

- 11.5 million people misused prescription opioids;
- 2.1 million people had an opioid use disorder;
- 42,249 people died from opioid overdoses; and
- The total economic burden to the United States has been estimated to be well over $500 billion.

This opioid epidemic claims the lives of more than 116 Americans every day and more Americans have died each year during the past decade from drug overdoses than motor vehicle accidents.

Just last week, the CDC published new data[2] on this issue that showed a 30 percent increase in opioid overdose visits to Emergency Departments between July 2016 and September 2017. A further analysis of this data revealed opioid overdoses increased for all segments of the population and in all regions, which included:

- 30 percent increase for men; 24 percent increase for women;
- 31 percent increase for people ages 25-34;
- 36 percent increase for people ages 35-54;
- 32 percent increase for people ages 55 and over; and
- 30 percent average increase for most states with the highest average increase of 70 percent in the Midwestern region.

We could endlessly debate the factors that have contributed to the rise of this widespread and deadly epidemic in America, and how best to curb its growth. However, today I am here to discuss two innovative programs that emergency physicians have developed to help ameliorate this epidemic: The Alternatives to Opioids (ALTO) program and Emergency Department-initiated Medication Assisted Treatment (MAT).

II. ALTO

A study published in the New England Journal of Medicine in February 2017, found a wide variation in the prescribing habits of doctors working in the same emergency departments all across the country. In fact, some doctors were three times as likely to prescribe painkillers for patients with similar ailments as their colleagues. This is where the evidence-based protocols of ALTO come in to play.

ALTO was developed by my team at St. Joseph's University Medical Center in New Jersey in 2016 – to address the very issue of variation and over-prescribing. Our multidisciplinary acute pain management program not only helps treat painful conditions for emergency department patients without using opioids, but also helps other patients with drug dependency and addiction. We started this program with a very simple premise: the best way to avoid opioid misuse and addiction is to never start a patient on opioids. Instead of using opioids, which mask or cover up pain, ALTO protocols use an evidenced base approach to manage the pain. ALTO protocols use specific non-addicting drugs and therapies that target receptor sites and enzymes that mediate the pain therefore stopping the pain at the site of the problem. For example, a patient with back pain, instead of receiving an opioid and muscle relaxant, the patient is given a layering of targeted therapies that include non-addicting medications and a trigger point injection resulting in pain management and improved patient experience of care.

I am proud to say that after two years of implementation at St. Joseph's - the ALTO program has witnessed tremendous success. Six months before the program was launched, physicians at St. Joseph's Emergency Department wrote over 4,000 prescriptions for opioids. One year later, with

the use of ALTO protocols, that number decreased by 46 percent. Two years later, we've seen an 82 percent reduction in opioid prescriptions. These statistics reveal that (evidence-based) changes to clinical treatment and protocols can have a dramatic impact in the fight against opioid addiction and overdose. And, even more importantly, the ALTO program can save lives. This is why H.R 5197 and the $10 million per year for three years it provides can help expand access to this evidence-based program to other Emergency Departments across the country.

I would be happy to answer any questions you may have about our ALTO program - including the specific alternative therapies we use in ALTO pain management, the multidisciplinary approach behind the success of ALTO, or the increased interest of ALTO by physicians and Emergency Departments all across the country.

III. ED-Initiated MAT

Another innovative program that has shown positive results in getting patients with opioid use disorders into treatment is Emergency Department (ED)-initiated Medication-Assisted Treatment (MAT). Beyond the high risk of overdose, patients with substance use disorders (SUDs) typically also have complicated health and social conditions and often seek care in the Emergency Department for treatment. This offers emergency physicians a unique opportunity to provide opioid misuse interventions and initiate referrals for continued treatment by appropriately trained pain management specialists, primary care providers, or addictions specialists, especially when confronted with a patient who has just experienced a non-fatal overdose.

Studies published in 2015[3] and 2017[4] showed that ED-initiated buprenorphine, versus simple referral for treatment or a brief intervention, is associated with increased engagement in addiction treatment, reduced use of illicit opioid use, and decreased use of inpatient addiction treatment services one and two months later. Data has shown that two months after their ED visit, 74 percent of patients who were given buprenorphine/naloxone (Bp/Nx) were engaged in addiction treatment, compared with 53 percent in the referral-only group, and 47 percent of those in the brief intervention with referral group.

One of the key elements of H.R. 5176, and frankly any successful ED-initiated MAT program, is the requirement that the health care site have agreements in place with a sufficient number of community providers to ensure a "warm hand-off" from the ED can be established. Initiating MAT in the ED can be the critical difference between a patient with a SUD following through on their addiction treatment or not, but just as important is ensuring sufficient access to and continuation of services in the outpatient setting.

This integrated, coordinated care model has shown great promise and H.R. 5176 is critical to validating that ED-initiated MAT can be not only efficacious, but cost-effective as well. This program can save lives. According to the 2015 study referenced previously, for those patients who were engaged in treatment at follow-up, only 11 percent who had initiated treatment with Bp/Nx in the ED were receiving inpatient care, while that number was 35-37 percent in the other groups.

Over the long-term, we need to also develop an appropriate, sustainable reimbursement structure that will foster and further enable the use of ED-initiated MAT. Such a structure should apply across private payers, Medicaid, and Medicare, given that all these populations can be affected by SUDs, as can any American.

IV. Conclusion

We appreciate what Congress has done so far to help address this opioid epidemic. The original Comprehensive and Addiction Recovery Act (CARA), 21st Century Cures Act, and the Excellence in Mental Health and Addiction Act included many useful programs to help with this national crisis and groups such as St Joseph's, ACEP, America's Essential Hospitals, and the New Jersey Hospital Association, were proud to offer our support for those bills. The financial commitment that lawmakers have made to fund these initiatives, especially the $6 billion that was recently included in the Bipartisan Budget Act of 2018, will be very helpful toward turning the tide against opioid misuse and we urge you and your colleagues to not only authorize HR 5197, The Alternatives to Opioids (ALTO) in the Emergency Department Act, and HR 5176, Preventing Overdoses While in Emergency Rooms (POWER) Act as part of CARA 2.0, but to seek full funding of these grant programs as well.

As you consider the various legislative proposals before your committee, I would like to encourage you to focus on evidence-based programs that promote adequate pain control, health care access, and allows for physician clinical judgment. For the patients I treat in the Emergency Department, there are circumstances when opioids are still the best clinical response to an acute emergency medical condition. Pediatric patients, the elderly, minorities and the cognitively

impaired are patients at high risk of inadequate pain management; and the emergency physician caring for the patient will need to ensure that an appropriate pain management plan in initiated.

It took many years to get to this crisis point and it will unfortunately likely take some time to resolve this epidemic, but we're on the right path. Provide us with the tools to help us administer the most appropriate care for our patients, based on their specific needs and circumstances, and we will provide a better future for them and society.

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[3] D'Onofrio G, O'Connor PG, Pantalon MV, et. al. Emergency department-initiated buprenorphine/naloxone treatment for opioid dependence: a randomized clinical trial. *JAMA*. 2015;313(16):1636-44.

[4] D'Onofrio GD, Chawarski MC, O'Connor PG, et. al. Emergency department-initiated buprenorphine with opioid dependence with continuation in primary care: outcomes during and after intervention. *J Gen Intern Med*. 2017;32:660-666.

Mr. BURGESS. Thank you, Dr. Rosenberg.
Ms. Bohlen, you are recognized for 5 minutes, please.

STATEMENT OF STACY BOHLEN

Ms. BOHLEN. Thank you, Chairman. Chairman Burgess and Ranking Member Green, members of the subcommittee, on behalf of the National Indian Health Board and the 573 federally recognized tribal nations we serve, thank you for holding this important hearing. And in my native language I say, miigwech. I am Stacy Bohlen. I am the chief executive officer of the National Indian Health Board and an enrolled member of the Sault Ste. Marie Tribe of Chippewa Indians in Michigan.

The current opioid epidemic represents one of the most pressing public health crises affecting tribal communities. While this epidemic is impacting many communities throughout America, it has disproportionately impacted tribes and has further strained the limited public health and healthcare resources that are available to the tribes. American Indians and Alaskan natives had the highest rate of drug overdose deaths every year from 2008 through 2015. A 519 percent increase in drug overdose deaths from 1999 to 2015 is also one of our statistics.

These demonstrate the critical need for more comprehensive interventions in tribal communities to improve prevention and treatment measures. The epidemic is so bad that several tribes throughout the country have declared a state of emergency to tackle the crisis. Historical and intergenerational trauma including trauma across the life span, lack of funding at the Indian Health Service, and a failure by states to include tribes in state level prevention and public health programs all contribute to this crisis.

In Minnesota, pregnant American Indian women were 8.7 times more likely to be diagnosed with maternal opioid dependency and American Indian infants were 7.4 times more likely to be born with neonatal abstinence syndrome, meaning that the repercussions of the trauma and this crisis are intergenerational.

But the lack of funding for the Indian health system overall is one of the greatest systemic contributors to this crisis. Deferral of needed care due to lack of funding, physician workforce shortages at IHS, has created greater dependence on opioids. Limited funding means denial of needed care nearly 80,000 times in 2016 alone. Instead of being referred for surgeries or simpler treatments, patients are offered and simply placed on prescription opioid medications to address their pain as they wait for treatment and sometimes they wait for years.

Policy solutions should focus on allowing tribes access to long-term, sustained resources improving data and disease surveillance, and traditional healing approaches. What would we like Congress to do? Well, number one, allow tribes access to the state targeted response to opioid epidemic grants. National Indian Health Board supports the provisions of H.R. 5140 that address this.

We also request that the legislation include a ten percent set-aside for tribes. Direct funding of tribes reinforces the tribal sovereignty and the government-to-government relationship between the federal government and the tribes. It also will ensure that trib-

al communities are directing the programming so it can be most effective.

Number two, establish tribally-specific funding streams such as behavioral health program for Indians modeled after the Special Diabetes Program for Indians. That is outlined in H.R. 3704, the Native Health Access Improvement Act.

Number three, ensure parity between states and tribes in any opioid related legislation advanced by this Congress. This means specifically including tribes as eligible entities and requiring tribal consultation information, data sharing, and funding set-asides at the state level.

Number four, ensure that cultural and traditional healing practices are able to be utilized with Federal resources that includes Medicaid funding. Tribal communities have been healing our own people for thousands of years and these practices are highly effective in the communities where they are used. And five, establish trauma-informed interventions in coordination with tribes to reduce the burden of substance use disorders including those involving opioids.

And we just learned that tribes received a $50 million set-aside in the fiscal year 2018 omnibus for the state opioid response grant and 5 million was set aside for tribal medication assisted treatments. This is very important to us. We know that members of this committee were activists in getting this effort to happen and we say a big thank you, chi-miigwech, and this is an excellent start.

Health information technology and data also represents a serious challenge when it comes to the opioid crisis. I understand that my time is expired and I want to be respectful of the other witnesses, so the rest of my remarks appear in our written testimony. Thank you, Chairman.

[The prepared statement of Ms. Bohlen follows:]

National Indian Health Board

Testimony of the National Indian Health Board
to the Committee on Energy and Commerce, Health Subcommittee

Legislative Hearing on Opioid Public Health and Prevention Efforts
March 22, 2018

Introduction

Chairman Burgess, Ranking Member Green and Members of the Subcommittee, the National Indian Health Board (NIHB) thanks you for holding this Legislative Hearing on Opioid Public Health and Prevention Efforts." On behalf of NIHB and the 573 federally-recognized Tribes we serve, I submit this testimony. My name is Stacy A. Bohlen and I am the Chief Executive Officer of the National Indian Health Board.

NIHB is a 501(c)3, not for profit, national Tribal organization founded by the Tribes in 1972 to serve as the unified, national voice for American Indian and Alaska Native (AI/AN) health in the policy-making arena. Our Board of Directors is comprised of distinguished and highly respected Tribal leaders in AI/AN health. They are elected by the Tribes in each region to be the voice of all 573 Tribes at the national level.

Since 1972, NIHB has advised the U.S. Congress, Indian Health Service (IHS), and other federal agencies about health disparities and service issues experienced in Indian Country. The current opioid epidemic represents one of the most pressing public health crises affecting Tribal communities. While this epidemic is affecting many communities throughout America, it has disproportionately impacted Tribes and has further strained the limited public health and healthcare resources available to Tribes. The federal government must take concrete action to ensure Indian Country has the tools it needs to address opioid abuse and heal Tribal communities.

Trust Responsibility

The federal promise to provide Indian health services was made long ago. Since the earliest days of the Republic, all branches of the federal government have acknowledged the nation's obligations to the Tribes and the unique trust relationship between the United States and Tribes.

The Indian Health Service is the primary agency by which the federal government meets the trust responsibility for direct health services. IHS provides services in a variety of ways: directly, through agency-operated programs and through Tribally-contracted and operated health programs; and indirectly through services purchased from private providers. IHS also provides limited funding for urban Indian health programs that serve AI/ANs living outside of reservations. Tribes may choose to receive services directly from IHS, run their own programs through contracting or compacting agreements, or they may combine these options based on their needs and preferences.

Today the Indian healthcare system includes 46 Indian hospitals (1/3 of which are Tribally operated) and nearly 630 Indian health centers, clinics, and health stations (80 percent of which are Tribally operated). When specialized services are not available at these sites, health services are purchased from public and private providers through the IHS-funded purchased/referred care (PRC) program. Additionally, 34 urban programs offer services ranging from community health to comprehensive primary care. To ensure accountability and provide greater access for Tribal input, IHS is divided into 12 geographic Service

Areas, each serving the Tribes within the Area. It is important to note that Congress has funded IHS at a level far below patient need since the agency's creation in 1955. In FY 2017, national health spending was $9,207 per capita while IHS spending was only $3,332 per patient.

Overview of the Opioid Epidemic in Indian Country

The national opioid epidemic represents one of the great public health challenges of the modern era. The Centers for Disease Control and Prevention (CDC) noted over 64,000 drug overdose deaths in 2016 alone, largely driven by prescription and illicit opioids.[1] Among AI/ANs, the rate of drug overdose deaths is twice that of the general population, according to the IHS. Deaths from prescription opioid overdoses increased four-fold from 1999 to 2013 among AI/ANs.[2] The CDC reported that AI/ANs consistently had the highest drug overdose death rate by race every year from 2008-2015, and the highest percentage increase in drug overdose deaths from 1999-2015 at 519%.[3] Deaths from prescription opioid overdoses increased four-fold from 1999 to 2013 among AI/ANs, with an opioid overdose death rate of 9.6 per 100,000 in 2015 – second only to whites.

Regional data trends further demonstrate the high burden of the opioid epidemic within Tribal communities. According to the State of Alaska Epidemiology Center, AI/ANs had the highest overdose death rate by race from 2009-2014 at 20.2 deaths per 100,000 population. Similarly, the Washington State Department of Health reported that from 2011-2015, the opioid overdose death rate was highest among AI/ANs at a rate of 29 deaths per 100,000 compared to 12 deaths per 100,000 for Whites.

The Indian Health system is chronically underfunded, understaffed and overextended. Limited Tribal and IHS public health and healthcare resources have been further inundated by this highly deadly and superbly costly epidemic. While the treatment and recovery costs are certainly great, the human toll of the epidemic on our Tribal communities is even greater. The state of Minnesota reported that pregnant AI/AN women were 8.7 times more likely to be diagnosed with maternal opioid dependency, and that AI/AN infants were 7.4 times more likely to be born with neonatal abstinence syndrome (NAS) – meaning that the repercussions and trauma of this crisis are intergenerational. Other secondary impacts include the undue burdens imposed on many AI/AN families struggling with opioid and substance use disorders, the children forced into foster care, and the kinship care networks that are strained beyond their ability.

While Tribal communities are certainly in need of expanded treatment resources, public health prevention must not be forgotten. This includes upstream prevention activities such as comprehensive substance use education in youth, expanded substance and alcohol use education and training for our providers, prevention of adverse childhood experiences, healing from historical and intergenerational trauma, and investment in culturally appropriate and Tribally-driven programming.

Bolstering Tribal public health surveillance infrastructure is also a major need. The CDC noted in 2017 that the actual drug overdose death count among AI/ANs may be underestimated by as much as 35% due to racial misclassification on death certificate data. That is truly unacceptable. Data is the backbone of any public health system, and without it the Tribes and IHS are unable to maintain accurate records of vital

[1] National Institute on Drug Abuse. 2017. Overdose Death Rates. Retrieved from https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates

[2] Indian Health Service. New effort targets drug overdoses in Indian Country. Retrieved from https://www.ihs.gov/newsroom/pressreleases/2015pressreleases/new-effort-targets-drug-overdoses-in-indian-country/

[3] Mack KA, Jones CM, Ballesteros MF. Illicit Drug Use, Illicit Drug Use Disorders, and Drug Overdose Deaths in Metropolitan and Nonmetropolitan Areas — United States. MMWR Surveill Summ 2017;66(No. SS-19):1–12. DOI: http://dx.doi.org/10.15585/mmwr.ss6619a1

statistics, to quantify disparities in health outcomes between AI/ANs and other populations, and to ultimately make true assessments of need. More importantly, Tribal leaders must have this information to make informed policy decisions and implement targeted programs. For instance, for the last 12 years, United South and Eastern Tribes Tribal Epidemiology Center (TEC) has been conducting a mortality analysis, and now has a limited amount of data that speaks to opioid abuse among AI/ANs in the eastern United States. From that data, they have learned that 9% of all deaths among their member Tribal Nations were somehow related to substance abuse between 2002 and 2012. Almost one in five substance use deaths were attributable to opioids, including heroin, with the vast majority of opioid deaths, 93%, prescription drug related. These statistics illuminate the critical need for more comprehensive interventions in Tribal communities to improve prevention and treatment measures.

Tribes also remain behind many other communities in their public health infrastructure, capacity, and workforce capabilities as a result of being largely left behind when the United States was modernizing its public health infrastructure. These obstacles have made it particularly difficult for Tribal communities to assemble a coordinated and comprehensive defense against major health emergencies, including the opioid epidemic.

At IHS, and indeed even at many Tribal facilities, deferral of care due to funding and workforce shortages has pushed more and more Tribal members towards prescription opioids to treat health conditions that would otherwise successfully be treated with non-opioid therapies. For instance, limited funding resulted in nearly 80,000 Purchased/Referred Care (PRC) services (an estimated total of $371 million) being denied in FY 2016 alone. This endless cycle of deferral and opioid dependency is a direct result of the underfunding of the IHS system, and must be stopped.

The CDC Guideline for Prescribing Opioids for Chronic Pain describes how opioid therapy should not be the first line of treatment for acute or chronic non-cancer related pain management, and should rarely, if ever, be prescribed with other medications such as benzodiazepines. Nevertheless, many Tribal members still report that opioids are some of the only options available to them to address their pain symptoms. Lack of reimbursement and access to non-opioid therapies, traditional medicine and other alternatives leaves both providers and patients in a catch-22 that ultimately leads to more harm.

Tribes throughout the country are finding that lack of adequate funding for the IHS exacerbates some of the systemic challenges currently afflicting the Indian health system and is further restricting their ability to confront the opioid crisis. The Bay Mills Indian Community, a Tribe located on the Upper Peninsula in Michigan, has capacity issues so severe that, even if that Tribe received federal funds to operate an opioids treatment outpatient program, the Tribe reports that their facilities are too small and outdated to be able to operate such a program on-site. NIHB has noted in previous testimony to Congress that IHS's facilities construction budget is so underfunded that a facility built today would not be able to be replaced for 400 years. These chronic funding issues have limited the ability of Tribes to confront the opioid crisis without additional, sustained Congressional support.

The Red Cliff Tribe of Chippewa Indians in Wisconsin lacks resources to keep up with the latest training practices available to healthcare providers. While the Tribe has started a Harm Reduction Program to provide access to Naxolone, lack of substance abuse and addiction training among Tribal providers limits the program's reach and uptake in the community. The Red Cliff Police Department reported 346 investigations on drug use in 2016, an increase of almost 100 from the year prior. The total population of the reservation is under 1,000.

Policy Solutions

A) Access to Federal Opioid Resources

Addressing the opioid epidemic is a nationwide priority; however, access to critical opioid prevention and treatment dollars are not reaching many of the Tribal communities that are in serious need of these funds. As the federal, state, and local governments are working together to ensure a coordinated, comprehensive response, Tribal Nations are frequently excluded from these efforts. Failure to include Tribal Nations when seeking solutions to the opioid epidemic will result in major gaps in the ability of the United States to eradicate opioid addiction in this country. These gaps in coordination are detrimental not just from a healthcare and treatment perspective, but from a law enforcement perspective, as well. As the trustee to Tribal Nations and in pursuit of a more comprehensive response to this crisis, the federal government must facilitate and require collaboration between Tribal governments and other units of government. Outreach from the Committee, as well as future legislation, should promote and require this necessary intergovernmental collaboration.

H.R. 5140 – Tribal Addition Recovery Act (TARA)

The CURES Act provided $1 billion in funding over a two-year period to states and territories to combat the opioid crisis. Tribes were not eligible entities for this critically important funding. Although a small number of states subsequently allocated CURES funds to Tribes, access was not at the level of need, nor was it equitably distributed. Furthermore, as the trust responsibility is exclusive to Tribal Nations and the federal government, Congress must not circumvent this sacred duty by forcing Tribes to go through state agencies for these funds. In addition, many Tribes have historically had complicated relationships with state governments as a result of having to compete for limited dollars. Providing direct funding to Tribes, as outlined in H.R. 5140, would solve this issue.

Forcing Tribes to go to states diminishes the federal trust relationship for health and means that little, if any, funding reaches the Tribal communities. It also erodes Tribal sovereignty and the constitutional relationship set up between the Tribes and the federal government. Tribes are not subservient to the state governments, but exist as equal, sovereign partners with the federal government, and H.R. 5140 would correct an error in the law that erroneously left Tribes of the direct funding pool.

An example of the current funding structures can be seen in Ho-Chunk Nation in Wisconsin. Like many Tribes, Ho-Chunk has seen an increased number of infants born with substance addiction and NAS, as well as an increase in opioid-related overdose deaths in the community. The Tribal government declared a State of Emergency regarding the opioid crisis and is in the process of developing a Tribal Action Plan within their departments. A major problem for the Tribe is that the grant money the state receives and distributes to the Tribes is not sufficient to meet the added burden the Tribe's behavioral health facility is experiencing.

In Minnesota, the Department of Human Services reported that the age-adjusted death rate due to drug poisoning is four times higher among AI/ANs compared to whites. Further, despite representing roughly 1.1% of the population for the state, AI/ANs accounted for 15.8% of those who entered treatment for opioid use disorder. Yet, when the state passed through funding under the STR program, it gave Tribes funding far below the needed 15 percent.

H.R. 5140 would also help get resources to Tribal communities in a more efficient way. Forcing Tribes to go to states diminishes the federal trust relationship for health and means that little, if any, funding

reaches the Tribal communities. Tribes should be put in charge of their own funding because they will know the strategies that will help challenges in their own communities. Time and again, we have seen that when Tribes are given funding directly outcomes are better and funds are used more efficiently. When state priorities are driving the programming decisions, the unique needs of Tribal communities are often left out.

We are also encouraged to see that TARA includes an extra $25 million for the program. However, we also recommend that H.R. 5140 include a specific 10 percent set-aside for Tribes and be distributed on a non-competitive basis. This will make sure that the funds are actually reaching the communities in need. Legislation has been introduced in the Senate – S. 2437, the Opioid Response Enhancement Act – that would provide this set-aside.

In short, H.R. 5140 is a critical piece of legislation that will be an important first-step in getting funding to Tribal communities. NIHB urges that the Committee swiftly act on H.R. 5140.

Discussion Draft of a Bill to Improve Fentanyl Testing and Surveillance

The Committee's consideration of the bill to improve fentanyl testing and surveillance would provide grants to federal, state, and local agencies for the establishment or operation of public health laboratories to detect fentanyl, its analogs, and other synthetic opioids. NIHB suggests that Tribes and Tribal organizations (as defined in section 4 of the Indian Self-Determination and Education Assistance Act) be added to the list of eligible grantees. Tribal health programs have needs similar to other health providers, so it is essential that they are included in this type of funding. Fentanyl-related overdoses have been on the rise in Tribal communities in recent years, but Tribal resources to tackle the crisis have been limited. Improving fentanyl surveillance and testing will help Tribes target their prevention, treatment and intervention efforts to the communities that need it most.

Discussion Draft of a Bill to Enhance and Improve State-run Prescription Drug Monitoring Programs

Prescription Drug monitoring programs (PDMPs) can be an important tool in tracking opioid abuse or misuse. However, integration between IHS and Tribal health providers with state-level PDMPs has been mixed at best. In order to fully overcome this crisis, it is critical that Tribes be included in the development and implementation of state PDMPs. Therefore, we request that the legislation statutorily require states to conduct meaningful consultation with the Tribes on the implementation of any PDMP in the state about how to better track, report and assess Tribally-specific prescriber and dispenser practices.

Additionally, the draft bill would authorize "Evidence-Based Prevention Grants" and "Enhanced Surveillance of Controlled Substances grants." In both of these cases, Tribes and Tribal organizations should be allowed to receive this funding. Tribal public health systems, including Tribal Epidemiology Centers (TECs), are at the frontlines of treating and preventing the opioid crisis, but, as discussed above, are often not included in state-level initiatives. Therefore, direct funding will enable this important work to reach Tribal communities.

NIHB also recommends including language that would allow the technical assistance authorized to states (Sections 399V-7 (a)(1)(B) and 399V-7(b)(1)(B)), also be authorized to Tribes, Tribal organizations and Tribal Epidemiology Centers. Again, it is critical to ensure that this funding reaches the Indian health

system so that we can close gaps in opioid abuse disorder disease surveillance and prevention. The requirement for routine technical assistance to Tribes, Tribal organizations and Tribal Epidemiology Centers is also statutorily required under Section 214 (C) of the Indian Health Care Improvement Act.

The Eliminating Opioid-Related Infectious Diseases Act

The Eliminating Opioid-Related Infectious Diseases Act will authorize the CDC to undertake an injection drug use-associated infection elimination initiative and work with states to improve education, surveillance and treatment of injection drug-use associated infections, like human immunodeficiency virus (HIV) and hepatitis. The legislative language notes that "public and private entities" would receive the available grant funding. However, we believe that this should also clearly state that Tribes and Tribal organizations are eligible for funding. In addition, NIHB recommends adding "Tribes and Tribal Epidemiology Centers" to Section 317N(a)(1). It is critical that this funding reach Indian Country. AI/ANs have the highest rates of hepatitis C by race (twice the national average) and recently there have been spikes in cases linked to injection drug use.

In addition, we call upon Congress to:

- Establish Tribally-specific funding streams such as a Special Behavioral Health Program for Indians, modeled off the very successful Special Diabetes Program for Indians, so that Tribes can develop their own programs to address substance misuse and dependence in their communities. NIHB supports legislation that has been introduced for this purpose, H.R. 3704 the Native Health Access Improvement Act.
- Ensure parity between states and Tribes in any new opioid-related legislation advanced in Congress. This means not only including Tribes as eligible entities, but also requiring Tribal consultation, information and data sharing, and funding set asides, where applicable. For example, the Senate is considering the "Comprehensive Addiction and Recovery Act (CARA) 2.0" (S. 2456) legislation should include Tribes and Tribal organizations in several sections of the bill. This includes **Section 6** which establishes funding for regional technical assistance centers to focus on addiction recovery and naloxone training/dissemination; **Section** 7 which allows states to increase the 3-day limit on first time opioid prescriptions found in Section 3 if the state passes a law or implements a statewide regulation should include Tribal law as well; and **Section 10** which provides funding to states for addiction treatment programs targeted toward pregnant and post-partum women. Finally, we recommend adding language to **Seetion 13** that would require states to consult with Tribes on the implementation of prescription drug monitoring programs.
- Establish trauma-informed interventions in coordination with Tribes to reduce the burden of substance use disorders including those involving opioids.
- Include set asides for Tribes within the $6 billion in opioid program funding for Fiscal Years 2018 and 2019 authorized in the Bipartisan Budget Act of 2018 (P.L. 115-123).

FY 2019 Budget Proposal

NIHB and Tribes were glad to see that the FY 2019 President's budget request proposed $150 million in funding to "provide multi-year competitive grants based on need for opioid abuse prevention, treatment,

and recovery support in Indian Country."[4] Tribes are supportive of this additional funding, but many Tribes have expressed concerns that competitive grant programs are not the solution to long-term, broad-based funding. Competitive grants erode Tribal sovereignty and do not honor the federal trust responsibility. Furthermore, when Tribes are forced to apply for grants it takes away scarce staff and resources from other program-oriented work leading to diminished program effectiveness across the board. We look forward to working with Congress as this policy is developed to ensure that the proposed funds truly reach the areas with greatest need and fully honor the promises made to our ancestors. In addition, we note that other federal agencies – such as the Substance Abuse and Mental Health Services Administration and the Centers for Disease Control and Prevention – should have funding made directly available to Tribes.

B) Supporting Traditional Healing Initiatives

Tribal communities have been healing their people for thousands of years, and these strategies are highly effective in the communities where they are employed and engaged. Yet, it is often the case that traditional healing practices are not do not meet mainstream criteria for data collection under federal grants, which puts Tribes at a disadvantage when applying for and administering federal programs. It is critical that Congress support these traditional practices by providing funding – including Medicaid reimbursement— for traditional healing methods.

H.R.5272, the Reinforcing Evidence-Based Standards under Law in Treating Substance Abuse (RESULTS) Act

H.R.5272, the Reinforcing Evidence-Based Standards under Law in Treating Substance Abuse Act, requires entities applying for federal grants and cooperative agreements for mental health or substance use disorder (SUD) treatment to demonstrate how their program is evidence-based. NIHB requests an amendment to this bill that would permit Tribes and Tribal organizations to also utilize traditional, culturally-based and promising practices as well as evidence-based practices. Culturally-based programming helps Tribes tailor initiatives to the specific needs of their community, while also honoring Tribal sovereignty and the right to self-determination. Evidence-based programs that do not integrate traditional Tribal practices are often not be as effective at improving health outcomes as programs that do. Many Tribal public health programs – including the well-known and highly successful Special Diabetes Program for Indians (SDPI) – combine Tribal best practices with evidence-based practices. It has worked. As a result of SDPI, A1C levels among American Indians and Alaska Natives nationwide are down by an entire percentage point, and End Stage Renal Disease – one of the biggest contributors to Medicare costs – has decreased by 54%. SDPI demonstrates that using a combination of Western medicine with traditional healing practices can make major, positive gains when it comes to treating and preventing disease in Tribal communities. The same approach will help ensure the highest possibility for success in reducing mental health and SUD health disparities in Tribal communities.

Tribal Healing to Wellness Courts

In addition to traditional healing practices, we urge Congress to support innovative, culturally-appropriate Tribal restorative justice models through sustained funding. Established as alternatives to conventional

[4]U.S. Department of Health and Human Services. "FY 2019 Budget in Brief." February 12, 2018. Pg. 28.

sentencing for non-violent individual offenders, Tribal Healing to Wellness Courts promote long-term recovery through treatment, community healing resources, and the Tribal justice process by using a multi-disciplinary approach to achieve the physical and spiritual healing of participants.

For example, the Penobscot Nation, has operated a Healing to Wellness Court (HTWC) since 2011. Any individual Penobscot Nation citizen who is charged with a non-violent crime can petition to participate in the HTWC program. Once accepted into the program, the individual must agree to enter a guilty plea for the crime charged against him/her, but his/her sentence is "deferred" to allow the individual to go through the program. Then, a comprehensive, holistic plan is developed in collaboration between 10 Tribal government departments to address the individual's treatment needs in four phases:

- Phase I: Introduction/Education. This phase is focused on detoxification and beginning treatment and generally lasts 180 days.
- Phase II: Personal Responsibility. This phase is focused on stabilization and treatment and generally lasts 120 days.
- Phase III: Cooperation/Accountability. This phase is focused on maintenance and treatment and generally lasts 120 days.
- Phase IV: Completion/Continuing Wellness. This phase is focused on graduation and aftercare and generally lasts 120 days.

Successful completion of the program results in a dismissal of the participant's guilty plea. Over two dozen individuals have gone into the program since 2011. Recidivism is extremely low. The biggest problem that the Penobscot Nation has is that they do not have sufficient resources to accommodate all the individuals who are interested in participating in the program. While, the program is funded mainly through the Bureau of Indian Affairs, with supplemental funding from the Indian Health Service, the Department of Justice, and the Department of Housing and Urban Development, this is administratively burdensome and unlikely to result in additional resources for the Court. Similarly, while some grants offered by the Substance Abuse and Mental Health Services Administration (SAMHSA) could possibly be used for this purpose, SAMHSA's application requirements and standards often serve to preclude smaller, less resourced Tribal Nations from applying. The recovery model offered by Tribal Healing to Wellness Courts should be supported by this Congress, as it seeks to incentivize long-term sobriety and reduce criminal recidivism among drug offenders. In order to accomplish this, NIHB urges this Committee to consider dedicated, sustained funding for this infrastructure in Indian Country.

C) Health Information Technology (IT) within the Indian Health System

The federal government has not met its trust responsibility as it relates to updating and modernizing the physical and technological infrastructure within IHS and Tribal health facilities and health IT systems. The current primary Electronic Health Record (EHR) system IHS uses is the Resource and Patient Management System (RPMS), an integrated public health information system based on the U.S. Department of Veteran's Affairs (VA) VistA system. It is a comprehensive suite of applications that supports virtually all clinical and business operations at IHS and most tribal facilities, from patient registration to billing. RPMS is comprised of over 80 software applications and is designed to track patient and population based clinical and practice management applications. However, various concerns and challenges have been cited regarding RPMS. Some notable issues are:

- Many Tribes utilize different EHR systems instead of RPMS;

- Smaller Tribal health facilities do not have the bandwidth to fully operationalize RPMS, and would benefit from the ability to share new components such as files that contain all available drugs instead of just some;
- Some smaller Tribal health clinics are in need of greater training and technical assistance on how to utilize the system most efficiently;
- There is a need to further streamline the system and align it with other EHRs utilized by Tribes;
- Robust and timely IT support is not routinely available;
- Interoperability is incomplete, meaning that if a patient is referred to another clinic that utilizes a different system, the patient records are more than likely not cross-referenced which leads to inconsistencies in patient records.

Issues also exist in terms of RPMS interactions with Prescription Drug Monitoring Programs (PDMPs). PDMPs are state-run electronic databases that track controlled substance prescriptions. Across the board, utilization of PDMPs is inadequate. A national survey of primary care physicians found that 86% of the time, physicians did not check their statewide PDMP prior to prescribing an opioid, despite the fact that 72% of primary care physicians are aware of their state's PDMP.[5]

It is important to note the limitations of the PDMP system, both generally and in its usefulness for IHS and Tribal providers, pharmacists and public health practitioners. One, PDMP laws and regulations differ by state. In other words, whereas one state may require providers to update the system within a 24 hour period, other states only require updating the system every few days, or even over a longer period of time. Further, interstate sharing of PDMP data is not streamlined, which creates gaps in monitoring especially for individuals living in border towns, or for reservations that traverse multiple state boundaries. Additionally, to NIHB's knowledge, only the state of Alaska decreed a special consideration for IHS providers to access the PDMP system, which may explain why IHS established memorandums of understanding (MOU) with state agencies to permit IHS access and reporting. Also, there is currently no Tribally-specific PDMP system. The FY 2017 House Appropriations Bill authorized $1 million to IHS to establish such a system; however, to NIHB's knowledge, this system has not yet been implemented. Finally, no PDMP system collects racial demographics, limiting its value as a tool for public health monitoring for Tribes and Tribal Epidemiology Centers.

Due to budgetary constraints, IHS has not been able to support operations and maintenance for the certified RPMS site. Other federal agencies, like the Veterans' Administration, are in the process of moving away from RPMS-like systems toward more integrated software platforms, where EHRs and PDMPs can communicate under an interoperable platform. Unless Congress intervenes, this will create a disconnect between IHS and other agencies.

NIHB supports E-prescribing, especially given its potential to reduce the spread of prescription opioid abuse, and encourages IHS to utilize it where practicable. However, most IHS and Tribally run health facilities are in rural areas where limited broadband make widespread adoption of E-prescribing unrealistic without Congressional intervention. To ensure that E-prescribing is a viable tool in the Indian health system, Congress must first continue, and expand, its investment in rural broadband to incorporate rural Tribal communities.

Telehealth is a much-needed and successful innovation in rural areas. For example, the Eastern Aleutian Tribes, a healthcare provision organization serving 8 Alaska Native communities, has begun using

[5] Office of Management and Budget. Circular A-130. Appendix III. *Security of Federal Automated Information Resources.*

telemedicine to diagnose conditions, prescribe treatment, and conduct follow up examinations. Many Tribes in remote Alaska communities, often disconnected by the road system and only accessible by plane or boat, do not have access to medical providers regularly and have come to rely on telemedicine to fill a gap in healthcare provision. However, this was only accomplished through sustained investment in rural broadband. Greater network bandwidth and broadband access is a critical need, demonstrated by a 2018 FCC report that found as many as 35% of individuals living in Tribal lands lack broadband access, while in some Tribal communities as much as 80% lack broadband access.

To ensure Tribes are able to utilize Health IT to the greatest extent possible in confronting Indian Country's opioid epidemic, Congress should:

- Provide adequate support, funding, and oversight as IHS moves away from the RPMS system toward a more integrated platform that can better interact with E-prescriptions and EHRs.
- Provide oversite to IHS to implement a Tribally-specific PDMP system than can interact with state PDMPs.
- Review and support IHS's list of Tribal broadband projects, and also include direct funding to Tribes to improve their broadband and telehealth infrastructure.
- Mandate State-Tribal consultation on changes to state PDMPs.
- Incentivize providers to adopt E-prescription as a way to reduce the needless and harmful spread of opioids.
- Eliminate the requirement for Tribal providers to obtain the Secretary's authorization to be designated as an Internet Eligible Controlled Substances Provider, as it imposes an undue burden that delays the delivery of much-needed treatment resources, especially given that no other providers are subject to this requirement. [6]

Tribal Response to Opioids

Despite these challenges, Tribes across Indian Country have engaged in multifaceted response efforts that traverse the prevention, treatment and interdiction landscape. For instance, after declaring a state of emergency on the opioid epidemic in March 2016, the Mashpee Wampanoag Tribe in Massachusetts partnered with the IHS to assemble more resources to address the growing number of overdose deaths in their community. The Tribe worked towards establishing an integrated community intervention model, implementing the CDC Guideline for Prescribing Opioids for Chronic Pain, and developing an opioid response grounded in the social determinants of health. The Tribe worked with Tribal Police and Homeland Security to create prescription drug drop boxes, developed a 24-hour call line for crisis intervention, and established a Tribal Coordinating Committee to create a 5 year Tribal Action Plan to address alcoholism and substance abuse issues.

In Washington State, the Muckleshoot Tribe has been operating a successful behavioral health program for the past few years. The initiative includes a medication-assisted treatment program where Tribal members are able to receive Suboxone or Vivitrol for treatment of opioid use disorder. The program has proven successful, as compliance with the program reached 94% in July, 2017. Muckleshoot has distributed close to 4,000 kits of Naloxone as of August 2017, and also operates a syringe service program to help reduce the risk of co-occurring health conditions such as HIV and Hepatitis C.

In Oklahoma, the Chickasaw Nation launched the "Define Your Direction" campaign, which is an education initiative encouraging Tribal youth to make healthy choices and be positive role models when

[6] (21. U.S.C. 829) Section 311(g)(2)

it comes to resisting prescription drug misuse and underage drinking in their communities. Some outcomes of the program thus far include equipping all Chickasaw Nation Lighthorse officers with Naloxone; distributing more than 400 medication lockboxes to Elders; recording significant reductions in prescription drug misuse within the past 30 days among 6th, 8th, 10th and 12th graders; and reductions in risk factors such as early drug use initiation and low neighborhood attachment among Tribal youth.

NIHB encourages the Committee Members to connect with the Tribes in your home states to learn more about current initiatives and gain further insight into technical assistance and funding needs, so that programs such as these are replicated in more and more Tribal communities.

Conclusion

Again, NIHB would like to thank the Committee for holding this hearing and soliciting input from a variety of stakeholders. Indian Country has seen over the past several years that opioids do not face barriers in entering Tribal communities. To truly address this problem, Congress must ensure that Tribes receive direct funding, and are included any type of national-level opioid legislation moving forward. For any follow up questions, please contact Stacy Bohlen, NIHB's Chief Executive Officer, at sbohlen@nihb.org or 202-507-4070.

Mr. BURGESS. Thank you for your testimony. Without objection, your full remarks will be made a part of the record.

Ms. Horan, you are recognized for 5 minutes.

STATEMENT OF ALEXIS HORAN

Ms. HORAN. Thank you. Chairman Burgess, Ranking Member Green, and subcommittee members, my name is Alexis Horan, Vice President of Government Relations for CleanSlate Addiction Treatment Centers. CleanSlate is grateful for the opportunity to testify on H.R. 3692, the Addiction Treatment Access Improvement Act, and H.R. 5102, the Substance Use Disorder Workforce Loan Repayment Act, two bills that will expand access to high quality treatment and promote the growth of a stable, high quality, substance use disorder workforce capable of meeting the growing demand for evidence-based treatment for opioid use disorder.

CleanSlate is an office-based opioid treatment program. That means we help patients overcome their addictions using pharmacotherapies including buprenorphine and naltrexone, more commonly known as Suboxone and Vivitrol, in combination with supportive counseling and clinical and social care coordination services. Our treatment centers are physician practices staffed by a combination of physicians, nurse practitioners, physician assistants, care coordinators, and support staff each of whom play a critical role in delivering pharmacotherapy-based treatment for opioid and alcohol use disorders.

CleanSlate operates 41 centers across eight states, including Massachusetts, Indiana, Pennsylvania, Texas, Florida, Arizona, Wisconsin, and Connecticut, with 8,000 patients currently under our active care. Since our inception in 2009, we have treated nearly 28,000 patients which we believe gives us a keen understanding of the role medical treatment for opioid addiction can play in ending the opioid epidemic.

We plan to open our first centers in Ohio and Kentucky this spring. Our decision to open a new center sets in motion an intensive recruiting, contracting, and community outreach effort. Sadly, there is no shortage of demand for our treatment services, but providing treatment to meet demand is increasingly difficult primarily due to the challenges we face in finding willing, experienced prescribers with sufficient buprenorphine waiver slots to support our program.

Fully 20 percent of CleanSlate prescribers are at or near their prescription limits. Despite our own internal workforce building efforts and the addition of advanced practice clinicians to the pool of eligible prescribers, we are not always able to fully meet the demand for treatment in the communities we serve. The Comprehensive Addiction and Recovery Act of 2016 took important steps toward helping close this treatment gap. However, demand for opioid use disorder treatment continues to grow while the workforce does not grow commensurately.

To give a sense of the dynamic we face, in 2017 CleanSlate hired and trained 85 providers for medication assisted treatment through our internal program, 58 of the 85 providers did not have their prescribing waiver before they came to CleanSlate. Even with these additions we constantly face capacity challenges. H.R. 3692, the

Addiction Treatment Access Improvement Act, and H.R. 5102, the Substance Use Disorder Workforce Loan Repayment Act, will meaningfully close key parts of the treatment gap that exist in our country and we appreciate that these measures are under active consideration by the committee today.

Broadening the pool of eligible prescribers and their capacity for highly qualified providers to treat larger panels of patients, simply stated, would enable CleanSlate clinicians and others around the country to treat more patients immediately. Allow me to share the experiences of some of our centers to illustrate this point.

Our Anderson, Indiana treatment center currently employs four prescribers who are authorized to prescribe MAT for a combined total of 190 patients. Still, we have 60 patients on a waiting list at Anderson. As a result, some patients are driving over an hour away to another CleanSlate program in Indianapolis to access treatment.

Alternately, our Scranton, Pennsylvania center has nine prescribers who currently treat 570 patients with 100 treatment slots still available. That may sound like a lot of capacity, but in January 85 new patients joined that center and in February 66 joined. At that rate, our capacity to treat more people could and likely will be filled by the end of April.

H.R. 3692, the Addiction Treatment Access Improvement Act, introduced by Representative Paul Tonko, addresses and alleviates these challenges by allowing a larger pool of advanced practice clinicians to prescribe MAT by making that prescriptive authority permanent instead of sunsetting the authority as it is under CARA, and by allowing highly credentialed prescribers or those working in qualified practice settings like CleanSlate to treat up to 100 patients at the outset instead of just 30 as is under current law.

As stated before, prescription limitations are not the only barrier to expanding access to treatment. There remains a dearth of providers who are willing to work in this field due in part to the complex medical, behavioral, and social needs of patients with opioid use disorder as well as the stigma associated with the patient population. These factors make provider recruiting a challenge.

Retaining a high quality, compassionate workforce is also a challenge. H.R. 502, the Substance Use Disorder Workforce Loan Repayment Act, introduced by Representative Katherine Clark, authorizes a robust loan repayment program for a wide range of full-time substance use disorder professionals who provide treatment in underserved areas. Not only will this legislation incentivize newly minted providers to begin careers that involve treating substance use disorders, the bill will also help stabilize the workforce by meting out payments over 6 years which should counter attrition that is all too common in this field.

CleanSlate strongly supports these important bills and thanks Representatives Tonko and Clark for their thoughtful contributions toward addressing an opioid epidemic that affects us all. Together, H.R. 3692 and H.R. 5102 directly address barriers that preclude providers from adequately providing effective treatment for opioid and other addictions.

Thank you, Chairman Burgess, Ranking Member Green, and members of the subcommittee once again for the opportunity to

speak in support of these bills and on behalf of my organization and the addiction treatment field at large. The hearings you are holding are tremendously important to increasing awareness and building support for the policy changes needed in our field and we look forward to assisting you in any way. Thank you.

[The prepared statement of Ms. Horan follows:]

U.S. House Energy and Commerce Subcommittee on Health

Combatting the Opioid Crisis: Prevention and Public Health Solutions

March 21-21, 2018

Chairman Burgess, Ranking Member Green, and Subcommittee Members, my name is Alexis Horan, Vice President of Government Relations for CleanSlate Addiction Treatment Centers. I have nearly 15 years of experience in developing and supporting addiction treatment policy. I served as Senior Vice President of Government Relations and Clinical Practice at the American Society of Addiction Medicine for over 11 years and then for two years as an Expert Consultant to Health and Human Services' Assistant Secretary for Planning and Evaluation, in support of the Department's Opioid Initiative treatment portfolio. I am grateful for the opportunity to lend my addiction treatment policy expertise and the collective experience of CleanSlate's clinicians and patients to this hearing and to the conversation around reversing the course of the opioid epidemic, improving patient access to life-saving pharmacotherapy-based addiction treatment, and to building an engaged and sustainable addiction treatment workforce.

Background on CleanSlate Addiction Treatment Centers

CleanSlate is a physician-led organization that provides office-based, outpatient medication-assisted treatment for opioid and alcohol use disorders. Founded in Massachusetts, we now operate 41 centers across eight states - Massachusetts, Indiana, Pennsylvania, Texas, Florida, Arizona, Wisconsin, and Connecticut - with 8,000 patients currently under our care. Since our inception in 2009, we have treated nearly 28,000 patients, which we believe gives us a keen understanding of the role medical treatment for opioid addiction can play in ending the opioid epidemic.

Our treatment program is based on evidence-based treatment protocols, as specified in the American Society of Addiction Medicine clinical guidelines and in the recently issued SAMHSA TIP 63, Medications for Opioid Use Disorder. That means that we help patients overcome their addictions using pharmacotherapies including buprenorphine and naltrexone (more commonly known as Suboxone and Vivitrol, respectively) in combination with supportive counseling and clinical and social care coordination services. We utilize a high frequency visit model that encourages patients' accountability to their treatment goals while also supporting stringent anti-diversion controls. Our treatment centers are staffed by a combination of physicians, nurse practitioners, physician assistants, care coordinators and support staff. Each member of the CleanSlate clinical team plays a critical role in helping patients regain their health and their dignity, thereby supporting them in rebuilding long-neglected bridges back to their communities and their livelihoods.

Our success in deploying a group practice model is owed in part to the provisions in the Comprehensive Addiction and Recovery Act of 2016 that allows nurse practitioners and physician assistants to prescribe buprenorphine and allows highly credentialed physicians and those that work in qualified practice settings, like CleanSlate's programs, to increase their buprenorphine patient panels. These new authorities have enabled us to further optimize the use of our providers' buprenorphine patient panels and therefore increase our operating capacity at a time when demand for treatment far exceeds supply. In our experience, by providing our prescribers with the administrative and sophisticated case management support often necessary to support a patient's primary care, counseling, insurance,

transportation, housing and employment needs, our providers can focus their time and energy toward direct patient care.

Unfortunately, even with these important legislative and organizational advantages, we are not always able to fully meet the demand for treatment in the communities we serve. There remains a dearth of physicians and advance practice clinicians who are willing to work in this field or interested in going through the process required to acquire and utilize a waiver to prescribe buprenorphine. Even those who have waivers to prescribe often do not serve the maximum number of patients they are permitted to treat, due in part to the complex medical, behavioral and social needs of patients with opioid use disorder. This makes provider recruitment a challenge. Retaining a high quality, compassionate workforce is also a challenge. The stigma of patients with substance use disorders, community and health care provider misconceptions about medication-assisted treatment, marginalization by peers, surveillance by various oversight authorities, and stressful work environments result in a high rate of turnover in the addiction treatment field. These workforce limitations, combined with federal and state limitations on clinician scope of practice and treatment center capacity, stymie the ability of high quality, well-intentioned treatment programs to narrow the treatment gap.

CleanSlate is grateful for the efforts of this committee to address these challenges; in particular, for two bills that I have been asked to address today in my testimony. Together, H.R. 3692 and H.R. 5102 will expand access to high-quality treatment and promote the growth of a stable, high quality substance use disorder workforce capable of meeting the growing demand for evidence-based treatment for opioid use disorder and substance use disorders more broadly.

H.R. 3692, the Addiction Treatment Access Improvement Act

H.R. 3692, the Addiction Treatment Access Improvement Act, introduced by Representative Paul Tonko, seeks to extend buprenorphine prescriptive authority to a larger pool of advanced practice clinicians, notably adding clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwifes as qualified practitioners, and to eliminate the current time limitations on their prescriptive authority. Moreover, the Addiction Treatment Access Improvement Act would allow some highly qualified prescribers with additional credentialing and those working in qualified practice settings to immediately apply for waivers to prescribe buprenorphine to up to 100 patients at a time, bypassing a requirement that they hold a 30-patient waiver first.

The experience of our treatment center in Anderson, Indiana illustrates why it would be beneficial to enact H.R. 3692 into law. In 2016, CleanSlate opened our Anderson center; in nearly two years of treating patients there, we have recruited, trained and staffed 4 prescribers, all new to addiction medicine. Collectively, today, they are able to treat 190 patients. More recently, we have hired a part-time physician who is contributing 188 of his 275 treatment slots to our program. However, Anderson still has a waiting list of 60 patients today. Some of those patients are traveling to our next closest center, over an hour away in Indianapolis, which is less than ideal for patients who are seeking to work and support their families as they receive treatment. The current buprenorphine prescription limit dictates our treatment capacity rather than the talent and resources of our health professionals within our treatment center. Further, the rules and oversight that come with this prescriptive authority adds to the stigma that discourages providers from caring for these patients who are frequently medically complex and difficult to treat.

We are struggling to find more prescribers to increase capacity; if we did find a new provider, they likely would only be able to take on 30 patients due to the current limits on prescribing buprenorphine. Were this bill the law today, we would not have a patient waitlist at Anderson and we would see a meaningful increase in the number of patients that could be served by other qualified providers throughout the United States.

H.R. 5102, the Substance Use Disorder Workforce Loan Repayment Act

H.R. 5102, the Substance Use Disorder Workforce Loan Repayment Act, introduced by Representative Katherine Clark, authorizes a loan repayment program for full-time substance use disorder treatment professionals who provide treatment in a mental health professional shortage area or in a municipality reporting a higher than average drug overdose death rate. The Substance Use Disorder Workforce Loan Repayment Act recognizes the broad spectrum of substance use disorder treatment professional fields and the variety of treatment locations where patients receive treatment. This bill would authorize $25 million over ten years to reimburse eligible student loans of up to $250,000. This funding, bolstered by the Opioid State Targeted Response Grants authorized in the 21st Century Cures Act, is a significant investment in building the addiction treatment workforce and in addressing the nation's opioid epidemic more generally. Not only will this legislation incentivize newly-minted providers to explore careers that involve treating substance use disorders, the bill will also help stabilize the workforce by meting out the payments over a six-year period, which should counter attrition that is all too common in the field. As important as workforce stability is to an employer in this specialized field, it is even more important to supporting long-term patient-provider relationships. For many addiction patients, recovery can be a long road. The longer a patient remains in treatment, engaged and connected to a provider, the greater the likelihood of treatment success.

Together, these bills will meaningfully close key parts of the treatment gap that exists in our country. First and foremost, HR 3692 and HR 5102 directly address barriers that preclude providers from adequately providing effective treatment for opioid and other addictions. H.R. 3692 recognizes the limitations in both the burdensome process required to become a buprenorphine provider and the authorized prescriber's capacity to adequately meet the demand for evidence-based opioid use disorder treatment. H.R. 5102 addresses the workforce shortage more generally, an issue that compounds the difficulty in building a pool of committed, high quality MAT prescribers.

CleanSlate thanks the Energy and Commerce Committee for holding this and other hearings that are shining a bright light on the opioid epidemic and justifying the urgency of an expanded federal response to it. We appreciate Representatives Tonko and Clark, and the sponsors of the other bills being reviewed this week, for elevating and addressing the many, interconnected issues that must be addressed in order to permanently change how we manage addiction in our country. I am grateful for the progress that has been made, but there is a long way to go to ensure that all the patients in need of treatment for addiction can access it. CleanSlate will continue to do its part, going where patients are in need, delivering effective, dignified, and compassionate care that our patients, all patients, deserve and want.

Sincerely,

Alexis Geier Horan
Vice President, CleanSlate

Mr. BURGESS. And we thank you for your testimony. We thank all of you for your testimony this afternoon and thank you for bearing with us through what has been a pretty long day. At this time we will move into the question portion where members are each recognized for 5 minutes for a series of questions.

And if he is ready, I will yield to the gentleman from Virginia, Mr. Griffith, 5 minutes.

Dr. Bucshon, Mr. Griffith requests that I recognize you.

Mr. BUCSHON. I would be happy to do that. Thanks, Mr. Chairman.

Since you were the last one to talk, I think maybe I will ask you a question. First, I have, it is a little opening kind of statement, then I will ask the other members of the panel.

So, doctors do not prescribe insulin to a diabetic without education, support, or routine follow-up care. That said, prescribing buprenorphine without wraparound services, I would argue, is substandard care. I am fully supportive of doing everything we can to combat the opioid crisis ravaging the country. That includes expanding access to medication assisted treatment, Section 303 of CARA I helped author, for example. However, it is important that we do so in a thoughtful way.

I was a heart surgeon before, so I am a medical person. A health professional with no expertise in addiction medicine, for example, can now prescribe ultimately buprenorphine to 275 patients. That is about 14 patients per day. These patients are seen just once per month. Do you think that a provider seeing 14 patients a day is consistently able to provide the comprehensive, therapeutic services that best fits the clinical needs of his or her patients?

Ms. HORAN. Well, thank you for that question. To the training part, and I can only speak on behalf of CleanSlate and how we train and educate our physicians, our physicians do come from a wide range of backgrounds. Regardless of their background, however, they are all put through about a 4-week training program, internally with us, which includes a combination of didactic and onsite learning and training.

In terms of the wraparound services we provide as an organization, all of our clinicians are trained in supportive counseling. We staff care coordinators at most of our centers to make sure that the patient has at least access to, and not just access to in terms of here is a business card, good luck finding it in the community, but a warm connection to the referrals that we have made. That is part of the community outreach in terms of how we set up in a new community.

So our providers are, we believe, providing extensive supportive counseling and then relying on the expertise that is in the community to fill their primary care, dental care, OB-GYN care, additional behavioral healthcare needs.

Mr. BUCSHON. So I guess if you hired someone new and they go through their training, would you think that they should be able to see 14 patients a day, all month, right off the bat? Because I think that is in your testimony and based on the legislation is what you are implying that they should be able to go right to the full amount right off the bat.

Ms. HORAN. I do. We do, because we believe that we have established programs that provide the administrative care coordination and clinical support necessary to enable that physician or that nurse practitioner or physician assistant to really attend to the patient's addiction treatment needs.

Mr. BUCSHON. Because I think, in CARA we were trying to expand the scope of who can do this with a 3-year, with a pilot, expanding the type of practitioner. But do you think we should really lock in this big of an increase in the number of patients, really, before we have seen a single piece of data from HHS as was part of CARA to see if these practices are successfully treating patients in adhering to the evidence-based guidelines and ensuring that buprenorphine or methadone or whatever, buprenorphine, which is one of the most diverted medications, is not being further diverted? Because the whole point was if we expanded this we wanted to get data to see if that was successful.

Ms. HORAN. Right, right. Again I am going to speak on behalf of CleanSlate here and I will answer it in two parts. One, we feel like we have some data that shows that our treatment programs are successful. We worked with one of our payers to look at our patient outcomes and we showed patients who had been in treatment with us for 6 months had shown, as compared to the treatment they had for 6 months prior, showed a 35 percent reduction in use of ERs, a 25 percent reduction in any in-hospital stay, and reduced their conversion to Hepatitis C by about 80 percent.

So we feel that at least again in our program, a program that really wraps not just the patients around with services, but the providers that work with them, the tools that they need to do their job well, we believe that MAT can be successful. We have worked now for almost a year with advanced practice clinicians, thanks in part to the CARA bill, and they are incredible additions to our team. There is no way we would be able to meet the demand for treatment in the communities without them and they work in collaboration with our physicians in almost every scope of practice.

Mr. BUCSHON. Yes. I would just say this, and some of my personal views is sometimes the ends doesn't always justify the means. I get that there are a lot of people out there on waiting lists, but as a healthcare provider I think we also want to be cautious. Your program is excellent, but there are others out there that probably are not.

And so when we try to put public policy in place we want to make sure, I do at least, we think about the patient at the end of the day and across the country what is going to work. So I would argue against immediately expanding to 275 without some sort of a ramp-up and that is my personal view. I yield back, Mr. Chairman.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back. The chair recognizes the gentleman from Texas, Mr. Green, 5 minutes for your questions, please.

Mr. GREEN. Thank you, Mr. Chairman. I want to thank all our panelists for joining us today, and I will start my questions with Ms. Nickel.

Ms. Nickel, you note in your testimony that I have been working with Congressmen Guthrie, Luján, and Bucshon to introduce the

Comprehensive Opioid Recovery Centers Act. In your testimony you highlighted that of the 21 million Americans who need treatment for a substance use disorder like opioids, only ten percent receive such treatment.

This almost begs the question, why aren't more Americans in need receiving that treatment?

Ms. HULSEY NICKEL. Our treatment system has a lot of gaps that we need to fill and there are lots of silos and fragmentation. And I believe the CORC Act will help us to fill in some of those gaps and make sure that for example, going to three different places to receive a medication if you have an opioid use disorder can be very difficult and we need to make sure we are streamlining how to have patient-centered care so the right medication is identified and given to that patient based on a doctor's advice and not just who you happen to find near you or on a Google search or by calling someone off of a commercial.

We need to make sure that this is led by health care and have better provision of evidence-based service.

Mr. GREEN. What are the most common barriers to receiving that treatment?

Ms. HULSEY NICKEL. I think we have some pair issues with finding coverage and how do you pay for this. We have a lot of navigation problems that when this hits your family you usually are thinking about like how do I Google someplace and empty out my savings account, rather than how do I go find the right physician or a counselor to help me build a treatment plan for myself or for my loved one?

So I think the externalization from health care of removing this out of our healthcare system is one of the biggest barriers to making sure that we get the treatments to all the patients that need it.

Mr. GREEN. One of the unique requirements of our legislation is the need for treatment centers to have trained personnel responsible for outreach to the key community stakeholders such as institutions of higher education and the criminal justice system. Can you speak to the importance of this community integration as part of the treatment and recovery?

Ms. HULSEY NICKEL. Absolutely. Addiction is an illness that begins mostly in adolescence or young adulthood. Ninety percent of those that have a substance use disorder it began in those ages. So that component with higher education or even earlier, very important to make sure that you are initiating treatment and intervening early. Right now this is the only disease that we wait for it to worsen before we treat it. Can you imagine like waiting for an amputation before you would treat diabetes?

So when you have those community outreach functions out of your legislation and make sure that we are getting the help that we need into the places where you can intervene earlier and have better outcomes for that patient.

Mr. GREEN. OK. Through your work with the Addiction Policy Forum do you have experience with treatment that have included outreach to these key community stakeholders? If so, can you share how community outreach has and has not improved the treatment outcomes?

Ms. HULSEY NICKEL. I think any opportunity you have for community outreach is going to improve your outcomes and your access to care. We need to vastly expand that type of service and coordination. We need to go into younger ages and also figure out new ways to get into families and communities so that they know how to ask for help and where to go for evidence-based care.

High schools, through employers and through the workplace, through colleges, through our churches, it doesn't really matter how they come in the door, but you need to make sure that they find the right help so they don't get taken advantage of directed to nonevidence-based care that is going to have poor outcomes.

Mr. GREEN. In your work with your family members, people who unfortunately have lost their battle with addiction as a result of the opioid overdose, how common is it their loved ones completed treatment without being offered a range of treatment options and the necessary support services?

Ms. HULSEY NICKEL. Unfortunately, of all of our families a very large majority could not find evidence-based care. They were denied care. They were offered very short periods of treatment, 14 days or 21 days, instead of the long-term wraparound care that they are needed. As I mentioned, trouble accessing medications to treat addiction, not providing MAT for someone who has an opioid use disorder, you are going to have a very, very difficult time having a positive outcome. So this is common in the stories we hear over and over again of not having that quality care.

Mr. GREEN. OK. Well, Ms. Hulsey Nickel, thank you. Last month, the CDC published troubling new data showing that between July 2016 and September 2017 opioid overdoses visits to emergency room departments increased by 30 percent. In addition, opioid overdoses are increasing among men and women of all ages from all parts of the country. This data highlights the increasing severity of the opioid epidemic and the critical role emergency departments must play in response to this.

And I will yield back what little time, I don't have any time left.

Mr. BURGESS. No, you don't. The gentleman's time is expired. The chair recognizes the gentleman from Oklahoma, 5 minutes for your questions, please.

Mr. MULLIN. Thank you, Mr. Chairman, and thank you once again for your continued effort on holding these hearings. It means a lot to me and so many other families. Thank you to the panel for being here too and sticking with us. It has been a long day and so I do appreciate it.

Stacy, thank you for working with us on the IHS Task Force, coming in and talking to the staff, just Monday, and educating us and working with us trying to figure out how we can help better serve Indian country as a whole, and as you said in your testimony that it is disproportionately high of accidental overdoses inside of Indian country.

I represent the great State of Oklahoma. I am Cherokee myself and, I have the highest Native American population of any district and so this hits home really tough. And part of what we are trying to do is make sure that it is not overlooked.

Tribes are unique because we are considered sovereign nations and so by getting funding to Indian country is vitally important be-

cause most health care for Native Americans are done within the IHS system. That was the Federal Government obligation through the treaties to which they were signed. And I understand most people don't understand that but it is where I grew up my whole life. I am still living in Indian country. I still live at the same place I was raised and my family was raised. We are generational there.

I have got a question for you though. What are the benefits to direct funding the tribes throughout this program?

Ms. BOHLEN. Thank you, Congressman.

Mr. MULLIN. No, thank you.

Ms. BOHLEN. Well, first of all, directly funding the tribes upholds the Federal Government trust responsibility and as you so eloquently expressed the promises that were made in the treaties to the tribes. The trust relationship that is established through the Constitution, Federal law, and so forth, is a relationship between the Federal Government and the tribes.

When funding for programs is sent to the states with the hope or maybe even the intention that the state will share that funding with the tribes, there is no legal obligation and there is no accountability whatsoever on whether any of that money will reach the tribes and that is largely because the trust responsibility cannot be delegated to the states.

Mr. MULLIN. Right.

Ms. BOHLEN. It has to be honored at the federal level. So the benefits are tremendous. If I may, Special Diabetes Program for Indians, it is not a large investment from the government to the tribes, but it is a public health program that is taking the best of Western medicine and the best of tribal traditional practices and implementing a preventive treatment program that is probably, after immunizations, the most successful public health program in the country. The tribes know how to do this.

Mr. MULLIN. Right. And I want to elaborate just a second on what you said it is not their obligation. It is not the State's obligation. The treaty was made with the Federal Government and it is not a handout. It is payment from land that was taken from the tribes for years and years ago and that obligation and that payment still stays in place.

And for tribes to be able to ask the State for it, the State does look at it as it is not our obligation and which it is not, it is not any fault to the State. Oklahoma deals with this in a very unique way. I have 19 different tribes just in my district and we have a unique relationship with the States. But we do have to realize that through the grant programs they need to be available to the Indian country also.

So, one more question for you. Can you discuss the technical challenges that we have that is hampering Indian country with getting the data and the information that they need?

Ms. BOHLEN. Yes, I can talk about that briefly. The health IT system in Indian country, it does not have great interoperability among the various electronic health records and so forth, that the tribes who are self-governing may choose to use an application that is different from what the Indian Health Service uses which is the RPMS system. And RPMS system is very cumbersome in terms of

trying to extract data and trying to make the picture that you actually want to make out of the disparate ways that data is collected.

There needs to be an investment in Indian country to advance electronic medical records. The agency, I believe, States it would require $3 billion over 10 years to bring that system into par with what the rest of America is experiencing.

Mr. MULLIN. Thank you so much. My time is out. Thank you, Stacy, again for working with us. Thank you, Chairman. I yield back.

Mr. BURGESS. The chair thanks the gentleman. The chair recognizes the gentleman from Maryland, Mr. Sarbanes, 5 minutes for your questions, please.

Mr. SARBANES. Thank you very much, Mr. Chairman. I want to thank the panel for very compelling testimony. I wanted to focus particularly on H.R. 5102 which has been mentioned. This is a bill that I am very proud to be cosponsoring with Mr. Guthrie on this committee, but the prime sponsors are Katherine Clark of Massachusetts and Congressman Hal Rogers who have really taken the lead on this issue of trying to respond to shortages in the workforce.

And it has been touched on by Ms. Horan, but I wanted to again go over some of the statistics and information we have that call upon us to have an aggressive and, I think, creative response to the provider shortage. We know that there are workforce shortages for all of the various substance use disorder healthcare professional categories across the United States. According to SAMHSA in 2012, in addition, the turnover rates in the addiction services workforce ranged from 18.5 percent to over 50 percent. And in a recent survey, nearly half of the clinical directors and agencies that specialize in providing a substance use disorder treatment acknowledge real difficulty in trying to fill these open positions and then keep them filled, dealing with the lack of qualified applicants on the one hand and the inability to keep folks in place on the other hand.

In Maryland, where we are certainly facing as every State in the country is a severe crisis in terms of substance use disorder and the effects of the opioid addiction epidemic, I have been hearing this as well. Recently I met with the head of Baltimore Medical System, which is one of our federally qualified health centers in Maryland, and she told me about her own difficulty in finding and keeping healthcare professionals that specialize in this arena.

So the bill that has been introduced by Congresswoman Clark and Congressman Rogers and is being cosponsored in this committee by Mr. Guthrie and myself, we create a pretty creative loan repayment program for substance use disorder treatment providers. Participants in this program could receive up to $250,000 in loan forgiveness if they agree to work as a substance use disorder treatment professional in an area that is most in need of their services. So that could be a mental health professional shortage area or in a county or municipality that has overdose death rates above the national average. That would be one qualifying category.

Participants can work in a wide range of facilities, which is important. Community health centers, I alluded to that. Hospitals, recovery programs, correctional facilities, et cetera, wherever the

need exists in a significant way. And it will be available to a broad range of direct care providers including physicians, registered nurses, social workers, other behavioral health providers.

So we are hoping that this will allow us to attract new providers into this very, very important field and it has received strong endorsements from the American Society of Addiction Medicine, the National Council for Behavioral Health, the Addiction Policy Forum, and so forth. So again I am very proud to be part of this.

I did want to ask you, Ms. Horan, just to speak, if you could, with a little more detail to what you have seen and gathered by way of data and otherwise about this shortage in these particular areas of practice and what it would mean to have this kind of an incentive program in place to address it.

Ms. HORAN. Sure. Thank you for the opportunity. Again I am going to speak from CleanSlate's perspective on this because I think it is a slice of, I think, reality that might reflect what other programs like ours are facing.

Recruitment is an ongoing challenge. There are not a lot of highly trained physicians or advanced practice clinicians with a lot of addiction medicine background or addiction psychiatry background. Many of those that are out there are working in the field already. So we are always looking for new, compassionate, committed talent to try and help us both grow our programs across the country, but just try and keep the programs that we have running.

As you mentioned, turnover is very high for various reasons in the field. And turnover, while it might be a bear for us in terms of, the administrative side of it, the biggest problem is the danger to patient continuity of care. And so any effort, particularly this one, I think, will really help us bring, and probably newer, younger talent to the field, the folks that are really carrying the highest debt burden at this point and that is a good thing.

I think these are probably folks who are graduating within the last couple of years who may have had a little bit more of the addiction and pain education in medical school, we hope, but also who might not have some of the biases about addiction treatment that exist in other parts of the treatment. So certainly for us it is just another wonderful tool that we have in our toolbox to try and recruit the best, just so that we can provide our patients with the best care. Thank you.

Mr. SARBANES. Well, thank you for your testimony. I yield back. And hopefully we will get this through and help will be on the way. Thank you. I yield back.

Mr. BURGESS. The chair thanks the gentleman. The chair recognizes the gentleman from Georgia, 5 minutes for your questions, please.

Mr. CARTER. Thank you, Mr. Chairman, and thank all of you for being here. I have described the opioid epidemic in our country as being twofold. First of all, we have that part that is somewhat tangible that we can somewhat put our arms around, that is, how do you control these numerous prescriptions that are being written, limiting the number of prescriptions, limiting the pills, those things are somewhat tangible.

But then we talk about all those millions of people who are addicted now and how do you deal with that? That is a whole dif-

ferent subject, if you will, and a whole different situation. That is why I am so glad to see all of you here and I appreciate it very well, very much.

And, Dr. Rosenberg, I want to start with you, because as the only pharmacist currently serving in Congress I find it fascinating that—I feel like there is a big void that exists right now in medicine. And I have preached this to the pharmaceutical manufacturers that we have opioids and once you get past opioids we really don't have anything else to prescribe.

You have ibuprofen and tramadol and then you go to opioids and there is a big gap there. And I have been on the pharmaceutical manufacturers. We need to fill in that gap. And over my career I have witnessed miracles come out of research and development, but I still haven't seen them fill in that gap. That is why I am so interested in your program. And I want to tell you that until this hearing I was not familiar with it, but I commit to you that I am going to study it. I do think there is value in this. There are alternatives that can be used that we need to use as opposed to just putting people on the opioids.

I can remember practicing my pharmacy across from a dental clinic and they would always give them three prescriptions—ibuprofen, the pain pill, and the antibiotic. And they would come in and say oh, I don't need the antibiotic, I just need the pain pill. Yes, right. Well, we finally passed a self-imposed rule, you had to get the antibiotic if you are going to get the pain pill.

But, really, I am going to study more, so I want to acknowledge you. Now, I want to go to Ms. Nickel.

I found your testimony to be fascinating and I want you to know how much I appreciate what you are doing. I had the opportunity along with Chairman Burgess and Mr. Green to attend a conference a couple of weeks ago and we heard from a retired sheriff from West Virginia who told the story about a young man, a boy who was always late for school and who was in a family of opioid addicts.

And instead of the police officer just simply turning him into juvenile detention he decided to mentor him and when he was mentoring him he had a birthday. And he asked him, he said, what do you want for your birthday? And he said I want a clock. And the policeman said why would an 8-year-old want a clock? And he said, because I don't want to be late. I want to be on time. He didn't even have a clock.

And that is why I find your story so fascinating. How do you break that cycle? What was different? What broke it for you? How can we mentor people? We know particularly us in Congress that, you know, it is just cyclical and the generations it is hard to break those cycles like that.

Ms. HULSEY NICKEL. Thank you. You know, when I get asked this question I sort of come back to it is all about science. We need to use evidence-based and science programs and interventions for kids that are impacted by this epidemic, kids like me, and we need to find them early and we need to give them the services right away.

And I love that you mentioned mentoring because that was one of the key components for me as well. The mental health depart-

ment in our county assigned me a big sister when I was 11 years old and it was the first person I had ever met that had gone to college and was professional and a mentor and a real guide for me. But I also had mandated mental health. There were loving family members that I was put with in kinship care, living with my grandma, my grandparents. And we know to identify children that are impacted. And there is trauma. There is adverse child events.

Mr. CARTER. Right.

Ms. HULSEY NICKEL. You are susceptible to lots of things. So we need to identify all these kids early and then get them the services that they need.

Mr. CARTER. I am sure probably many of you read the book, Hillbilly Elegy, and, you know, J.D. Vance and that story, what a fascinating story. And it is just what you are saying, same scenario.

Mr. Hampton, I also found your testimony to be fascinating. Thank you for being here and thank you for what you are doing. I wanted to ask you, and I really want to ask all of you, what works? That is something I am struggling with because so many of my colleagues think all we have got to do is throw money at it and we know it has got to be more than that. What programs work?

Mr. HAMPTON. Thank you for that question, Congressman. It is a matter of throwing money at things, but I think it is a matter of throwing money at the right things, first of all.

Mr. CARTER. OK, fair enough.

Mr. HAMPTON. So the Surgeon General's 2016 report, and then I will go into my own personal experience, said that after year 1 people like myself we are considered in remission after year 1 of recovery. After 5 years we have an 85 percent chance at maintaining long-term recovery. So the question becomes why are we not supporting people beyond that in that first critical first year, but also up to those 5 years? For me——

Mr. CARTER. Because this is a lifelong challenge.

Mr. HAMPTON. It is a lifelong challenge. For me, I had been through treatment multiple times, detox multiple times. I will say treatment works. Treatment saved my life. But my 18 friends who have died in the last 2 years all had been through treatment, all had been through detox. Where we, I believe the system is failing is we are not spending enough time and money on recovery and recovery support services and we are constantly, you know, we are bunching up treatment with recovery. Treatment is not recovery. Recovery happens when you leave treatment.

Mr. CARTER. I am way over my time but I have to ask and I am going to ask, do programs with a spiritual component work better than others?

Mr. HAMPTON. Congressman, there are multiple pathways to recovery. Personally, me, I am a member of a 12-step fellowship and that is what works for me, but I have seen programs for all sorts of different people, faith-based, folks who are agnostic. It works and there are many different ways that people do this.

Mr. CARTER. That is the big challenge for us that we find. We want to fund the programs that work, but it is just a struggle.

Mr. HAMPTON. I will add to that, every year SAMHSA—I went this year in September, they release all the numbers. We know, the

Federal Government knows how many people are addicted to heroin, how many people are using cocaine, all the different drugs, the age groups, State by State data. There are 23 million people that are living in long-term recovery in the United States and I don't believe that the Federal Government has spent time studying us and how we achieved it. So maybe that would be a good first step.

Mr. CARTER. Again I want to thank all of you for being here and I yield back, Mr. Chairman.

Mr. BURGESS. The gentleman yields back. The chair thanks the gentleman. The chair would inquire of the gentleman of Oregon, do you wish to—pass on questions.

So the chair will recognize the gentleman from Virginia, 5 minutes for your questions, please.

Mr. GRIFFITH. Thank you very much, Mr. Chairman. And I appreciate all of you being here. As I think one of the previous members said, it has been a long day for you all. We know that and we appreciate you being here.

Ms. Nickel, I am going to address most of my questioning to you. I represent 22 counties, mostly rural, and seven independent small cities. The biggest one is about 25,000. The smallest of my cities is 3,500. We are all in an area that is underserved for drug abuse and mental health so we have problems there.

So that is where I am coming from when I ask these questions because we don't have enough treatment centers. In fact, in a huge number of my counties they just don't have anywhere to go. And I had some folks who are recovering and trying to do what they can, but there is no long-term treatment there. So that is where my questions are coming from and keep that in mind, if you would, with the answers to them.

So part of that is it is obviously important to build a pipeline of qualified healthcare providers that have been trained in substance use disorder treatment and pain management education, and as I understand it, the TEACH Act will help highlight curricula from centers of excellence and disseminate these best practices widely. What types of healthcare workers will the bill educate and how will the TEACH Act take into consideration the smaller institutions that are educating healthcare workers with limited resources, because if you are just doing the big ones you are not going to reach all of my counties.

Ms. HULSEY NICKEL. Absolutely. Thank you so much for that, Congressman. The TEACH Act will help to make sure that we get the right curriculum and training to all different kinds of healthcare providers, from specialty physicians, emergency departments, primary care, pediatricians, nurse practitioners. We need to move this to a chronic disease model, chronic care, and make sure that we have qualified and trained healthcare providers in all different types of settings, hospitals, in your regular doctor's office or your pediatrician's office so they can identify and assess and treat substance use disorders more early.

This is particularly important for rural communities where you are not going to find as much specialty treatment. Very long distances, we are doing work on the ground in a few places like Ohio in rural communities, very difficult to find medication-assisted treatment, providers that can prescribe the medicines that you

need to treat opioid use disorder that can do that long care follow up. And it also is true we need to have long-term care plans—12 months, 3 years, 5 years—depending on the severity of that substance use disorders, and TEACH Act will give healthcare providers the tools that they need to assess, identify, and make sure we build those treatment plans.

Mr. GRIFFITH. I appreciate that. Also, the Comprehensive Opioid Recovery Centers Act will identify some of the best centers in America providing care for addiction and recovery. And from what I understand, these centers deliver the full complement of addiction services. Congress will direct funding to support those centers and they in turn will provide documentation and data on their effectiveness, their models of care, and their collaboration with their communities.

Is the goal of the bill to scale up and spread so that there are more centers of excellence across the U.S. or is the goal to lift all boats with the rising tide so that any facility can improve even if they are not able to reach the centers of excellence level? And obviously when you don't have any you may need to start with something. Even if it doesn't meet the gold standard, we would like to have something that meets at least the silver standard.

But what do you think? Will the bill help with that?

Ms. HULSEY NICKEL. I believe so. I think it could help actually with both. I think creating these centers of excellence so we can really advance what patient-centered care looks like, to take down these silos to have better coordinated care, and then the lessons learned from these centers to be applied throughout our healthcare systems and to all of the components that we need to treat this illness. So I think it will actually have both effects.

We have a lot of rural communities that are struggling with this illness and we need to have more evidence and more new programs and protocols in place that we get to them quickly. And I believe that the Comprehensive Opioid Recovery Centers bill will help to do that.

Mr. GRIFFITH. I appreciate that. And for those folks who came in to see me, I hope this helps them know that we are trying to find something and several of those folks as I said were in recovery. Complement all, it is not easy.

I appreciate you, Mr. Hampton. But all those that we have had testify over the last couple of days, there have been a number of people that have had issues who are now in recovery and I compliment you all. And look, we have to realize there is a lot of talent out there that we are wasting if we don't use those people who are in recovery. And I yield back.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back. Does the gentleman from Oregon seek recognition?

Mr. SCHRADER. Yes, just briefly, Mr. Chairman. I want to thank the panelists for coming and sharing their stories. That will help us craft hopefully a better solution at the end of the day. I am in a listening mode right now and appreciate it very much, but a colleague of mine I would like to yield to, the Ranking Member Mr. Green, for some salient questions, please.

Mr. GREEN. I want to thank my colleague for yielding to me.

I have got a question for you, Ms. Deal-Smith, but when I was practicing law and dealt with clients through the mental health process I saw so many times when people were—it was a revolving door and a lot of things that we don't understand that this is a lifelong illness.

And I would see these patients, or clients of mine on a regular basis. I said, why weren't you, you left here, you had medication, you were doing fine. And a number of them said, well, I felt so good I didn't think I needed my medication. And I said, do you have anybody in your household that has heart trouble? I don't know if that is cured but you have to take the medication.

And so, but this is a lifelong illness in some cases and we need to recognize that. But sure, we would like a cure, but we would like a cure for cancer too, but we are still trying to manage it, so. But, Ms. Deal-Smith, how much of are you comfortable sharing, can you tell us about the background and history with substance use disorder?

Do you want to turn on your mike?

Ms. DEAL-SMITH. So my addiction started at an early age. I was 12 years old when I had my first alcohol and it progressed as the years went by and when I was like 28 years old I got into trouble with my addiction. I got a DWI and I had to go to residential treatment for 28 days. And in that treatment center I was given the tools to learn about my addiction and how to help myself get through hard times when they would be coming up and when I got out of treatment I had a director where I worked that helped me through the process because he was in recovery himself.

So I had a lot of support in my recovery and that is what I bring here is I am there for the people that are in recovery. I help them get along. I take them to the hospitals, the medications that are prescribed for them can they take this, can they not take it, so I talk to the therapists and the counselors, the substance abuse counselors and we find a good, a better way to treat them.

And if it is an opioid that they are prescribed we have to say, OK, is this good for them? The person is in recovery, no, it is not good for them. Let's look for another alternative so we can assist with getting them through this hard time. So that is part of my job is to be there for the client when they need you most and that is in early recovery.

Mr. GREEN. Congratulations. You were able to go from your history to be a peer support specialist. What do you think is the most important aspect of your job working with people in recovery, because if it works we would like to see how it works around the country, so.

Ms. DEAL-SMITH. It works because people like me who is in recovery are there to help them guide through the hardest time of their life to educate them and say, no you can't do this, yes you can do this. I will help you. I will do this. They meet me halfway and I meet them halfway. So I am able to be there for them when they need me the most.

I have people that are taking care of them at night and then they can call me when the clients, the relatives, need help, need assistance. I am there for them. I am there all the time.

Mr. GREEN. Thank you.

Thank you, Mr. Chairman. I yield back.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back.

Mr. Tonko, you are not on the subcommittee, but do you wish to be recognized for questions?

Mr. TONKO. I do.

Mr. BURGESS. You are recognized for 5 minutes.

Mr. TONKO. Thank you, Mr. Chair and Ranker Green. I thank you both for waiving me on to the subcommittee. I am grateful that the committee has decided to focus its attention on this life and death issue. It means a lot to the communities that I represent in the capital region to see Congress working together across the aisle to reduce the burden of this deadly opioid epidemic.

In particular, I am pleased that we are considering two bipartisan bills that I have had a hand in authoring, the Addiction Treatment Access Improvement Act and the TEACH to Combat Addiction Act. Combined, these bills would expand access to medication assisted treatments for opioid use disorders and help to prepare our next generation medical workforce to tackle the disease of addiction.

So, Ms. Horan, thank you for your testimony in support of the Addiction Treatment Access Improvement Act. In your written remarks you discuss the importance of including nurse practitioners and physician assistants as part of the addiction workforce. Can you go into a bit more detail about how NPs and PAs are integral to addiction care at CleanSlate and how integrating other high skilled nursing professions might enhance CleanSlate's ability to provide high quality substance use treatment?

Ms. HORAN. I would be happy to. Thank you for the question. I think, first and foremost, they help us meet the demand in the communities. As we have mentioned before we have talked about workforce shortages, some of the limitations around prescriptive authority, even if you can and are willing to do it, and the nurse practitioners and physician's assistants have been willing, wonderful, warm additions to our team.

I would say more than that they work alongside in strong collaboration with our physicians to prescribe, rather to provide a whole host of clinical services from physical exams to the support of counseling to medication management. They are part of the backbone of our clinical program. In terms of adding additional highly trained, interested, invested prescribers, we welcome them all. It is not easy to find folks who are this eager and this willing to work in the space and if they want to be part of the solution and join our team, we more than welcome them.

Mr. TONKO. Thank you. And I would think struggling with that illness, when you have the moment of clarity, treatment on demand is essential.

Again, Ms. Horan, how do CleanSlate and other high quality treatment centers work to minimize the risk of diversion of medication assisted treatment and how would the Addiction Treatment Access Improvement Act specifically encourage expanded treatment capacity in high quality settings like CleanSlate?

Ms. HORAN. Again thank you for the question. So I am not sure I talked much about our treatment model aside from who staffs it.

We are what we call a high touch model so the patients that come to our centers are seen with a high level of frequency. So the sicker you are, the more severe your illness is, the more frequently you will be seen. That would be about twice a week.

And then as you progress in your recovery, we are looking for markers of recovery, a number of things that are telling us that you are getting better, you will be seen once a week. Even at your most stable you won't be seen less than once a month. So that is important for a number of reasons. One, it is a way to keep the patient and the provider accountable to the patient's goals. Two, it brings them into the office with enough frequency where and in each visit they are given urine drug screens and other things. So we are testing for not just the drugs of, you know, of misuse but to make sure that they are taking the medication properly.

We also do more standard diversion control tactics. We do random pill, or patient recalls where they have to come in and bring their films and then we count films. And I think those things all combined we feel pretty secure that our patients are using the medications as prescribed.

Should a patient for some reason be found to have diverted the medication for purposes other than why we prescribed it that would be a cold stop for us. That would be a reason why we would ask a patient to leave. Now having said that, it is not in the interest of the patient or in the interest of the community to not make sure that that patient is somewhere else. Typically they will be referred up to methadone or somewhere else in the community.

So I just want to make clear that they are not being exited to nothing. And there will be instances when they can rejoin depending on the circumstances but, generally speaking, diversion, we take a pretty hard stance on that.

Mr. TONKO. Thank you. In your testimony you described waiting lists to access treatment in your facility in Anderson, Indiana. Unfortunately this is not an isolated phenomena as I have spoken with individuals in my district who have had to wait a year or more for a treatment slot. When an individual who is struggling with addiction is faced with barriers to treatment like waiting lists, what does that do for their chances of recovery?

Ms. HORAN. Well, first and foremost, The data shows that if access to MAT is a relapse prevention tool it also greatly increases, or reduces the chances that our patients will overdose. So when patients come to our centers, we have talked about readiness for change. Readiness for change means we want to open the door and bring them in right away. To have to turn a patient away means that we feel like we have put them at risk for relapse or for overdose. Moreover, it is just demeaning and demoralizing to finally be ready for change, to be ready to enter treatment, and to not be able to access it when you are ready for it.

We will do everything we can to ensure that that patient even if they can't be seen in our center is at least seen in a treatment program within the community or within, as in the case of the Anderson patients can access the next closest CleanSlate Center. But it is just, fundamentally it is a lost opportunity that really shouldn't exist.

Mr. TONKO. Thank you, Mr. Chair. I yield back.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back. Does the gentleman from Texas have another request?

Mr. GREEN. Mr. Chairman, I have a unanimous consent request to place into the record a statement from Congressman Bill Pascrell in support of H.R. 5197, the Alternative to Opioids in the Emergency Department Act, and also a statement from Congresswoman Katherine Clark and Congressman Hal Rogers in support of H.R. 5102, the Substance Use Disorder Workforce Loan Repayment Act of 2018. I ask unanimous consent to place those in the record.

Mr. BURGESS. Without objection, so ordered.

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

Mr. BURGESS. The chair will recognize himself for 5 minutes for questions.

Dr. Rosenberg, I was intrigued by your testimony and your alternatives that you use in your emergency department. There is an ancillary bill that is not directly related to what you are doing, but it seems to me that it has some connection. Dr. Gottlieb, yesterday, when he, the commissioner of the Food and Drug Administration, was talking to us talked about the difficulty of developing new treatments for pain and that the datasets are sometimes vague and indecipherable. And you seem to be doing though some work with what you described as alternative pathways. Is that correct?

Dr. ROSENBERG. That is correct.

Mr. BURGESS. So the bill that, actually it is only in draft form right now and it is one that is under development, but it is to encourage the Food and Drug Administration to develop draft guidance for alternative pain medicines and use and breakthrough designation along that development pathway. Again Dr. Gottlieb referenced how difficult that is in the research and regulatory environment, but you seem to have found a way to make that useful. Is that correct?

Dr. ROSENBERG. That is correct, Mr. Chairman.

Mr. BURGESS. What, if I may ask, if it is not proprietary, what is it? You reference enzymes in your testimony.

Dr. ROSENBERG. The principles behind the ALTO protocol is to really increase the number of tools in the physician's toolbox. As one of the congressmen suggested, there used to only be Tylenol, Motrin, and opioids, and if I wanted to guarantee the patient the best treatment we would give them opioids. Obviously that was a bad decision.

The principles between ALTO and the development of the ALTO protocols was really to search the world literature for existing protocols that existed without the use of opioids. Let me just give a quick example. Renal colic, if anybody had kidney stones, is a tremendously painful condition. But there have been treatment protocols and treatment successes in the literature using IV lidocaine that we used to use commonly for cardiac issues, now that works tremendously well for people with renal colic. It does two things. One, it relieves the pain. And we have to do more study on this, but it seems like it passes the kidney stone more quickly.

So the real secret behind ALTO is finding existing protocols, not going through an I or a B, not doing a lot of studies, at least that is how we created it by taking the protocols that are out there. We

use medications like nitrous oxide and do nerve blocks and lidocaine and use patches, but it is a layering of different medications and protocols together to get the maximum benefit for the patient.

Mr. BURGESS. Well, I thank you for that. It is very intriguing. Of course I am old enough to remember when we had toradol and stadol as new medicines.

Dr. ROSENBERG. Yes, indeed.

Mr. BURGESS. We no longer have those in our toolbox.

Mr. Hampton, thank you for being here. Your testimony, very compelling. We have heard and learned something around sober homes or sober living homes and I assume you are from California——

Mr. HAMPTON. That is correct.

Mr. BURGESS [continuing]. Since your representative is Representative Chu. Now there was recently some news from California about, I think, new regulations at a state level that they were applying to sober living homes. Do I recall that correctly?

Mr. HAMPTON. Actually, yes, Congressman. I have been working on that legislation also. Yes.

Mr. BURGESS. And so I wasn't sure what it was, so I Googled it and then what impressed me was the vast number of sober living homes that are available. Sober living homes California, and there is a lot of stuff that comes up on the little iPad. And we have had some hearings in the Oversight Subcommittee and I will say this as delicately as I can, but apparently all sober living homes are not created equal. Is that fair to say?

Mr. HAMPTON. That is correct, yes.

Mr. BURGESS. And I don't know whether it was you or someone else who referenced that how you get to treatment may vary and it could be through an advertisement on the television. We have all seen the advertisements. I have wondered about the advertisements. Pretty hard for a patient to discern what is reasonable, what is not. They are in trouble, they know they need help, here is someone offering help.

So take us through that a little bit how, from a patient's perspective how do you navigate that?

Mr. HAMPTON. Currently, it is nearly impossible, I would say, to be able to find an ethical, stable home without having firsthand knowledge of the home or a referral from a trusted family or friend. As you know, there is a lot of claims-based marketing that is going on, false claims-based marketing that is going on with treatment centers and with sober homes.

Luckily for me, my story happens that I, it is by sheer luck that I sit here today and that I found my way into a stable recovery residence. I had lived in Florida for some time also. That is where I am from. So I had been through multiple unscrupulous homes.

Families have a very hard time navigating the system.And I think that there is a solution to, you referenced California so the outcome of my friend Tyler dying was not just going to Congresswoman Chu and looking at the federal level, but it was going to our state senator as well and assembly members and drawing up legislation.

When we came up with SB–1228 there was no standard. There was no Federal standard. There were no best practices that the

Federal Government was publishing saying here is what a recovery residence should look like. I believe that that is a solution. It would have helped us with crafting the California legislation and I do believe other states are looking for that as well and part of that should be a ban on claims-based marketing.

There Re a lot of good places that people could find and we could draw them a road map, but unfortunately they don't have the types of budgets that some of these unscrupulous operators have because of the fraud they have committed and money that they have made off of the others' backs.

Mr. BURGESS. Well, perhaps you will be good enough to share with the subcommittee some of the data that you have collected over time and that is a much longer conversation, but we may ask, if you would, to submit that in writing.

And I do recall during the previous Congress we worked on the CURES for the 21st Century bill and the mental health title in that and also the peer support that I think you described seemed at some times to be almost as effective as the medication assisted therapies. Is that a fair statement?

Mr. HAMPTON. Yes. IThat is a fair statement. I think that again there are varying ways of recovery. I would say that peer support, in my opinion, medication assisted treatment does not work without the wraparound services as we have heard and the peer support. We need more MAT.

I am a supporter of MAT in other but going back to the housing issue, MAT is not welcome in, I would say, the super majority of sober homes in the United States. There is a huge disparity in terms of the services that someone on MAT can receive. So that is something that the states, I believe, need to deal with as well.

Mr. BURGESS. Very well. Well, you have been a great panel. And seeing there are no further members wishing to ask questions, I again want to thank our witnesses for being here today. I do want to submit statements from the following for the record.

Regarding H.R. 5102: the American Medicine Foundation, the Addiction Policy Forum, the American Academy of Addiction Psychiatry, the American Association of Colleges of Osteopathic Medicine, American Nurses Association, American Osteopathic Association and the Massachusetts Osteopathic Society, the American Society of Addiction Medicine, Association for Behavioral Healthcare, the Coalition to Stop Opioid Overdose, the International Certification & Reciprocity Consortium, Legacy Community Health, National Board of Certified Counselors, the National Council for Behavioral Health, the United States Representatives Clark and Rogers.

Regarding the Mullin Amendment in the Nature of a Substitute to H.R. 3545, a Partnership to Amend Part 2, Confidentiality Coalition, Premier, America's Essential Hospitals, Congressman Patrick Kennedy, National Governors Association, President's Commission on Combating Drug Addiction and the Opioid Crisis.

Articles from the following: The Journal of Accountable Care, American Journal on Addictions, New England Journal of Medicine, Journal of American Medicine, Ascension Michigan, Bloomberg Health Data Management.

And further statements from the following: The American Academy of Neurology, the American College of Obstetricians and Gynecologists, the American Society of Addiction Medicine, the Electronic Health Record Association, Keith Pardieck, National Association of Chain Drugstores, National Coalition on Health Care, Ohio State University, United South & Eastern Tribes Sovereignty Protection Fund.

And I would also like to submit Congressman Patrick Kennedy's statement for the record. He was unable to join us yesterday due to weather, but had planned on it.

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

Pursuant to committee rules, I remind members they have 10 business days to submit additional questions for the record. I ask the witnesses to submit their responses within 10 business days upon receipt of the questions. Without objection, the subcommittee then stands adjourned.

[Whereupon, at 2:54 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

March 22, 2018

Chairman Greg Walden
2185 Rayburn HOB
Washington, D.C. 20515

Ranking Member Frank Pallone
237 Cannon HOB
Washington D.C., 20515

Subcommittee Chairman Michael Burgess
2336 Rayburn HOB
Washington, D.C. 20515

Subcommittee Ranking Member Gene Green
2470 Rayburn HOB
Washington, D.C. 20515

Dear Chairman Walden, Ranking Member Pallone, Subcommittee Chairman Burgess and Ranking Member Green:

Thank you and all the members of your committee for your tireless efforts to examine and pass legislation that will help confront the opioid epidemic that plagues our great Nation. The committee continues to conduct a thoughtful and thorough examination of best options to save lives and improve the lives of so many American citizens.

My name is Sunil Bhonsle and I am the CEO of Titan Pharmaceuticals, Inc. Titan is a specialty pharmaceuticals company that develops therapeutics for select chronic diseases utilizing its innovative, long-term, continuous drug delivery platform, ProNeura™. The company's lead product is Probuphine®, a six-month buprenorphine implant for the maintenance treatment of opioid addiction. The U.S. Food and Drug Administration approved Probuphine on May 26, 2016. Probuphine is the first marketed product to provide maintenance treatment of opioid addiction continuously for six months following a single administration procedure.

Opioid addiction is a medical condition that is increasingly recognized as a global epidemic by world health authorities. Addiction is a primary, chronic disease of brain reward, motivation, memory and neurobiological circuitry. It is characterized by cravings, accompanied by a lack of impulse control, as well as cycles of relapse and remission. If left untreated, addiction is a progressive disease that often results in disability or premature death.

We strongly believe that addiction requires long-term treatment plans and medical care; abstinence is rarely a successful therapeutic approach. The current gold standard for medication assisted therapy (MAT) in the U.S. is buprenorphine. While daily or more frequently dosed sublingual formulations of buprenorphine (like Suboxone® or Zubsolv®) are widely used as a treatment for opioid addiction, there are challenges with this option, including patient compliance (mean number of days on treatment is 51 days nationally according to HHS ASPE), dosing that results in variable medication levels, diversion and abuse of the medication.

Given the significant health epidemic of opioid addiction in the U.S., health care providers and federal officials are seeking ways to ensure greater access to safe and effective treatments for the disease, while minimizing the risk of diversion and abuse. The U.S. Health and Human Services (HHS) Department recently announced that it will move to expand access to MAT by revising the regulations related to the

prescribing of buprenorphine to treat opioid dependence. The HHS revision to the regulation will hopefully provide a balance between expanding the supply of buprenorphine-based treatment, encouraging use of evidence-based MAT, and minimizing the risk of drug diversion.

Treatment options that minimize the risk of abuse and diversion, such as Titan's Probuphine (buprenorphine) implant, could increasingly play a crucial role in the maintenance treatment of patients suffering from opioid addiction. In addition to ensuring patient access to these long acting treatment options, there are provider and payer strategies which should be considered as part of a comprehensive healthcare approach, and we would be happy to provide specific recommendations that may encourage adoption of new treatment regimens. One important strategy to encourage the adoption of long acting formulations, which are injectable or implantable, would be to exempt such products from being included in the DATA 2000 physician patient cap, and this could be accomplished as part of the revisions to the regulations planned by the HHS under the authority of the Secretary. This would enable health care providers to expand their practice with new treatment modalities without having to compromise on the ongoing treatment of current patients.

We have conducted several controlled clinical studies over the past few years and established that Probuphine is safe and effective. In the most recent six-month clinical study among patients who were treated with Probuphine - three out of four patients remained free from illicit opioid use - and 82.1 % of patients did not need supplemental buprenorphine treatment. I think all lawmakers and healthcare professionals would agree that all forms of alternative treatment must be given full and extensive trial and consideration. We see our delivery platform as an important step forward in opioid treatment and we look forward to working with the Congress and the Administration to increase its exposure to interested federal and state partners. We would appreciate the opportunity to testify before your august committee to talk about this treatment.

Thank you and best regards.

Sunil Bhonsle President & CEO

The Addiction Medicine Foundation
Advancing Medical Practice in Addiction Prevention and Treatment

The Addiction Medicine Foundation

2 Wisconsin Circle, Suite 700 • Chevy Chase, MD 20815

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February 26, 2018

The Honorable Harold D. Rogers
2406 Rayburn House Office Building
Washington, DC 20515

The Honorable Katherine M. Clark
1415 Longworth House Office Building
Washington, DC 20515

Dear Congressman Rogers and Congresswoman Clark:

On behalf of The Addiction Medicine Foundation, I am writing to thank you for your efforts to help build the addiction treatment workforce in the United States and to give you our strong support and endorsement for your proposed legislation, the Substance Use Disorder Workforce Loan Repayment Act of 2018. Key provisions of this draft legislation would provide incentives for physicians to enter the new subspecialty of addition medicine. These include: up to $250,000 in medical school, residency or other education and training loan forgiveness in exchange for six years of professional practice in the field in an area of high need; repayment for years served (1/6th for each year) if the full six year period cannot be completed; and allowance for up to a year of non-work time (for example for maternity/paternity leave, other health reasons, etc.) that would extend the six year period. We also are heartened by the proposed funding of $25 million annually with a ten year authorization; this investment and long term commitment would help to create a needed pipeline of professionals entering the field.

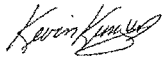
As you proceed with this and other legislation to address the unhealthy substance use and addiction crisis in the country, we strongly recommend that you proceed in a comprehensive fashion, including all addictive substances (alcohol, nicotine, controlled prescription, illicit and other addictive drugs) and including prevention and early intervention as well as treatment and disease management.

Phone: (301) 656-3378 • Facsimile: (240) 762-5422
E-mail: email@addictionmedicinefoundation.org

Use of any substance increases the chances of use of and addiction involving others and cessation of use of one substance, unless addressed in a comprehensive way, is often followed by substitution with another. Further, we will never treat our way out of the addiction crisis; we must also focus on the front end to prevent unhealthy use and intervene early to prevent costly health and social consequences. Finally, we recommend that you consider support for physicians who agree to serve as addiction faculty and as state and local addiction medical staff. The broad change that is needed in medicine is driven by fellowship training, support for which is included in this bill. However, fellows are not only trained as expert clinicians but also as faculty to teach others and as change agents to drive knowledge and practice across public policy and programs.

Again, we are grateful for your recognition of the importance of addressing unhealthy substance use and addiction as health issues and your work to build the healthcare addiction workforce. If we can provide any further information as you proceed with your deliberations, please let us know.

Best Regards,



Kevin Kunz, M.D., M.P.H., DFASAM
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ADDICTION POLICY FORUM

March 20, 2018

The Honorable Michael Burgess, Chairman
Subcommittee on Health
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Gene Green, Ranking Member
Subcommittee on Health
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman, and Ranking Member:

I am writing on behalf of the Addiction Policy Forum to express our support for the Substance Use Disorder Workforce Loan Repayment Act of 2018 (H.R. 5102), which will incentivize health professionals to provide substance use disorder treatment in underserved communities.

All over the United States, communities are reporting that there are not enough treatment specialists available to help the growing number of Americans struggling daily with substance use disorder. From physicians, to nurses, to addiction counselors and other behavioral health specialists, additional treatment workers with proper training and experience are desperately needed across the nation. Attracting new providers to the demanding field can be difficult, and even when healtheare professionals do join the substance use disorder treatment workforce, burnout is a significant problem, further compounding the shortage of treatment staff with significant experience. In 2012, the turnover rates in the addiction services workforce ranged from 18.5% to more than 50%

The scope of the problem is not just anecdotal. More than 62 million people (20-23 percent) in the U.S. live in rural or frontier counties and 75 percent of these counties have no advanced behavioral health practitioners. In 2015, the Substance Abuse and Mental Health Services Administration (SAMHSA) reported that an estimated 21.7 million people aged 12 or older (8.1 percent of that population) needed substance use disorder treatment, but only an estimated 2.3

million of that population received treatment at a specialty facility. Stated plainly, only 10.8 percent of adolescents and adults who needed treatment received it.

Introduced recently by Representative Katherine Clark and Representative Hal Rogers, the Substance Use Disorder Workforce Loan Repayment Act would help address these serious gaps in services. Specifically, the legislation would bolster the critical substance use disorder treatment workforce by creating a student loan repayment program for healthcare professionals who enter and work in the substance use disorder treatment field. In an effort to attract the full range of experts needed for comprehensive substance use disorder treatment, the program would be available to a broad range of healthcare professionals including doctors, nurses, social workers, and mental health professionals. To qualify for the program, applicants must agree to be employed in a full-time substance use disorder treatment job in a direct patient care role located in either a Mental Health Professional Shortage Area or in areas experiencing a higher than average overdose death rate.

This legislation would be a significant step toward addressing the serious workforce shortages in SUD treatment across our nation, which is why we urge Congress to pass the Substance Use Disorder Workforce Loan Repayment Act quickly.

Sincerely,

Jessica Hulsey Nickel
President and CEO
Addiction Policy Forum

CC: The Honorable Greg Walden
The Honorable Frank Pallone

American Academy of Addiction Psychiatry
Translating Science. Transforming Lives.

P 401 524-3076
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www.aaap.org

March 20, 2018

The Honorable Katherine Clark
The Honorable Hal Rogers
U.S. House of Representatives U.S. House of Representatives
1415 Longworth House Office Building 2406 Rayburn House Office Building
Washington, D.C. 20515 Washington, DC 20515

Dear Representatives Clark and Rogers,

On behalf of the American Academy of Addiction Psychiatry, representing nearly 2,000 Addiction Psychiatrists, I am writing to thank you for your leadership in authoring legislation to create a student loan forgiveness program for addiction treatment professionals. Your bill, the Substance Use Disorder Workforce Loan Repayment Act of 2018, would improve access to desperately needed substance use treatment services for millions of Americans across the country.

Across the nation, communities are confronting an opioid addiction crisis while at the same time experiencing an ongoing labor shortage among addiction professionals, slowing the response to the crisis. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), 22 million Americans aged 12 or older have experienced a substance use disorder. Yet only 1 in every 10 people living with addiction receives treatment services. Your legislation would help addiction treatment providers meet the rising demand for treatment by strengthening their ability to attract and retain high-quality staff.

One major barrier to confronting our nation's opioid crisis is the lack of a sufficient addiction treatment workforce. Community-based addiction and mental health treatment providers report high turnover rates and difficulty in filling vacant positions. Salaries in behavioral health care—***particularly in addiction services***—are well below those for parallel positions in other health care sectors and in business (SAMHSA, 2013). Your bill offers providers a powerful recruitment tool to increase the number of dedicated and well-trained addiction treatment professionals working in

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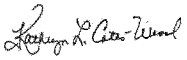
Kathryn Cates-Wessel, CHIEF EXECUTIVE OFFICER

high-need communities, including those areas hit-hard by the opioid epidemic.

Loan forgiveness programs have proven successful in helping primary care and mental health clinics attract a well-trained workforce into medically underserved areas, yet addiction treatment providers have not had the same access to federal loan forgiveness funds. By creating a loan forgiveness program dedicated specifically to substance use disorder services, your legislation would grow the availability of substance use disorder treatment professionals. By increasing addiction treatment capacity nationwide, your bill helps to implement a comprehensive strategy to address the nation's growing addiction crisis.

Thank you for your dedication to expanding access to lifesaving treatment for millions of Americans living with substance use disorders. AAAP looks forward to working with you and your colleagues to see this important legislation through to passage.

Sincerely,



Kathryn Cates-Wessel
CEO, American Academy of Addiction Psychiatry

aacom®
AMERICAN ASSOCIATION OF
COLLEGES OF OSTEOPATHIC MEDICINE

March 20, 2018

The Honorable Katherine Clark
U.S. House of Representatives
1415 Longworth House Office Building
Washington, DC 20515

The Honorable Harold Rogers
U.S. House of Representatives
2406 Rayburn House Office Building
Washington, DC 20515

Dear Representatives Clark and Rodgers:

On behalf of the American Association of Colleges of Osteopathic Medicine (AACOM), I offer support for H.R. 5102, the *Substance Use Disorder Workforce Loan Repayment Act of 2018*. Thank you for your leadership in introducing this vital legislation, which seeks to increase the number of qualified health professionals working in substance use disorder roles in areas where the opioid epidemic has impacted communities most.

AACOM represents the 34 accredited colleges of osteopathic medicine in the United States. These colleges are accredited to deliver instruction at 51 teaching locations in 32 states. Six of the colleges are public and 28 are private institutions. In the current academic year, these colleges are educating nearly 29,000 future physicians—more than 20 percent of all U.S. medical students.

AACOM applauds your efforts in working to address this crisis in our nation's health care system. As educators of future physicians, we strongly support policies, including the *Substance Use Disorder Workforce Loan Repayment Act of 2018*, that aim to encourage health professionals to practice in medically underserved communities where there is a shortage of substance abuse disorder treatment professionals.

There is a clear need for programs that encourage greater connection and services between traditionally underserved communities and the physician workforce by creating opportunities for health professionals to practice in these regions of the country in exchange for loan repayment. H.R. 5102 offers a much-needed solution to transition health professionals into medically underserved areas and reduce growing disparity in health care services in our country, which in turn will help combat the opioid epidemic.

On behalf of AACOM, I offer our support for the *Substance Use Disorder Workforce Loan Repayment Act of 2018* and thank you for your leadership and dedication to supporting policies that make it more affordable for physicians and other health professionals to give back to underserved communities.

Respectfully,

Stephen C. Shannon, DO, MPH
President and CEO

Office of Government Relations
600 New Jersey Avenue NW
Suite 330
Washington, DC 20001-2005
www.aacom.org

ANA
AMERICAN NURSES ASSOCIATION

March 19, 2018

The Honorable Katherine Clark
U.S. House of Representatives
1415 Longworth House Office Building
Washington, DC 20515

The Honorable Hal Rogers
U.S. House of Representatives
2406 Rayburn House Office Building
Washington, DC 20515

Dear Representatives Clark and Rogers,

Representing the interests of our nation's more than 3.6 million registered nurses, the American Nurses Association (ANA) writes to express its strong support for the Substance Use Disorder Workforce Loan Repayment Act of 2018.

Registered nurses are practicing on the front lines of the opioid crisis and know firsthand the importance of ensuring access to vital substance use disorder treatment. Our nation's ability to make progress against this crisis depends heavily on having a strong, highly trained health workforce.

The Substance Use Disorder Workforce Loan Repayment Act of 2018, which seeks to incentivize students to pursue substance use disorder treatment professions by providing student loan relief, is critical to ensuring we are building a highly trained workforce that can meet these challenging times.

Nurses work in virtually every health care setting, providing expert, compassionate care for people throughout all stages of life, condition, disability, or disorder. As the organization representing the nation's largest, most trusted group of health care professionals, ANA thanks you for your leadership on this critical matter.

Please let us know how we might be a resource as you seek to advance this bill in the 115th Congress.

Sincerely,

Michelle M. Artz
Director, Department of Government Affairs

8515 Georgia Ave., Suite 400
Silver Spring, MD 20910
www.nursingworld.org

AMERICAN **OSTEOPATHIC** ASSOCIATION

TREATING OUR FAMILY AND YOURS

February 27, 2018

The Honorable Katherine Clark
U.S. House of Representatives
1415 Longworth House Office Building
Washington, DC 20515

Dear Representative Clark:

The American Osteopathic Association (AOA) and Massachusetts Osteopathic Society (MOS), together represent more than 137,000 osteopathic physicians (DOs) and osteopathic medical students, including more than 1,100 DOs practicing in Massachusetts. We write to express our gratitude for your leadership in crafting the *Substance Use Disorder Workforce Loan Repayment Act of 2018*, and for collaborating with AOA in developing the legislation. We applaud your initiative and strongly support your bipartisan efforts to strengthen our substance abuse treatment workforce and for providing greater access to care for patients who need them most.

As you are aware, overdoses from prescription opioids have dramatically increased in the United States. Today, according to the Centers for Disease Control and Prevention, 40% of all U.S. opioid overdose deaths involve a prescription opioid. In 2016, more than 46 people died every day from overdoses involving prescription opioids. Along with this growing epidemic is the continued shortage in our health care workforce. The Council of Graduate Medical Education projects a shortage of 85,000 physicians in 2020 – the impact of which will be more dramatic in rural communities.

The *Substance Use Disorder Workforce Loan Repayment Act* addresses these critical issues by providing an additional path for health care providers to practice in rural and underserved communities, which allows for greater access to care for those suffering from substance use disorder. This legislation will strengthen rural health care systems and will improve access to care for patients in rural communities – a longstanding shared commitment of the osteopathic profession.

Osteopathic physicians in particular fill a critical need in our nation's health care system, as many practice in rural and underserved areas. Further, osteopathic physicians are trained in a "whole person" approach to care, which involves treating all aspects of a patient's illness or injury, including the use of nonpharmacologic treatment strategies for acute or chronic pain. With the focus on the whole patient as the guiding philosophy of osteopathic medicine, we believe that treatment strategies must be comprehensive and able to address each individual patient's needs.

We thank you for your leadership in authoring this important legislation that will help build a well-equipped workforce to combat the current rise in substance use disorders. The AOA and its members stand ready to assist you in securing its enactment into law.

Sincerely,

Mark A. Baker, DO
President, AOA

Mekkin Lynch, DO
President, MOS

ASAM American Society *of* Addiction Medicine

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March 7, 2018

The Honorable Hal Rogers
U.S. House of Representatives
2406 Rayburn House Office Building
Washington, DC 20515

The Honorable Katherine Clark
U.S. House of Representatives
1415 Longworth House Office Building
Washington, DC 20515

Re: H.R. 5102, Substance Use Disorder Workforce Loan Repayment Act of 2018

Dear Representatives Rogers and Clark,

On behalf of the American Society of Addiction Medicine (ASAM), the nation's oldest and largest medical specialty society representing more than 5,100 physicians and allied health professionals who specialize in the treatment of addiction, I am writing to offer our support for your bill, the Substance Use Disorder Workforce Loan Repayment Act of 2018.

The current addiction treatment gap will never be closed with the current addiction treatment workforce. There are simply too few physicians and other clinicians with the requisite knowledge to meet the needs of the estimated 20.1 million Americans suffering from untreated substance use disorders. To make a meaningful and sustainable impact on the current opioid overdose epidemic, and to stave off future epidemics related to other addictive substances such as cocaine, benzodiazepines or methamphetamine, it is imperative that our country make strategic investments to incentivize clinicians to work in programs and practices that specialize in the treatment of substance use disorder and addiction.

The Substance Use Disorder Workforce Loan Repayment Act would create a more robust treatment workforce by helping participants who pursue full-time substance use disorder treatment jobs in high-need geographic areas repay their student loans. ASAM supports the goals of your bill and its efforts to address the opioid crisis by incentivizing physicians and other clinicians to work in substance use disorder treatment programs and practices.

11400 Rockville Pike Suite 200 Rockville, MD 20852
Phone: 301-656-3920 | Fax: 301.656.3815
www.ASAM.org

Thank you for your leadership in introducing this important legislation, and we look forward to working with you to secure its passage.

Sincerely,

Kelly J. Clark, MD, MBA, DFASAM
President, American Society of Addiction Medicine

ABH

ASSOCIATION
FOR BEHAVIORAL
HEALTHCARE

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Vicker V. DiGravio III PRESIDENT / CEO
Karin Jeffers, LMHC CHAIR

February 27, 2018

Congresswoman Katherine Clark
1415 Longworth House Office Building
Washington, DC 20515

Dear Congresswoman Clark:

The Association for Behavioral Healthcare (ABH) writes today in strong support of the soon to be introduced *Substance Use Disorder Workforce Loan Repayment Act of 2018.* We commend you for your work in addressing the workforce shortages that plague treatment providers across the country as they work to treat individuals who suffer from opioid addiction.

ABH is a Massachusetts-based, statewide association representing more than eighty community-based mental health and addiction treatment provider organizations. Our members are the primary providers of publicly-funded behavioral healthcare services in the Commonwealth, serving approximately 81,000 Massachusetts residents daily, 1.5 million residents annually, and employing over 46,500 people.

As you well know, Massachusetts and the United States are in the midst of an unprecedented opioid epidemic. In Massachusetts alone, 1,977 individuals died of opioid related deaths in 2017. This is a decrease of 179 individuals from 2016, the first year-over-year decline in several years. The treatment community is grateful for the continued commitment of Congress to combatting this epidemic, but the demand for treatment continues to outpace capacity.

ABH members continue to report difficulty in recruiting and retaining adequately trained staff to serve individuals across the addition treatment system. Based on data from a 2017 survey of ABH members, we know that the overall pay rates in Massachusetts acute care hospitals are significantly higher than in the behavioral health organizations in the state. The overall pay gap for comparable jobs was approximately 22.8%. The Substance Abuse and Mental Health Services Administration (SAMHSA) reported to Congress in 2013 that the "growing workforce crisis in the addictions field" is due to a variety of factors, including stigma, an aging workforce and inadequate compensation. [1]

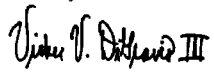
This legislation is essential as it allows individuals who chose to work in the addiction field to access student loan repayment, and it includes and encourages the participation of a wide variety of professionals and paraprofessionals. The treatment system relies on staff practicing at the top of their licensure in order to serve more clients, supported by direct care staff and recovery coaches.

[1] https://store.samhsa.gov/shin/content/PEP13-RTC-BHWORK/PEP13-RTC-BHWORK.pdf

The legislation enumerates a number of important positions, and allows the Secretary of Health and Human Services to determine other relevant professionals as he/she sees fit.

ABH is pleased to offer our strong support for this important piece of legislation. Should you have any questions or need further information, please do not hesitate to contact me at 508-647-8385 x 11 or vdigravio@abhmass.org.

Sincerely,



Vicker V. DiGravio III
President/CEO

COALITION TO
STOP OPIOID
OVERDOSE

March 19, 2018

The Honorable Hal Rogers
U.S. House of Representatives
2406 Rayburn House Office Building
Washington, DC 20515

The Honorable Katherine Clark
U.S. House of Representatives
1415 Longworth House Office Building
Washington, DC 20515

Re: H.R. 5102, Substance Use Disorder Workforce Loan Repayment Act of 2018

Dear Representatives Rogers and Clark,

The undersigned mental health, substance use disorder, and health care professional organizations in the Coalition to Stop Opioid Overdose are writing today to express our support for your bill, the Substance Use Disorder Workforce Loan Repayment Act of 2018.

The Coalition to Stop Opioid Overdose (CSOO) is a coalition of diverse organizations representing health care and social service professionals and advocates united around common policy goals that will lead to meaningful and comprehensive policies to reduce opioid overdose deaths through prevention, treatment and recovery support services.

The morbidity and mortality statistics related to addiction, and in particular opioid addiction, are astounding. From 1999 to 2016, there have been over 200,000 overdose deaths related to prescription opioids making it the current leading cause of accidental death in the U.S.[i,ii]

To turn the tide of the opioid epidemic in the U.S., we need to build a more robust treatment workforce. There are simply too few clinicians with the requisite knowledge to meet the needs of the estimated 20.1 million Americans suffering from untreated substance use disorders. To make a meaningful and sustainable impact on the current opioid overdose epidemic, it is imperative that our country make strategic investments to incentivize clinicians to work in programs and practices that specialize in the treatment of substance use disorder and addiction.

The Substance Use Disorder Loan Repayment Act would create a more robust treatment workforce by helping participants who pursue full-time substance use disorder treatment jobs in high-need geographic areas repay their student loans, and the undersigned members of CSOO are proud to support it. Thank you for your leadership in introducing this important legislation. We look forward to working with you to secure its passage.

Sincerely,

Academy of Integrative Pain Management
American Association of Nurse Practitioners
American College of Osteopathic Emergency Physicians
American Psychiatric Association
American Psychological Association

COALITION TO
STOP OPIOID
OVERDOSE

American Society of Addiction Medicine
A New PATH (Parents for Addiction Treatment and Healing)
Association for Behavioral Health and Wellness
CADA of Northwest Louisiana
California Consortium of Addiction Programs & Professional
Connecticut Certification Board
HIV Alliance
IC & RC
Illinois Association of Behavioral Health
National Association of Clinical Nurse Specialists
National Council for Behavioral Health
Shatterproof
The Kennedy Forum
Treatment Communities of America
Young People in Recovery

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[i] Frenk SM, Porter KS, Paulozzi LJ. Prescription opioid analgesic use among adults: United States, 1999–2012. NCHS data brief, no 189. Hyattsville, MD: National Center for Health Statistics. 2015.
[ii] Hedegaard H, Warner M, Miniño AM. Drug overdose deaths in the United States, 1999–2016. NCHS Data Brief, no 294. Hyattsville, MD: National Center for Health Statistics. 2017.

IC&RC

The Honorable Katherine Clark
1415 Longworth House Office Building
Washington DC 20515

Dear Rep. Clark,

We write today in support of HR 5102, the "Substance Use Disorder Workforce Loan Repayment Act." The importance of SUD professionals, and the role they play in our public health continuum, can no longer be overlooked.

IC&RC is the global leader in the credentialing of prevention, addiction treatment, and recovery professionals. Organized in 1981, it provides standards and examinations to certification and licensing boards in 24 countries, 47 states and territories, five Native American regions, and all branches of the U.S. military. Quality and integrity are the foundation of IC&RC's work. IC&RC's credentials use the latest research on evidence-based practices, and they are updated every five years and subjected to an extensive process of peer review.

According to the National Survey on Drug Use and Health, approximately 22,700,000 people in the United States needed substance use disorder treatment in 2013, but only 2,500,000 people received it. Furthermore, current treatment services are not adequate to meet demand. There are approximately 32 providers for every 1,000 individuals needing substance use disorder treatment. In some States, the ratio is much lower. The U.S. Bureau of Labor Statistics projects that there are currently 95,000 substance abuse counselors in the united states, and that by 2022, there will be enough demand to require over 116,000. Your legislation will go a long way towards addressing these shortfalls, improving a system of care that is vital to thousands of people from Massachusetts and millions of Americans.

We thank you for your continued commitment to this issue, as you have always been one of our greatest champions in Congress. You have our unwavering support.

Sincerely,

Dave Turpin

David Turpin
President
IC&RC

Mary Jo Mather
Executive Director
IC&RC

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LEGACY COMMUNITY HEALTH
1415 California St. | T (832) 548 5100 | LegacyCommunityHealth.org
Houston, TX 77006 | F (832) 548 5092

March 12, 2018

Re: Support for HR 5102, the "Substance Use Disorder Workforce Loan Repayment Act of 2018"

Dear Member of Congress:

On behalf of Legacy Community Health, one of the largest community health centers in the nation, we appreciate the opportunity to express our **support for HR 5102, the "Substance Use Disorder Workforce Loan Repayment Act of 2018."** The bill will create a program for participants to work as substance use disorder treatment employees for up to six years in exchange for student loan repayment of up to $250,000 per participant.

Investing in the repayment of student loans for Substance Use Disorder employees will help attract new talent to the workforce, and ensure those new employees continue working by spacing out payments over six years. We encourage Congress to vote for this legislation.

Thank you for your consideration of our comments. If I can be of further assistance to you, please do not hesitate to contact Lindsay Lanagan at LLanagan@LegacyCommunityHealth.org.

Sincerely,

Katy Caldwell

Katy Caldwell, CEO

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Alexandria, Virginia
22314 USA

TEL: +1.703.732.6328
FAX: +1.703.919.0897
www.nbcc.org

March 9, 2018

The Honorable Hal Rogers
2406 Rayburn HOB
Washington, DC 20515

RE: Endorsement of H.R. 5102, Substance Use Disorder Workforce Loan Repayment Act of 2018

Dear Congressman Rogers,

I am writing on behalf of the National Board for Certified Counselors (NBCC) to endorse H.R. 5102, the Substance Use Disorder Workforce Loan Repayment Act of 2018. NBCC is the national credentialing organization for the counseling profession, representing over 63,000 National Certified Counselors (NCCs) in the United States. NBCC also develops and administers the examinations for licensure of mental health counselors in all 50 states, Puerto Rico, and the District of Columbia.

The Substance Use Disorder Workforce Loan Repayment Act is of critical importance because it will increase the addictions workforce. The timing could not be more urgent, as the nation faces the opioid crisis. There are not enough addiction counselors to meet the public need and people are dying as a result. Opioid abuse, hospitalization, and death are skyrocketing, and Congress needs to act.

Providing loan repayments to addiction counselors will strengthen the workforce and increase the number of professionals available to meet this demand. Directing the funding to areas with high rates of overdose death and mental health professional shortages will ensure that the neediest populations are served by this legislation.

The NBCC supports the Substance Use Disorder Workforce Loan Repayment Act and is committed to passage of this legislation through Congress. Please contact me at bergman@nbcc.org or 703-739-6208 with any questions about this letter. Thank you for your leadership on this important policy.

Sincerely,

David M Bergman

David M. Bergman
Vice President of Legal and External Affairs
National Board for Certified Counselors

NATIONAL COUNCIL
Healthy Minds, Strong Communities
Jeff Richardson, MBA, LCSW-C, Board Chair
Linda Rosenberg, MSW, President and CEO

February 27, 2018

The Honorable Katherine Clark
U.S. House of Representatives
1415 Longworth House Office Building
Washington, D.C. 20515

The Honorable Hal Rogers
U.S. House of Representatives
2406 Rayburn House Office Building
Washington, DC 20515

Dear Representatives Clark and Rogers,

On behalf of the National Council for Behavioral Health and our 2,900 community-based mental health and addiction treatment member organizations, I am writing to thank you for your leadership in authoring legislation to create a student loan forgiveness program for addiction treatment professionals. Your bill, the Substance Use Disorder Workforce Loan Repayment Act of 2018., would improve access to desperately needed substance use treatment services for millions of Americans across the country.

According to the Substance Ahuse and Mental Health Services Administration (SAMHSA), 22 million Americans aged 12 or older have experienced a substance use disorder. Yet, only 1 in every 10 people living with addiction receive treatment services. This unmet need, known as the "treatment gap," is caused in large part by severe workforce shortages in the addiction treatment field. Your legislation would help addiction treatment providers meet the rising demand for treatment by strengthening their ability to attract and retain high-quality staff.

One major barrier to confronting our nation's opioid crisis is the lack of a sufficient addiction treatment workforce. Community-based addiction and mental health treatment providers report high turnover rates and difficulty in filling vacant positions. Salaries in behavioral health care – ***particularly in addiction services*** – are well below those for parallel positions in other health care sectors and in business (SAMHSA, 2013). Your hill offers providers a powerful recruitment tool to increase the number of dedicated and well-trained addiction treatment professionals working in high-need communities, including those areas hit-hard by the opioid epidemic.

Loan forgiveness programs have proven successful in helping primary care and mental health clinics attract a well-trained workforce into medically underserved areas, yet addiction treatment providers have not had the same access to federal loan forgiveness funds. By creating a loan forgiveness program dedicated specifically to suhstance use disorder services, your legislation would grow the availability of substance use disorder treatment professionals. By increasing addiction treatment capacity nationwide, your hill helps to implement a comprehensive strategy to address the nation's growing addiction crisis.

Thank you for your dedication to expanding access to lifesaving treatment for millions of Americans living with substance use disorders. The National Council looks forward to working with you and your colleagues to see this important legislation through to passage.

Sincerely,

Linda Rosenberg

Linda Rosenherg
President and CEO
National Council for Behavioral Health

PARTNERSHIP TO AMEND 42 CFR PART 2

A COALITION OF OVER 40 HEALTH CARE STAKEHOLDERS COMMITTED TO ALIGNING 42 CFR PART 2 (PART 2) WITH HIPAA TO ALLOW APPROPRIATE ACCESS TO PATIENT INFORMATION THAT IS ESSENTIAL FOR PROVIDING WHOLE-PERSON CARE.

March 21, 2018

The Honorable Markwayne Mullin
United States House of Representatives
1113 Rayburn House Office Building
Washington, DC 20515

The Honorable Earl Blumenauer
United States House of Representatives
1111 Longworth House Office Building
Washington, DC 20515

Dear Representatives Mullin and Blumenauer:

The undersigned members of the Partnership to Amend 42 CFR Part 2 (Partnership) and additional stakeholder organizations applaud your leadership on the issue of substance use disorder privacy records and strongly support your bill, the Overdose Prevention and Patient Safety (OPPS) Act, H.R. 3545, to align 42 CFR Part 2 (Part 2) with the Health Insurance Portability and Accountability Act (HIPAA) for the purposes of health care treatment, payment, and operations (TPO). We appreciate the provision in your bill that strengthens protections against the use of substance use disorder records in criminal proceedings.

The Partnership is a coalition of over 40 health care stakeholder organizations committed to aligning Part 2 with HIPAA to allow appropriate access to patient information that is essential for providing whole-person care.

The federal regulations governing the confidentiality of drug and alcohol treatment and prevention records, Part 2, set requirements limiting the use and disclosure of patients' substance use records from certain substance use treatment programs. Obtaining multiple consents from the patient is challenging and creates barriers to whole-person, integrated approaches to care, which are part of our current health care framework. Part 2 regulations may lead to a doctor treating a patient and writing prescriptions for opioid pain medication for that individual without knowing the person has a substance use disorder. Separation of a patient's addiction record from the rest of that person's medical record creates several problems and hinders patients from receiving safe, effective, high quality substance use treatment and coordinated care.

We are pleased that your bill would align Part 2 with HIPAA's consent requirements for the purposes of TPO, which will allow for the appropriate sharing of substance use disorder records to ensure persons with opioid use disorder and other substance use disorders receive the integrated care they need. Additionally, as we do not want patients with substance use disorders to be made vulnerable as a result of seeking treatment for addiction, this legislation strengthens protections of their records.

As you know, the Substance Abuse and Mental Health Services Administration (SAMHSA) released final rules in 2017 and 2018 which take some steps to modernize Part 2, but do not go far enough. Legislative action is also necessary in order to modify Part 2 and bring substance use records into the 21st Century. We thank you for leading that effort and look forward to working with you to advance this important bipartisan legislation.

Sincerely,

Academy of Managed Care Pharmacy
American Association on Health and Disability

American Health Information Management Association
American Hospital Association
American Psychiatric Association
American Society of Addiction Medicine
American Society of Anesthesiologists
America's Essential Hospitals
America's Health Insurance Plans
AMGA
Association for Ambulatory Behavioral Healthcare
Association for Behavioral Health and Wellness
Association for Community Affiliated Plans
Blue Cross Blue Shield Association
The Catholic Health Association of the United States
Centerstone
Confidentiality Coalition
Employee Assistance Professionals Association
Global Alliance for Behavioral Health and Social Justice
Hazelden Betty Ford Foundation
Health IT Now
Healthcare Leadership Council
InfoMC
The Joint Commission
The Kennedy Forum
Mental Health America
National Alliance on Mental Illness
National Association of ACOs
National Association of Psychiatric Health Systems
National Association of State Mental Health Program Directors
Netsmart
Otsuka America Pharmaceutical, Inc.
Premier Healthcare Alliance
Smiths Medical

Additional Stakeholder Organizations
Adventist Health
Adventist Health System
Aetna
AnMed Health
Anthem
Ascension
Association of American Medical Colleges
Atlanticare
Atrius Health
Aurora Health
Avera Health
Banner Health
Baptist Healthcare System
Beacon Health Options
East Alabama Medical Center
First Health of the Carolinas
Greater New York Hospital Association
Henry Ford Health System

Johns Hopkins Health System
Lehigh Valley Health Network
LifeBridge Health
Marshfield Clinic
Mercy Health
Methodist Health System
Morehouse School of Medicine
Mosaic Life Care Medical Center
Mountain States Health Alliance
New Directions Behavioral Health
PerformCare
SSM Health
St. Joseph's/Candler
Summa Health
Trinity Health

Attachment 6

February 20, 2018

The Honorable Greg Walden
Chairman
U.S. House of Representatives
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Frank Pallone
Ranking Member
U.S. House of Representatives
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Walden and Ranking Member Pallone,

The Confidentiality Coalition is writing to you to urge passage of H.R. 3545, the Overdose Prevention and Patient Safety (OPPS) Act, to enable the appropriate exchange of necessary information among medical professionals who are treating individuals with substance use disorders, including opioid abuse. While the Confidentiality Coalition commends the U.S. Substance Abuse and Mental Health Service Administration's (SAMHSA's) ruling to amend 42 C.F.R. Part 2 to better align Part 2 regulations within the Health Insurance Portability and Accountability Act (HIPAA) to integrate behavioral and physical healthcare, we believe this ruling does not go far enough to help increase access to relevant health information among patients, payers and providers while concurrently protecting patient privacy.

The Confidentiality Coalition is a broad group of organizations spanning all sectors of healthcare working to ensure that policies are implemented to appropriately balance the protection of confidential health information with the efficient and interoperable systems needed to provide high quality healthcare. Access to timely and accurate patient information leads to both improvements in quality and safety and the development of new lifesaving and life-enhancing medical interventions.

The Confidentiality Coalition is comprised of hospitals, medical teaching colleges, health plans, pharmacies, pharmaceutical companies, medical device manufacturers, vendors of electronic health records, biotech firms, employers, health product distributors, pharmacy benefit managers, health information and research organizations, clinical laboratories, and others. Through this diversity, we develop a nuanced perspective on the impact of any legislation or regulation affecting the privacy and security of health consumers.

Current federal regulations governing the confidentiality of drug and alcohol treatment and prevention records (42.C.F.R. Part 2 (Part 2)) preclude the Centers for Medicare & Medicaid Services (CMS) from disclosing medical information to healthcare providers for care coordination, including those engaged in accountable care organizations and bundled payment organizations. These regulations currently require complex and multiple patient consents for the use and disclosure of patients' substance use records that go beyond the sufficiently strong patient confidentiality protections that were subsequently put in place by HIPAA.

Electronic health records and value-based payment models such as Accountable Care Organizations (ACOs), Health Information Exchanges (HIEs), Medicaid Health Homes and related Medicare and Medicaid integrated care programs were designed to create a more holistic, patient-centered approach to healthcare where providers work together to coordinate across their traditional silos and in some cases are held jointly accountable for the quality, outcomes and cost of that care. Critical to making these new models work for patients is having access to the individuals' health records, including those related to substance use disorders. CMS provides participating providers of Medicare ACO and bundled payment organizations with monthly Medicare Parts A, B and D claims under data use agreements that include criminal penalties for misuse. Yet, due to outdated laws mentioned above, CMS is forced to remove *all* claims where substance use disorder is a primary or secondary diagnosis. Patient safety is also threatened with the potential pharmaceutical contraindications that could occur without access to the full medical record. Without this critical information, providers are prevented from understanding the full extent of their patients' medical needs.

We commend SAMHSA's recent rule making efforts, and understand the agency has probably gone as far as possible in regards to attempts to modernize the Part 2 Rule. To sufficiently address the need for further reform, Representatives Markwayne Mullin and Earl Blumenauer have introduced H.R. 3545 to ensure healthcare providers have access to the full medical record, including information on substance use disorders, to effectively and safely treat patients suffering from substance use disorders while guaranteeing the privacy and security of substance use medical records. In particular, H.R. 3545 would reinforce and expand existing prohibitions on the use of these records in criminal proceedings.

We urge the Committee to consider H.R. 3545 to amend 42 CFR Part 2 and align with HIPAA's treatment, healthcare operations and payment policy as one of several potential solutions Congress passes to help with the opioid crisis. Thank you for your attention to this important matter.

Sincerely,

Tina Grande

Tina Grande
Healthcare Leadership Council on behalf of the Confidentiality Coalition

cc: U.S. House of Representatives

PREMIER TRANSFORMING HEALTHCARE TOGETHER

March 21, 2018

The Honorable Markwayne Mullin
U.S. House of Representatives
1113 Longworth House Office Building
Washington, DC 20515

The Honorable Earl Blumenauer
U.S. House of Representatives
1111 Longworth House Office Building
Washington, DC 20515

Dear Reps. Mullin and Blumenauer:

On behalf of the Premier, an alliance of more than 3,900 hospitals (approximately 80 percent of U.S. hospitals), hundreds of thousands of physicians and other clinicians and 150,000 other sites of care, we write in strong support of the Overdose Prevention and Patient Safety Act (H.R. 3545).

Premier focuses on improving population health through the promotion of collaborative learning opportunities, identification of clinical best practices and systematic use of data and analytics. With a large, geographically-diverse provider network, nationwide data representing 45 percent of U.S. discharges and significant research and clinical expertise, Premier is uniquely positioned to address important questions on strategies aimed **at curbing the growing opioid epidemic** in the United States.

According to a recent Premier survey, approximately 90 percent of C-Suite leaders from Premier member health systems are prioritizing strategies to curb opioid use. The majority are focusing their efforts on conducting patient assessments with standardized tools upon admission to evaluate pain levels, staff education on resources for safe opioid use and alternative methods for pain relief. Premier resources and capabilities are being leveraged with existing efforts by our health system members and by both professional organizations and federal agencies to reduce the impact of opioid misuse and promote safer, effective, evidence-based pain management practices.

Incredibly, one of the main impediments to these efforts is a more than 40 year-old law that restricts providers' ability to identify patients with substance use disorders. This 1970s rule governing the confidentiality of drug and alcohol treatment and prevention records (42.C.F.R. Part 2 (Part 2)), which predates HIPAA and its robust patient confidentiality protections, prevents CMS from disclosing to providers their patients records on substance use without complex and multiple patient consents. Thus, CMS removes claims records where substance use disorder is a primary *or secondary* diagnosis before sending data to providers.

13034 Ballantyne Corporate Place T 704.357.0022 F 704.357.6611 Charlotte, NC 28277 | 444 North Capitol Street, N.W. T 202.393.0860 F 202.393.6499 Suite 625, Washington, DC 20001 | PREMIERINC.COM

Failure to update Part 2 means that CMS must remove data relating to substance use, which translates to providers being prohibited from reviewing ***roughly 4.5 percent of inpatient Medicare claims*** and 8 percent of Medicaid claims, despite being accountable for the outcome of their patients' health and cost of care (NEJM).

This poses a serious safety threat to patients with substance use disorders due to risks from drug contraindications and co-existing medical problems. It also means these patients may not receive care coordination and management. Access to data drives risk modeling, and can help providers identify patients who may benefit from targeted interventions, implement effective patient engagement initiatives, design and evaluate quality improvement initiatives, examine information to eliminate gaps in clinical care and curb costs. The removal of data related to substance use leaves providers "flying blind" when it comes to being fully informed about their patients' history and unable to effectively treat and coordinate their care. Providers cannot safely prescribe medication-assisted treatments (MAT) like buprenorphine, for instance, if they can't see the full medical record? Buprenorphine and other medication assisted treatments coming to the market contraindicate with many drugs, especially those for patients suffering from schizophrenia and bipolar disorder.

These outdated regulations run counter to new, innovative Medicare delivery care models, such as accountable care organizations (ACOS) and bundled payments, which require intense care coordination and in which healthcare providers are at financial risk when caring for these patients. Disparate treatment for alcohol and substance disorder information compared with other types of health information (for example, mental health), impedes comprehensive data sharing, the development of a complete patient-centered care approach to care and the ability of healthcare providers to engage in managing their entire population's health.

The solution is to pass the Overdose Prevention and Patient Safety Act (HR 3545), which would amend Part 2 to align with HIPAA's treatment, payment and operation protections and to allow sharing of medical records among providers for those with addictions, just like we have done for every other disease and condition since 1996. If enacted, the legislation would have an immediate impact in the fight against opioid misuse, at virtually no cost to the taxpayer. Premier urges Congress to swiftly pass this legislation in order to improve outcomes and remove this information barrier to responsible care.

Sincerely,

Blair Childs
Senior vice president, Public Affairs
Premier healthcare alliance

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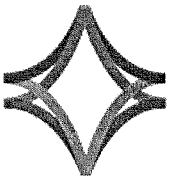

Statement for the Record
Committee on Energy and Commerce
Subcommittee on Health

Combating the Opioid Crisis: Prevention and Public Health Solutions
March 21-22, 2018

Thank you for your work regarding the nation's opioid crisis. America's Essential Hospitals appreciates your committee's dedication in its response to this public health threat, which affects all communities nationwide. Below, we outline the unique role essential hospitals play in addressing the opioid crisis, share issues that impact our hospitals, and comment on several bills before your committee.

America's Essential Hospitals is the leading association and champion for hospitals and health systems dedicated to providing high-quality care to all people. Filling a vital role in their communities, our 325 member hospitals provide a disproportionate share of the nation's uncompensated care and devote about half their inpatient and outpatient care to Medicaid or uninsured patients. Through their integrated health systems, members of America's Essential Hospitals offer primary care through quaternary care, including trauma care, outpatient care in ambulatory clinics, public health services, mental health and substance abuse services, and wraparound services vital to disadvantaged patients. More than a third of patients at essential hospitals are racial or ethnic minorities who rely on the culturally and linguistically competent care that only our members can provide.

As pillars of their communities and trusted providers for all, essential hospitals have seen firsthand how opioid use disorders have affected individuals and their surrounding communities. Essential hospitals lead in efforts to improve population health and continue to develop innovative programs to prevent opioid misuse among the most vulnerable populations, and they provide treatment to all who need it. As you continue to develop policies to combat the crisis, we urge the committee to consider the unique role essential hospitals play in prevention of opioid misuse, as well as response and recovery for individuals struggling with opioid use disorders.

Essential Hospitals Response to Opioid Crisis

Essential hospitals play a unique and significant role in the opioid crisis. Hospitals are a main care provider for people experiencing opioid-related health problems, like infection or overdose, associated with substance misuse. As a result, hospitals have an enormous role to play in the prevention and treatment of this widespread problem. Essential hospitals have partnered with pharmacies, public health departments, law enforcement, emergency medical services, and other community providers to combat the crisis.

For example, an essential hospital in Massachusetts has been a national leader in fighting the opioid crisis. The hospital runs the largest primary care office–based opioid treatment program in New England. The program was the first of its kind in the nation and has been replicated in

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35 states. It employs a collaborative care model using nurse care managers to provide medication-assisted treatment (MAT) to individuals with opioid use disorder. The program has been tailored to meet the needs of other patient populations, including adolescents and pregnant women. In addition, this hospital created one of the first emergency department (ED)– and urgent care–based opioid treatment programs in the country, and its inpatient addiction consult service has reduced ED visits for participants by 30 percent. In partnership with the state health department, the hospital has pioneered naloxone distribution programs with law enforcement and other first responders and overdose bystanders.[1]

Evidence-based treatment programs, which can exist within or outside a hospital system, are a key component of combating opioid use. One of the most commonly used treatment models—MAT—uses counseling in combination with drugs, such as methadone and buprenorphine, to prevent withdrawal, suppress cravings, and support recovery. MAT has proved successful in decreasing mortality, decreasing risk of infection, improving social functioning, and increasing retention in rehabilitation programs. But there are large gaps between MAT capacity and demand. To meet this need, some health systems are developing their own infrastructure and care teams—which include physicians, licensed therapists, counselors, and/or recovery specialists—to treat opioid misuse.[2] Essential hospitals are deploying protocols that screen for opioid use, provide MAT as necessary, and pair patients with addiction counselors.

Additionally, essential hospitals are deploying targeted improvement efforts to address opioid prescribing patterns and align incentives that promote quality of care. For example, several essential hospitals have implemented new guidelines for prescribing opioids, particularly in the ED. These hospitals urge providers to first provide non-opioid options—ibuprofen and acetaminophen, for example—and then to explore alternative pain management, such as localized nerve-blocking methods. Hospitals engage physicians, pharmacists, and nurses to ensure all staff are committed to providing non-opioid regimens before prescribing stronger medications. Initial evaluations show that such policies reduced by nearly 50 percent the number of opioids prescribed to trauma patients.[3]

Essential Hospitals Face Challenges

42 CFR Part 2

Although essential hospitals have deployed innovative approaches to treat patients with opioid and substance use disorders, they continue to face challenges. When patients visit doctors and hospitals, most assume providers have a complete medical history and an awareness of addictions or substance use that need to be factored into treatment and prescribing. But that is not always the case, due to an antiquated regulation—42 CFR Part 2 (Part 2).[4] This regulation limits access to and use of patients' substance use records for certain substance use treatment programs. Obtaining multiple consents from the patient is challenging and creates barriers to whole-person, integrated approaches to care. As a result, many providers often learn of addiction problems only after an adverse event or an overdose. Part 2 regulations also might lead to a physician treating a patient and writing prescriptions for opioid pain medication for that individual without knowing the person has a substance use disorder. Separation of a patient's addiction record from the rest of that person's medical record creates several problems and

[1] Susman K. *The Opioid Crisis: Hospital Prevention and Response.* June 2017. https://essentialhospitals.org/wp-content/uploads/2017/06/Opioid-Brief-1.pdf. Accessed March 19, 2018.
[2] Ibid.
[3] Susman K. *The Opioid Crisis: Hospital Prevention and Response.* June 2017. https://essentialhospitals.org/wp-content/uploads/2017/06/Opioid-Brief-1.pdf. Accessed March 19, 2018.
[4] 42 U.S. Code § 290dd-2.

impedes patients' ability to receive safe, effective, high-quality substance use treatment and coordinated care.

It is crucial that Part 2 is better aligned with the Health Insurance Portability and Accountability Act (HIPAA) so that health care providers can provide comprehensive and coordinated substance use treatment and care. The Substance Abuse and Mental Health Services Administration (SAMHSA) recently released a final rule that takes some steps to modernize Part 2, but it does not go far enough.[5] Lawmakers must act to modify Part 2 and bring substance use records into the 21st century, allowing for appropriate levels of access for providers to have a complete picture of their patients. However, just aligning Part 2 for treatment purposes is an insufficient approach. Such an approach is inconsistent with HIPAA language on treatment, payment and health care operations, as care coordination activities are not considered a part of a patient's treatment. For Medicaid providers engaging in whole-person care management, it is difficult to separate treatment from payment and health care operations. Also, only aligning Part 2 with HIPAA for treatment activities could preclude a robust prescription drug monitoring program. Without all information about a patient available, it will be challenging to flag patients engaging in drug-seeking behaviors.

IMD Exclusion

Medicaid does not provide reimbursement for inpatient treatment in an institution for mental disease (IMD) with more than 16 beds. As states consider various approaches to combat the opioid crisis, this IMD exclusion has hampered comprehensive treatment approaches. The Centers for Medicare & Medicaid Services (CMS) has encouraged states to pursue innovations and strategies to address the opioid epidemic through Medicaid Section 1115 waiver demonstrations. In a November 2017 update to states, CMS outlined a streamlined approach to accelerate states' ability to respond to the crisis.[6] Several states, such as West Virginia, Maryland, and Virginia, have used this approach to start comprehensive, evidence-based prevention and treatment programs for Medicaid beneficiaries.

Additional Challenges

The Medicaid program covers MAT services as an optional benefit for states under the Medicaid statute, which has caused available services to vary widely across states.[7] This limits providers as they identify and employ the best treatment options for their patients

Essential hospitals also face the additional challenge of a workforce shortage for substance use disorder and behavioral health professionals. There has been a shortage of addiction specialists for decades, and the opioid epidemic only has increased demand.[8] SAMHSA recognized the serious workforce shortages for behavioral health professionals and funded several programs and initiatives to combat the issue. Essential hospitals operate on slim margins that might hinder them from offering competitive compensation packages to attract needed substance use disorder and behavioral health professionals. Not only do they have financial constraints, many essential hospitals find themselves either in extremely competitive urban markets or in less desirable geographic areas.

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[5] 82 *Federal Register* 6052. January 18, 2017.
[6] Centers for Medicare & Medicaid Services. *SMD #17-003 Strategies to Address the Opioid Epidemic.* November 1, 2017. https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf. Accessed March 19, 2018.
[7] Medicaid and CHIP Payment and Access Commission. *Medicaid and the Opioid Epidemic.* June 2017. https://www.macpac.gov/wp-content/uploads/2017/06/Medicaid-and-the-Opioid-Epidemic.pdf. Accessed March 19, 2018.
[8] Corwin E. *Shortage of Addiction Counselors Further Strained by Opioid Epidemic.* February 24, 2016.

Last, essential hospitals lack adequate reimbursement for integrated care. Overall care delivery is transforming across the health care industry, shifting from fragmentation and care siloes to a more integrated and collaborative system. In responding to the opioid crisis, essential hospitals recognize the complexity and importance of treating behavioral health issues, particularly as they relate to improving care for our nation's most vulnerable patients. Essential hospitals across the United States have dedicated substantial resources to developing innovative programs to improve care coordination among primary care, inpatient, behavioral health, and community-based services for individuals with behavioral health disorders. For example, an essential hospital in Washington state began a behavioral health integration program that incorporates behavioral health care managers and psychiatric consultants at 14 primary care clinics.[9] Primary care physicians in the clinics conduct routine screening for behavioral health disorders among patients, determine whether further assessment and diagnosis by behavioral health specialists is required, and, when necessary, provide warm handoffs to care coordinators within the same facility. As providers of care to vulnerable populations, essential hospitals are uniquely positioned to implement this kind of care. But funding shortfalls and reimbursement structures pose consistent and significant obstacles to integration.

Legislative Proposals

Prescription Drug Monitoring Programs and H.R. ____, to enhance and improve state-run prescription drug monitoring programs,

Prescription drug monitoring programs (PDMPs) are state-level interventions to improve opioid prescribing and inform clinical practice by tracking the prescribing and dispensing of controlled prescription drugs. Some states have implemented polices that require physicians to check a state PDMP to assess a patient's risk of substance use disorders or nonmedical use of controlled substances as part of the discharge planning and medication reconciliation process. The legislative proposal before the committee would seek to improve PDMPs by authorizing the Centers for Disease Control and Prevention to conduct certain surveillance activities to improve data collection and integration in physician clinical workflow.

We support the goal of reducing prescription drug abuse by increasing provider awareness of at-risk patients. However, the challenges associated with PDMPs—including issues with health IT interoperability, timely data transmission, and privacy and security—make this tool an unsatisfactory option for now. Further, the quality of PDMP data must be validated before its use in the context of a federal program, such as Medicaid. For example, PDMPs do not include data on physician specialty or patient diagnosis, which can make it difficult to distinguish legitimate use, such as higher doses for cancer pain management, from inappropriate use, such as use in pediatrics. Additionally, platforms differ by state, creating a lack of uniformity in accessing PDMP data. More work is needed to mitigate issues of cross-state PDMP data access—e.g., allow prescribers and dispensers to obtain patients' prescription records from across state lines to provide a more complete in-state and out-of-state medication history for at-risk patients. Continued state-level evaluation of PDMPs is needed to identify and evaluate promising practices and to build synergies necessary for application at the federal level. We hope the committee will consider these concerns.

H.R. 5197, Alternatives to Opioids in the Emergency Department Act

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[9] Rangarao S, Susman K. *Behavioral Health and Primary Care Integration at Essential Hospitals.* October 2015. http://essentialhospitals.org/wp-content/uploads/2015/10/BehavioralHealthBrief_FINAL.pdf. Accessed March 19, 2018.

We support legislation that would encourage alternatives for opioid use in hospital EDs. Specifically, we are encouraged by consideration of H.R. 5197, the Alternatives to Opioids (ALTO) in the Emergency Department Act. This legislation would allow hospitals to rein in opioid prescribing by assessing the use of alternate medication options for pain management. This protocol is currently underway at St. Joseph's Health, an essential hospital in Paterson, New Jersey, and is an effective tool to combat opioid addiction.

H.R. 5102, Substance Use Disorder Workforce Loan Repayment Act

Health care workforce shortages present significant challenges. Substance use disorder (SUD) treatment professionals are critical in the fight against opioid addiction, and creating incentives for health care and other social service professionals to treat individuals with SUDs will help to strengthen the workforce in an area with severe needs. Given the financial burden often placed on students training in health-related fields, H.R. 5102, the Substance Use Disorder Workforce Loan Repayment Act, will take a step in the right direction to encourage health professionals to work directly on SUD treatment. By offering student loan repayment for these professionals, essential hospitals, who often treat some of the most significant opioid addiction cases, will have greater access to trained SUD professionals and can expand their work already underway to fight opioid addiction.

H.R. 5261, Treatment, Education, and Community Help to Combat Addiction Act

America's Essential Hospitals supports H.R. 5261, the Treatment, Edueation, and Community Help to Combat Addiction Act, which would support learning institutions that specialize in SUD treatment education to improve how health professionals are taught about SUD and pain management for patients. This bill would help address gaps in educational programs provided to physicians at essential hospitals to ensure SUD patients receive the most comprehensive care for their exposure to opioids.

H.R. __, Poison Center Network Enhancement Act

The Poison Center Network Enhancement Act would reauthorize the national network of poison control centers, which offer free, confidential, expert medical advice and serve as primary resources for poisoning information. Essential hospitals frequently work in tandem with poison control centers to address public health emergencies, including opioid exposures. Specifically, these centers help lessen the burden on EDs through in-home treatment for opioid exposures. Reauthorizing this network would allow for broader communication between the centers to improve care for those exposed to opioids before they enter hospital systems.

Discussion Draft of H.R. __, A Bill to Support the Peer Support Specialist Workforce

We support including language to improve the peer support specialist workforce. This provision would expand Department of Health and Human Services grants to peer support specialist organizations providing recovery services. Peer support specialists are individuals recovering from a substance use disorder (SUD) who have received formal training on how to support and mentor other individuals new to the recovery process. Peer support has been a successful tool to support individuals newly diagnosed with a disease or disorder. Essential hospitals have successfully used multidisciplinary approaches to the treatment of individuals with SUDs, and peer support specialists can be a critical tool to an individuals' recovery.

We appreciate your consideration of these provisions and look forward to working with you to improve the legislative package to effectively counter this ongoing crisis.

THE HILL

People with addiction issues should be able to control their own health data

BY PATRICK J. KENNEDY AND KEVIN SCALIA, OPINION CONTRIBUTORS — 01/11/18 05:00 PM EST
THE VIEWS EXPRESSED BY CONTRIBUTORS ARE THEIR OWN AND NOT THE VIEW OF THE HILL

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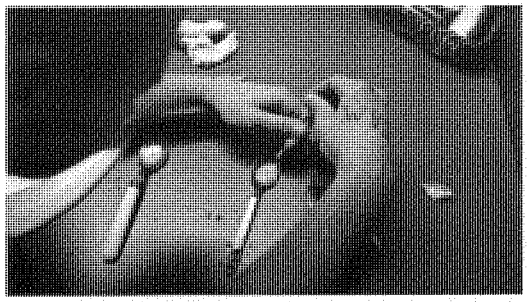

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Much of the discussion about the concurrent opioid and suicide epidemic in our nation centers on the need for increased funding and resources. However, another major hurdle we face involves decades-old federal health record privacy regulations containing complicated, cumbersome

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consent requirements that discriminate against and endanger people with a substance use disorder (SUD) or history of SUD treatment.

People with diabetes, asthma, HIV, cancer or a history of heart attack can easily share their health information with doctors. They can also take full advantage of electronic health information exchanges (HIEs) that reduce the risk of potentially deadly medication errors among care teams.

Why should it be any different for a person with a history of SUD? Why are brain diseases excluded from a comprehensive, collaborative approach to care?

The ultimate goal of consent should be to give people the power to share their own health data with healthcare providers, if they so desire. This power of consent should apply regardless of whether a person has a SUD, mental illness, cancer, diabetes or multiple co-occurring conditions. Likewise, if a person does not wish to share her health data, she should have the clear option to either opt-out or not opt-in to sharing that information.

Current federal privacy regulations (42 CFR Part 2), which only apply to people with a SUD, place restrictions on sharing your own health data with a history of SUD. Such regulation puts a burden on patients, their treating providers, and Health information exchange (HIEs), making it operationally expensive — and with today's existing HIE technology — extremely costly, to transfer and manage SUD data.

This makes it very easy for HIEs to just say no, we will not accept your SUD data — thereby denying a person with SUD who wants to share data the same access to care as a person with cancer or diabetes. In this case, the regulations are discriminatory, preventing people with a SUD from benefiting from coordinated, integrated care, and increasing the chance of inappropriate opioid prescribing.

Imagine you are scheduled for outpatient surgery at a local surgery center. You sign a consent form for your SUD treatment program to share information about your addiction to OxyContin with the surgery center. The surgery center makes a note in your health record, but your surgeon,

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who is employed at a separate clinic, isn't permitted to see that part of your health record and prescribes OxyContin post-op for your pain.

Incidents like this happen every day across the nation, and raise several major concerns:

Incomplete health record information

Despite recent updates to regulations by the Substance Abuse and Mental Health Services Administration (SAMHSA), there are still significant complexities in one's ability to consent to release SUD treatment information to treating providers. This data gap prevents doctors and others from seeing a full picture of their patient's health, substantially increasing the risk of treatment and prescribing errors.

Discrimination and lack of parity

Addiction is a disease, not a mindset or a moral failing. Outdated Part 2 regulations are aiding and abetting discrimination against people with a SUD.

Technology limitations

Some integrated healthcare delivery systems, such as HIEs, Medicaid Health Homes and Medicare Accountable Care Organizations (ACOs) won't accept a patient's data (who has a history of SUD treatment) because they lack the technology or financial resources to comply with current consent and data segmentation requirements. Ironically, these entities were designed to provide "whole-person" care that addresses a full spectrum of co-occurring brain and body health conditions, including addiction treatment.

What's the answer?

We are seeing some movement in the right direction. There are indications that SAMHSA may reopen the rulemaking process for further input. Reps. Markwayne Mullin (R-Okla.) and Earl Blumenauer (D-Ore.) have introduced the bipartisan Overdose Prevention and Patient Safety Act in the U.S. House. A bipartisan companion bill, the Protecting Jessica Grubb's Legacy Act (The Legacy Act), has been introduced in the U.S. Senate by Sens Joe Manchin (D-W.Va.) and Shelley Moore Capito (R-W.Va).

These bills more closely align 42 CFR Part 2 regulations with HIPAA, helping to ensure that all clinicians involved in a person's care get the full picture of their health. The bills also strengthen protections and prohibitions against disclosures of SUD information for criminal justice purposes — a legitimate concern of patient advocacy groups.

Most recently, during the fourth meeting of the President's Commission on Combating Drug Addiction and the Opioid Crisis, leaders from the nation's top insurance companies, as well as Commission members, overwhelmingly called for immediate 42 CFR Part 2 reform to stop the horrific cycle of preventable and unnecessary deaths in this country.

Recently, SAMHSA published a final rule that now allows for greater flexibility in the sharing of SUD treatment information by third parties for payment and healthcare operations. The final rule specifically excluded treatment, diagnosis and referral for treatment from the new, more flexible provisions.

Ironically, it's now easier for a person's SUD-related health information to be shared by payers, health plans and other entities for billing, payment, claims management and collections — than with the person's own healthcare providers for fully-informed diagnosis and treatment. The exclusion of treatment from the list of permissible activities for disclosure prevents people with an SUD from benefiting from coordinated, integrated care and exacerbates the stigma often associated with SUDs.

While HIPAA provides substantial protections for health information, it also provides something that Part 2 regulations cannot: patient choice. The decision to share critical health information should lie with the individual, not the Part 2 program, SAMHSA or the healthcare system.

Patrick J. Kennedy is the founder of The Kennedy Forum and former democratic congressman from Rhode Island. He is also a former member of the President's Commission on Combating Drug Addiction and the Opioid Crisis. Kevin Scalia is the executive vice president of Netsmart.

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GOVERNORS' RECOMMENDATIONS FOR FEDERAL ACTION TO END THE NATION'S OPIOID CRISIS

JANUARY 18, 2018

Opioids continue to fuel the worst drug overdose epidemic in our nation's history, claiming the lives of 115 individuals every day and devastating families and communities across the country.[1] Governors have been leading the fight against this deadly epidemic, working across all levels of government as well as with families, health care providers and others in the private sector to save lives, create a pathway to recovery for individuals struggling with addiction and prevent more people from becoming addicted. While progress has been made, the consequences of opioid addiction continue reverberating throughout society, devastating families and overwhelming health care providers, law enforcement and social services, with further downstream impacts on employers and the strength of the nation's workforce.

The federal government is a critical partner in governors' efforts to end the opioid crisis, providing essential resources and flexibility for states to mount a strong public safety response, prevent new cases of addiction and expand access to treatment and recovery services. Governors commend Congress and federal agencies for taking action over the last couple years to provide new funding and address barriers identified by states,[2] such as the lack of evidence-based guidance for opioid prescribing and federal limits on buprenorphine prescribing. More recently, the Administration declared the opioid crisis a nationwide public health emergency and committed to supporting states seeking to provide the full continuum of substance use disorder (SUD) treatment services through Medicaid – an important example of how federal partners can work with states to address specific requests for regulatory relief and flexibility. Governors also applaud the work of the President's Commission on Addiction and Opioids (Commission) for providing a new framework for federal action based on extensive consultation with states and other key stakeholders.[3]

Building on that important work, the nation's governors have come together through the National Governors Association (NGA) to identify additional recommendations for federal action. These recommendations reflect many of the Commission's priorities, including the critical need for state flexibility and significant federal resources to help states and local communities turn the tide on the opioid epidemic. Governors are eager to continue working with Congress and the Administration to strengthen the nation's response and help individuals and communities heal from this crisis.

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[1] Centers for Disease Control and Prevention, 2017: https://www.cdc.gov/nchs/products/databriefs/db294.htm
[2] National Governors Association, "Governors' Priorities for Addressing the Opioid Crisis," February 2016: https://www.nga.org/files/live/sites/NGA/files/pdf/2016/1602PrioritiesOpioidCrisis.pdf
[3] President's Commission on Combatting Addiction and the Opioid Crisis, Final Report, November 2017: https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-3-2017.pdf

FEDERAL SUPPORT AND COORDINATION

Increase federal support for state efforts to address the opioid crisis, with flexibility for states to meet the needs of their communities. Governors urge Congress and the Administration to increase federal funding to states for opioid/SUD-related activities and streamline the grant process by coordinating application and administrative processes. Increased coordination among federal agencies would reduce the administrative burden for states and federal agencies, freeing up valuable time and resources. As part of this new approach, the duration of federal grants should be extended beyond the typical one- or two-year funding cycle to help states plan and use federal dollars more effectively to address the epidemic. Additionally, federal funding should provide flexibility for states to meet community needs and emerging challenges, such as deadly new fentanyl analogues and the increased risk of infectious diseases, such as HIV and Hepatitis C. Below are additional state priorities for flexible federal funding.

- Evidence-based prevention curricula and programming for youth, particularly in underserved areas.
- Culturally-specific prevention, treatment and recovery services for American Indian/Native American populations and others that have been disproportionately impacted by the addiction epidemic.
- Maintenance and ongoing operation of state prescription drug monitoring programs (PDMPs).
- Analysts and other personnel for fusion centers and other state law enforcement entities responding to the threat of illicit opioids.
- Wider availability of naloxone at the state and local level, particularly for first responders, bystanders, third-parties and pharmacies.
- Data and information sharing initiatives between public health and law enforcement.
- State and local narcotics interdiction efforts and other officer safety programs.
- Capacity building for state medical examiners.
- National Guard Counterdrug activities to assist state public safety and public health surge capacity.
- State correctional health services and post-incarceration reentry services to connect individuals with treatment providers.
- Community-based initiatives that have shown positive outcomes by bringing together law enforcement, intervention and treatment services, prevention programs and recovery providers.

- *NOTE: Many states highlighted issues with sustainability, coordination, and flexibility of funds. This recommendation draws on the President's Commission recommendation to block grant funding at the federal level, to improve coordination and reduce burden on states. This is also augmented by the need for funding flexibility, with several examples suggested by Hawaii, Minnesota, Washington, and Vermont.*

Improve coordination within and across federal agencies involved in responding to the opioid crisis. Federal agencies are essential partners for governors working on the front lines of the opioid epidemic. Increased coordination and communication within and between federal agencies involved in those efforts would help improve coordination on the ground, avoid duplicative efforts and streamline grant requirements, freeing up valuable time and resources at the state level needed to mount an effective response to the opioid epidemic. This could be facilitated by an inter-agency task force or an existing entity empowered to bring executive agency leadership together regularly to enhance federal agency coordination and planning.

- *NOTE: Many states have highlighted this issue, particularly as more federal agencies have become engaged in providing funding and technical assistance to states. The coordinating entity could be situated in the White Hause or an agency – so long as it is truly empowered to serve its role.*

DATA AND INFORMATION SHARING

Align 42 CFR Part 2 with the Health Insurance Portability and Accountability Act (HIPAA). Protecting patient records is critical, particularly for those who have or are undergoing treatment for substance use disorder given the negative consequences of stigma often attributed to those individuals. However, federal privacy rules impede care coordination and threaten patient safety by prohibiting substance use disorder treatment providers from fully participating in electronic health information exchange, leaving treating providers without the full picture of a patient's history. Current restrictions on the ability of opioid treatment programs to report medications dispensed to their state PDMP limit providers' ability to prevent overdose and diversion, as well as potentially deadly medication interactions. Congress should pass legislation aligning 42 CFR with HIPAA, to bring substance use disorder information into alignment with the privacy protections governing other types of health data.

- *NOTE: A similar recommendation was included in NGA's 2016 priorities and the Commission's report. Aligning 42 CFR Part 2 with HIPAA is also the goal of H.R.3545, the Overdose Prevention and Patient Safety Act. Proposed changes to 42 CFR Part 2 have historically garnered strong resistance from some advocates.*

Require interoperability between electronic health records (EHRs) and state PDMPs. PDMPs are an important care management tool which allow clinicians to screen for opioid misuse, identify "doctor shoppers" and prevent medication interactions. The U.S. Department of Health and Human Services Office of the National Coordinator (ONC) has led several initiatives to improve the interoperability of EHRs and PDMPs, however, additional action is needed to make PDMPs more easily accessible to clinicians. Through the certification process, ONC should require that EHR vendors make their systems interoperable with all state PDMPs. ONC should also maintain Meaningful Use incentives for providers connecting to their state's PDMP.

- *NOTE: PDMP-EHR integration is a challenge frequently raised by states. State officials have highlighted the need for ONC to act to maintain meaningful use incentives for providers using the PDMP.*

Strengthen data monitoring initiatives and information sharing environments at the state level between public health and public safety. States routinely face regulatory and legal barriers to expanding state drug data systems and providing real-time information sharing across all sectors. The administration should issue guidance to facilitate more open data sharing environments that enable real-time surveillance, ensure that state PDMPs incorporate naloxone deployment data from all sources (e.g. Department of Transportation's (DOT) Emergency Medical Technician (EMT) overdose database) and reduce existing barriers to appropriate data sharing arrangements between public health and law enforcement. Further, Congress should provide the Department of Justice with increased federal funding to provide trainings and technical assistance that support state law enforcement and public health data and information sharing initiatives. For example, increased federal efforts can help establish new and/or enhance existing state-level drug monitoring initiatives and overdose fatality review teams between law enforcement and public health.

PREVENTION AND EARLY INTERVENTION

Develop an evidence-based national education and awareness campaign to promote prevention and reduce stigma associated with SUD. Governors applaud the President's announcement of a national advertising campaign to prevent youth and others from abusing opioids and illicit substances. Awareness-raising campaigns such as those utilized to reduce youth tobacco use need to be replicated with respect to opioids. Critically, this campaign should also address the misperception and stigma surrounding addiction that can prevent many individuals from seeking help. It is important that

the public recognize addiction as a treatable chronic condition, requiring the sustained, multifaceted approach typical in managing any chronic disease.

Require prescribers to register with their state prescription drug monitoring program (PDMP) and complete evidence-based training on pain management and substance use disorder upon receiving or renewing their Drug Enforcement Administration (DEA) registration. Attaching new requirements to DEA registration would help ensure health care providers have the tools and education needed to safely treat individuals with pain. State experience shows that requiring PDMP registration encourages prescribers to use the PDMP to prevent and identify opioid misuse and diversion. Though federal law requires health care providers to complete training and apply for a waiver to prescribe buprenorphine for opioid use disorder, federal rules do not include a similar education requirement for providers registering with the DEA to prescribe the opioid pain relievers that have fueled this deadly opioid epidemic. It is critical that any new federal education requirement feature evidence-based guidance regarding pain management and substance use disorder, including the Centers for Disease Control and Prevention's opioid prescribing guideline.

- *NOTE: This recommendation was carried over from NGA's 2016 priorities. The Commission's report similarly calls for training as a condition of DEA licensure.*

Continue building the evidence base for non-pharmacological treatments for pain and provide guidance to state Medicaid programs regarding best practices for covering these services. Nonpharmacologic interventions for pain treatment, such as acupuncture, cognitive behavioral therapy, mindfulness meditation and physical therapy are important tools in the management of chronic pain. While there is growing evidence to support the efficacy of these and other nonpharmacologic interventions, additional research is needed to better understand their role in managing pain, identify clinical best practices and develop new, non-addictive treatment options. Governors encourage the Department of Health and Human Services (HHS) to enhance its role in those efforts by investing in additional research and evaluation of non-pharmacological therapies for pain, as well as guidance to assist states in making appropriate coverage decisions in Medicaid and other state-administered health programs.

- *Note: The lack of effective alternative pain treatments has been highlighted by many states and health care providers. The Commission's report recommends additional resources for efforts underway to new, non-opioid pain relievers (as well as to develop additional MAT options).*

TREATMENT AND RECOVERY

Allow state Medicaid programs to offer the full continuum of evidence-based care, including residential treatment. As the largest source of coverage for behavioral health services, including treatment for opioid use disorder, Medicaid plays a critical role in helping states address the opioid crisis. The Institutions for Mental Diseases (IMD) exclusion generally prohibits state Medicaid programs from receiving federal reimbursement for adults between 21 and 65 receiving mental health or substance use disorder treatment in a residential treatment facility with more than 16 beds. This arcane federal policy, while well intentioned, limits states' ability to provide the full continuum of clinically appropriate care for Medicaid enrollees with SUD. Governors encourage the Administration to continue working with states to expedite approval of IMD waivers while also recognizing the need for a permanent, statutory solution to resolve this issue for all states. To that end, governors urge Congress to enact legislation that would create an exception to the IMD exclusion for individuals receiving SUD treatment.

- *NOTE: This recommendation was carried over from the NGA's 2016 priorities. The White House Commission's report recommends expedited appraval for state waivers to address IMD, rather than eliminating it altogether. A bill to eliminate the IMD exclusion, the Road to Recovery Act (H.R.2938), has*

been endorsed by the Bipartisan Heroin Task Force, a group led by Representatives Tom MacArthur (R-NJ), Annie Kuster (D-NH), Brian Fitzpatrick (R-PA), and Donald Norcross (D-NJ).

Fully Enforce the Mental Health Parity and Addiction Equity Act (MHPAEA). MHPAEA built on the Mental Health Parity Act by requiring health insurers and group health plans to provide the same level of benefits for substance use and mental health as they do for medical/surgical care. While parity is a requirement under federal law, enforcement remains a challenge for state and federal regulators. Governors urge the federal government, through HHS, to strengthen federal oversight and ensure parity violations do not limit access to substance use disorder treatment.

- *NOTE: A similar recommendation was included in the Commission's report.*

Provide state Medicaid programs flexibility to cover SUD and mental health services for individuals in custody prior to conviction and up to 30 days prior to release from prison or jail. Expanding access to evidence-based SUD and mental health services for justice-involved populations is a critical strategy for reducing opioid and other drug overdose deaths. SUD and mental illness are often co-occurring and significantly more prevalent among people in correctional settings. Moreover, individuals leaving incarceration and re-entering the community are at a dramatically higher risk of dying from a drug-related overdose. Medicaid coverage of SUD and mental health services for Medicaid-eligible individuals who are incarcerated pending disposition or nearing release would greatly enhance continuity of care and reduce a host of adverse outcomes, such as recidivism, emergency department visits and drug overdose. Governors urge CMS to use its authority under Section 1115 of the Social Security Act to grant states partial waivers of the inmate exclusion that would otherwise bar states from receiving federal Medicaid funding in these circumstances.

- *NOTE: Several states suggested Medicaid could play a role in covering targeted services for individuals while they are incarcerated.*

Ensure Medicare covers methadone for opioid use disorder in outpatient settings. The opioid crisis affects individuals of all age groups, including older adults. In 2016, one in three Medicare Part D enrollees received an opioid prescription and nearly 90,000 were found to be "serious risk" of opioid misuse or overdose, according to the HHS Office of Inspector General.[4] CDC found a 33 percent increase in older adult deaths from heroin between 2014 and 2015.[5] While Medicare covers methadone for opioid use disorder in inpatient settings, Medicare does not cover methadone provided in the community at opioid treatment programs – creating a significant barrier to treatment for many older adults. HHS should revise Medicare coverage requirements, to ensure that all Medicare individuals have access to methadone treatment for opioid use disorder if needed.

- *NOTE: A similar recommendation was included in the Commission's report.*

Recognize substance use disorder treatment facilities as approved sites for the National Health Service Corps program. The Health Resources and Services Administration (HRSA) administers the National Health Service Corps (NHSC) program, which awards scholarships and loan repayment to primary care providers in eligible disciplines. The NHSC supports over 10,400 medical, dental and behavioral health professionals who provide care to individuals at approved sites in urban, rural and frontier areas. Primary care and mental health clinics are approved sites for this program, while facilities providing substance use disorder treatment services are not. With the increasing demand

[4] HHS Office of Inspector General, "Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing," July 2017: https://oig.hhs.gov/oei/reports/oei-02-17-00250.pdf

[5] Centers for Disease Control and Prevention, "Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015," December 2016: https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm

for substance use disorder treatment, more professionals are needed to provide MAT and other behavioral health interventions. HRSA should expand the definition of approved sites to include substance use disorder treatment facilities, to increase access to care for individuals with addiction while also serving as a recruitment and retention opportunity for the field.

- *NOTE: A similar recommendation was included in the Commission's report.*

Promote universal substance use disorder screening for pregnant women and comprehensive standards for treating neonatal abstinence syndrome. HHS should issue guidance encouraging universal screening of pregnant women as part of comprehensive obstetric care, as recommended by the American College of Obstetricians and Gynecologists and American Society of Addiction Medicine.[6]

Provide guidance to hospitals on treating individuals experiencing an overdose. Admission to the hospital after an overdose creates an important opportunity to connect individuals with treatment and recovery services. Many states and communities have developed programs to dispatch peer recovery coaches to emergency departments (EDs) following an overdose, where they begin linking individuals with medication-assisted treatment (MAT) and other needed services in their community. Some hospitals are even ensuring the connection to treatment by initiating MAT in the ED. HHS could expand this and other hospital interventions by providing guidance on best practices for care following an overdose.

- *NOTE: This recommendation has been highlighted by states and other national experts.*

Permit medical residents to prescribe buprenorphine under an institutional DEA registration number. Currently, medical residents and other physicians must apply for a federal waiver in order to prescribe buprenorphine. DEA should remove this requirement for medical residents, who practice under physician supervision. Doing so would expand access to buprenorphine and help more residents learn how to manage individuals with opioid addiction.

- *NOTE: Recommendation was included in NGA's 2016 priorities.*

Permit Advanced Practice Registered Nurses (APRNs) to prescribe buprenorphine. CARA expanded buprenorphine prescribing privileges to nurse practitioners and physician assistants for five years, until October 1, 2021, addressing a key barrier to evidence-based MAT. To further expand the treatment workforce and better respond the growing need for services, governors encourage Congress to extend those privileges to all APRN roles – certified nurse practitioner, clinical nurse specialist, registered nurse anesthetist and nurse midwife – without the October 1, 2021 deadline for obtaining the required federal waiver.

Use authority under the public health emergency declaration to swiftly remove barriers to prescribing buprenorphine via telehealth. The Ryan Haight Online Pharmacy Consumer Protection Act prohibits providers from prescribing buprenorphine to individuals via telehealth, creating a barrier to care for individuals in rural areas who may not otherwise have access to an MAT provider. Governors urge the Administration to act quickly in addressing this challenge under the nationwide public health emergency declaration, which allows the HHS secretary, in coordination with the Drug Enforcement Administration (DEA), to carve out exceptions under the law. Governors encourage these agencies to work expeditiously to issue guidance on the policy and encourage providers to use telehealth to reach individuals in rural and other underserved areas. Given the time-limited nature of the public health

[6] The American College of Obstetricians and Gynecologists, "Committee Opinion: Opioid Use and Opioid Use Disorder in Pregnancy," August 2017: https://www.acog.org/-/media/Committee-Opinions/Committee-on-Obstetric-Practice/co711.pdf?dmc=1&ts=20171108T1550067088

emergency, Congress and the Administration should also pursue a permanent fix to ensure these individuals can continue receiving needed MAT services after the declaration expires.

ENHANCING SUPPORT FOR PUBLIC SAFETY

Prioritize federal support for state efforts that address justice-involved populations at risk from the opioid epidemic. The federal government has recently been doing a lot to support state efforts to provide criminal justice medication assisted treatment, treatment alternatives to incarceration, diversion programs, training for first responders on the use of drugs and devices to reverse the effects of opioids and, particularly for rural areas, support for heroin and fentanyl drug task forces. For example, Comprehensive Opioid Abuse Program (COAP) and Edward Byrne Memorial Justice Assistance (JAG) funding streams through the Department of Justice (DOJ) offer critical resources for state and local law public safety entities to address the epidemic, provide the full range of alternatives to criminal justice interventions, and strengthen new and ongoing partnerships with public health and other entities to tackle core issues that increase the addiction risk for vulnerable populations.

However, as noted in the "Federal Support and Coordination" section, additional assistance is needed. Increased JAG funding for state and local narcotic interdiction efforts and officer safety programs is needed. Further, Congress should both increase funding and emphasize the role of preparing for and connecting individuals to community-based treatment for programs that support state reentry efforts, such as DOJ's Second Chance Act and Residential Substance Abuse Treatment (RSAT) programs. In particular, federal efforts through the National Institute of Corrections (NIC), Substance Abuse and Mental Health Services Administration (SAMHSA), and the Office of Justice Programs (OJP) to bolster the capacity of state correctional health services and post-incarceration transition services to develop and provide MAT for justice-involved populations (e.g. correctional settings, outpatient treatment programs, drug courts) require increased congressional funding..

Expand assistance to and enhance the capacity of our Nation's laboratories. More assistance is needed to sustain the mission of supporting state and local forensic communities, such as accelerating state crime laboratory testing to identify and share real-time drug data. Forensic medical practitioners, medicolegal investigators, and experts of the medicolegal investigations community play a vital role in helping governors and states navigate the contours of the epidemic. Additional federal coordination and funding for state medical examiner offices would strengthen the nation's understanding of the epidemic and allow for a more targeted public safety and public health response by states.

Increase federal efforts to detect and prevent dangerous synthetic drugs like fentanyl and carfentanil from being shipped and disseminated throughout the United States. Bad actors in countries overseas violate U.S. customs laws and regulations by shipping drugs directly through the U.S. postal system, which does not require advance electronic customs data for the vast majority of mail entering the United States. Federal efforts to strengthen electronic customs regulations would assist state efforts to combat synthetic drugs and traffickers. Federal agencies can also develop better chemical screening devices to detect fentanyl and other synthetic opioids, which is critical for enhancing detection efforts by state and local law enforcement agencies.

Leverage the long-standing and institutional relationships between the White House Office of National Drug Control Policy (ONDCP) and state and local law enforcement. ONDCP plays an invaluable role at the national level in setting drug strategy, reducing drug use and its consequences, and encouraging strong collaboration between public health and public safety. For example, ONDCP's long-standing efforts to support High Intensity Drug Trafficking Areas and Drug Free Communities have provided states with critical resources throughout the opioid epidemic. ONDCP should also continue to convene and engage additional federal and non-federal agencies (e.g. CDC,

SAMHSA, state public health entities, etc.), with the goal of better understanding the priorities of both public health and public safety entities at all levels of government.

Strengthen support for regional High Intensity Drug Trafficking Areas (HIDTAs) and state law enforcement efforts to address the supply of illicit opioids. Since 1988, HIDTAs have provided essential support for states to forge stronger linkages between public health and safety professionals. With continued and/or additional federal support, innovative partnerships at the state and local level could be scaled up and replicated nationwide. Governors strongly urge the White House Office of National Drug Control Policy to continue to support the development of these public health and safety networks among regional HIDTAs. As fentanyl spreads, more HIDTAs across the country can play a critical role in fortifying personnel, intelligence, and data efforts by state law enforcement. State fusion centers and other state law enforcement entities require additional personnel and analysts from federal grant dollars. As cartels and drug distributors continue to change the supply of illicit opioids, states must continue to have representation on intergovernmental task forces and require grant funding to be flexible to meet the dynamic challenges in their own operating environment, such as direct investments in state and local narcotic interdiction initiatives and resources for officer safety. Further, the role of HIDTA should be expanded to allow for it to provide more robust assistance to state and local law enforcement led prevention efforts.

Ensure that state law enforcement priorities are incorporated into larger federal supply reduction efforts. For example, DOJ's Task Force on Crime Reduction and Public Safety proposes to examine violent crime, which often derives from transnational criminal organizations involved in illicit opioid distribution. Future DEA and Organized Crime Drug Enforcement Task Forces (OCDETF) Program) supply reduction priorities and strategies should incorporate concerns and key issues from state law enforcement, particularly those engaged on illicit opioid distribution. Such federal and state priorities should target transnational criminal organizations and violent gangs. Federal support for supply reduction efforts should prioritize both emerging and existing markets. Additionally, reinforce DEA's ability to regulate opioid distributors it suspects of misconduct.

Support research, development, and court admissibility of a simple, accurate and cost-effective roadside testing method for drugged driving. States have struggled to develop and implement an effective roadside test for the presence of controlled substances. The rise in the number of people with substance use disorders, together with the decriminalization, medical use, and legalization of marijuana has caused a corresponding increase in the number of drivers under the influence of controlled substances and motor vehicle fatalities. Without an effective way to test for the presence of these drugs, the risk to the motoring public is substantial and growing.

Increase support for National Guard Counterdrug Program. Governors and states partner with the Counterdrug Program to leverage their skills and resources (e.g. operational case support, intelligence support, technical support, reconnaissance missions, and specialized equipment) to assist wider state and local efforts to address illicit drugs and transnational threats. The National Guard can strengthen state efforts to reduce exposure to trauma, implement comprehensive prevention strategies, and provide screening support and services for service personnel and families with substance use disorders. Increased support for the program will allow greater program capacity, provide states with funds to partner with local agencies and community groups and augment state use of this program to cut illicit drug supply.

Embrace law enforcement's greater role in education efforts and prevention strategies. As the opioid epidemic has worsened, law enforcement officials are increasingly engaged in comprehensive educational and prevention activities in schools and communities. Such efforts must continue to be coordinated with existing prevention programs in schools and avoid increasing stigma and fear around punitive approaches for those who need access to treatment. Federal support for state law enforcement to engage in educational activities, such as DEA's 360 Strategy, should be expanded. Increasing police

prevention and intervention efforts in schools requires new and additional resources to support training for officers in school and community engagement and other educational activities.

CONTINUING EDUCATION

Treating Behavioral Health Disorders in an Accountable Care Organization

This program is supported by an educational grant from Otsuka America Pharmaceutical Inc and Lundbeck.

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Educational Objectives
At completion of this activity, the participant will be able to:
- Identify challenges for treating behavioral health disorders and the gaps in an accountable care organization (ACO).
- Explore opportunities to treat behavioral health disorders by establishing partnerships within an ACO.
- Examine best practices and examples of successful incorporation of behavioral health treatment within an ACO.

Target Audience: Pharmacists, physicians, and managed care professionals
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INTRODUCTION

Mental health conditions and substance use disorders (SUDs), referred to as behavioral health conditions, are a leading cause of global disability.[1] In the United States, an estimated 1 in 3 adults suffers from one or both of these disorders.[2] These individuals die, on average, 25 years earlier than the general population as a result of suicide or comorbid physical conditions, such as cardiovascular disease, diabetes, respiratory distress, or infectious disease (HIV/AIDS). They also incur significantly higher medical and societal costs.[3]

Estimated spending on behavioral health conditions varies depending on the study. One analysis based on 41 million individuals covered under Medicare, Medicaid, or commercial health plans who were treated for a behavioral health condition in 2012 estimated a cost of $525 billion, nearly half of the $1.7 trillion spent that year on all health-related expenditures.[4] Another analysis estimated a lower cost: $201 billion in 2013.[5] Both analyses, however, noted that spending on behavioral health conditions was the highest category of any other medical condition in the United States, topping cardiovascular disease and trauma (Figure 1[5]).

The number of people seeking services for behavioral health conditions is expected to increase over the next decade due to the Affordable Care Act, which mandates that insurance companies cover screening and other services for mental health and substance abuse conditions, and the Mental Health Parity and Addiction Equity Act, which requires that insurers provide equal coverage for behavioral and physical health conditions.[6,7]

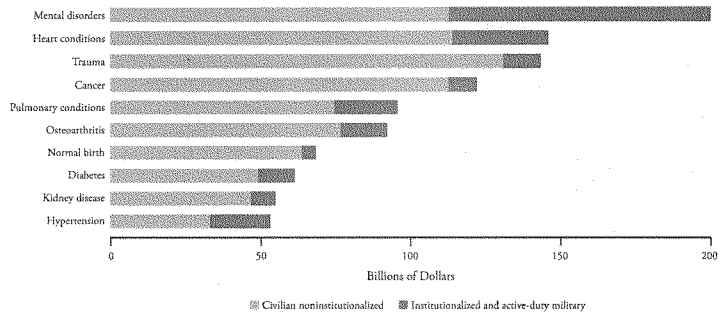
Despite the physical, economic, and societal consequences of behavioral health conditions, about one-third of individuals with these disorders receive no treatment, and the vast majority of the rest receive substandard treatment. This gap between needed care and received care increased by about two-thirds between 1997 and 2010.[8] Indeed, 70% of Americans in a recent poll from the Kennedy Forum felt that the country needed significant changes in the way it manages behavioral health conditions.[9]

Today, many individuals with behavioral health disorders receive care in the primary care or medical specialty, not behavioral health, setting.[10,11] Of those, up to 80% receive no treatment or substandard treatment for their behavioral health disorder.[10] This includes prescribing antidepressants for mild depressive symptoms, which are relatively ineffective, and the use of psychotropic medications with no documented behavioral health diagnosis.[12] Psychosocial approaches, which studies find can be just as effective as medication, are also underutilized.[9,13]

Prevalence of Comorbid Physical Conditions

Approximately 68% of those with behavioral health issues have comorbid physical conditions, typically chronic conditions such as asthma, low back pain, and diabetes.[14,15] These individuals have higher morbidity and mortality rates and are more likely to be nonadherent with medication than those with only a behavioral or physical health condition.[14,16] For instance, 21% of patients with chronic kidney disease (CKD) have comorbid depression regardless of their disease stage.[17] These patients are twice as likely to be

Figure 1. Ten Medical Conditions With the Highest Estimated Spending in 2013[5]



Source: Copyrighted and published by Project HOPE/Health Affairs as Rocheig C. Mental disorders top the list of the most costly conditions in the United States: $201 billion. Health Aff (Millwood). 2016;35(6):1130-1135. doi: 10.1377/hlthaff.2015.1659. The published article is archived and available online at www.healthaffairs.org.

hospitalized and have a 41% increased risk of all-cause mortality compared with patients with CKD who do not have depression.[18] Patients on hemodialysis have a 2-fold increased risk of death.[19]

Patients seen in the behavioral health setting who also require services for comorbid physical conditions report difficulties accessing medical care.[14] In one survey of 1670 adults with mental illness, one-third had difficulties accessing primary care, with 13% attributing this to stigma around their behavioral health condition.[20] Further, the care received is less likely to include prevention and screening, and this limited clinician time may lead to less time spent on psychosocial issues.[14] A review of the Veterans Affairs National Psychosis Registry showed poor adherence to medications for both psychiatric and medical conditions in patients with serious mental illness.[14] Not surprisingly, individuals with comorbid mental and physical health conditions use more health-related services than those without, even when controlling for the higher prevalence of physical health conditions among those with behavioral disorders.[16]

The Need for Integrated Care

Behavioral health disorders require long-term, chronic-care management similar to that needed for chronic physical conditions such as hypertension, diabetes, and asthma.[21,22] Such conditions respond best to management under a chronic-care model, which promotes enhanced access and care continuity, uses clinical information systems and decision support tools to identify and manage patient populations, provides self-management support to patients, and links patients to community resources. Under this model, providers also track and coordinate care and measure performance changes over time. Study results suggest this model can be implemented cost-effectively and even demonstrate some savings.[22,23]

In the behavioral health setting, a chronic care model requires integrating mental and substance abuse treatment with physical health management. This "integrated" model is described as "the care that results from a practice team of primary care and behavioral health clinicians, working together with patients and families, using a systematic and cost-effective approach to provide patient-centered care for a defined population."[24]

Settings may involve embedding behavioral health professions in a primary care setting or primary care providers in a behavioral setting, or developing a close relationship between behavioral and primary care practices despite different physical locations, even using telemedicine (Table 1[25]).[25]

Despite the robust literature demonstrating the benefits of integrated care models,[16] behavioral and physical healthcare delivery have traditionally operated in separate spheres.[22] Bringing the two together could not only improve outcomes, but also reduce costs.[26] Indeed, analyses suggest that integrating medical and behavioral services in Medicaid populations could save states between $3 and $9 billion, while integration could save all payers (including commercial) between $26.3 and $48.3 billion (2012 dollars) (Table 2[4,15]).[4,15] Updating benefit designs to reflect these improvements needs to be part of the move to accountable care organization (ACO) behavioral health integration.

These savings are already occurring at the state level. For instance, Missouri's Chronic Care Improvement Program, an integrative model designed for individuals with severe mental illness, such as schizophrenia, saved $8.3 million in its first year managing 6757 members, even with a $775,000 increase in outpatient costs.[15] In addition, the state's Community Mental Health Center healthcare homes (similar to patient-centered medical homes) for Medicaid-eligible individuals with severe and persistent mental illness, comorbid SUDs, and certain chronic health conditions reduced overall healthcare costs by 8.1% while significantly improving individual and societal outcomes.[4] When Kaiser Sacramento integrated medical and substance use treatments in primary care clinics for individuals in an outpatient chemical dependency recovery program, per-member-per-month (PMPM) costs dropped more than 50%, with significant declines in hospitalization rates, inpatient days, and emergency department use.[27]

Opportunities for Improvement

The Affordable Care Act created a pathway for greater integration of physical and behavioral health services when it expanded the development and use of ACOs. These integrated models of care are typically built around patient-centered medical homes. Payment is typically linked to the quality and cost of care, with value-based, rather than fee-for-service–based, reimbursement. A common reimbursement model is shared savings, in which the ACO shares in any savings with the payer over a defined timeline. In some instances, ACOs assume the risk for spending more than the financial target. Other ACOs take on even greater risk under capitation: such reimbursement models provide a financial incentive to hire case managers, social workers, pharmacists, and other allied health professionals to work with patients with comorbid behavioral health issues.[28]

ACOs are charged with managing the health of a patient population, which requires robust data systems, predictive analytics, and coordinated care. The goal is to achieve the Triple Aim of healthcare today: improved outcomes, improved patient experience, and reduced cost.[29] In 2015, 70% of Americans had access to an ACO, 44% to 2 or more, and between 15% and 17% (49 to 59 million) received care from an ACO.[30]

Integrating behavioral health management with physical health management in an ACO model could significantly improve population health management and outcomes, contributing to an ACO's ability to survive and thrive under risk-based reimbursement models.[29] This approach also fits with the ACO's team-based, coordinated care approach.[31]

Table 1. Substance Abuse and Mental Health Services Administration-Health Resources and Services Administration (SAMHSA-HRSA) Center for Integrated Health Solutions: Six Levels of Collaboration/Integration[25]

Coordination: Key Element: Communication		Co-Location: Key Element: Physical Proximity			Integration: Key Element: Practice Change
Level 1 Minimal Collaboration	Level 2 Basic Collaboration at a Distance	Level 3 Basic Collaboration Onsite	Level 4 Close Collaboration Onsite with Some System Integration	Level 5 Close Collaboration Approaching an Integrated Practice	Level 6 Full Collaboration in a Transformed/Merged Integrated Practice
Behavioral health, primary care, and other healthcare providers work:					
In separate facilities, where they:	In separate facilities, where they:	In same facility, not necessarily same offices, where they:	In same space within the same facility, where they:	In same space within the same facility (some shared space), where they:	In same space within the same facility, sharing all practice space, where they:
• Have separate systems • Communicate about cases only rarely and under compelling circumstances • Communicate, driven by provider need • May never meet in person • Have limited understanding of each other's roles	• Have separate systems • Communicate periodically about shared patients • Communicate, driven by specific patient issues • May meet as part of a larger community • Appreciate each other's roles as resources	• Have separate systems • Communicate regularly about shared patients, by phone or e-mail • Collaborate, driven by need for each other's services and more reliable referral • Meet occasionally to discuss cases due to close proximity • Feel part of a larger yet ill-defined team	• Share some systems, like scheduling or medical records • Communicate in person as needed • Collaborate, driven by need for consultation and coordinated plans for difficult patients • Have regular face-to-face interactions about some patients • Have a basic understanding of roles and culture	• Actively seek system solutions together or develop work-arounds • Communicate frequently in person • Collaborate, driven by desire to be a member of the care team • Have regular team meetings to discuss overall patient care and specific patient issues • Have an in-depth understanding of roles and culture	• Have resolved most or all system issues • Communicate consistently at the system, team, and individual levels • Collaborate, driven by shared concept of team care • Have formal and informal meetings to support integrated model of care • Have roles and cultures that blur or blend

Source: Heath B, Wise Romero P, Reynolds K. A review and proposed standard framework for levels of integrated healthcare. Washington, DC: SAMHSA-HRSA Center for Integrated Health Solutions. http://www.integration.samhsa.gov/integrated-care-models/CIHS_Framework_Final_charts.pdf. Published March 2013.

Some ACOs are improving their delivery of behavioral health care. For example, Crystal Run Healthcare ACO in New York, which participates in the Medicare Shared Savings Program (MSSP), has 3 psychiatrists in its medical building. These psychiatrists share a waiting room with their medical colleagues and use a connected electronic health record (EHR) system. They also formed a mental health assessment team comprising of primary care and specialty physicians who meet with mental health specialists to discuss cases requiring comanagement.[32]

The norm, however, is a continuation of siloed care. A survey queried 257 nationally representative Medicare, Medicaid, and commercial ACOs between 2012 and 2014, and was augmented with qualitative data from structured interviews with clinical leaders at 16 ACOs. It found that just 14% had fully integrated behavioral health and primary care teams and just 42% included behavioral health specialists among their providers.[29] Another survey found that more than one-third of ACOs had no formal relationship with behavioral health providers despite the fact that

Table 2. Projected Healthcare Cost Savings Through Effective Integration[4,15]

Population	Estimated Annual Savings
Commercial	$15.8-$31.6 billion
Medicare	$3.3-$6.7 billion
Medicaid	$7.1-$9.9 billion
Total	$26.3-$48.3 billion

Source: Melek SP, Norris DT, Paulus J. Economic impact of integrated medical-behavioral healthcare: implications for psychiatry. Denver, CO: Milliman, Inc. https://www.psychiatry.org/File%20Library/Psychiatrists/Practice/Professional-Topics/Integrated-Care/Milliman-Summary-Report-Economic-Impact-Integrated-Implications-Psychiatry.pdf. Published April 2014.

the majority of contracts included behavioral health metrics. Although 84% of ACOs had at least 1 contract with a payer that included responsibility for behavioral health services, just 66% of the largest commercial contracts included behavioral health services in the total cost of care.[29]

In another study, researchers analyzed Medicare claims for 20% of traditional beneficiaries with a mental health condition who received care in a Pioneer or MSSP ACO between 2008 and 2013 (they could not analyze SUD claims given federal confidentiality laws). They found cost savings in 2012 for Pioneer ACOs, primarily from a reduction in hospitalization, but the savings did not continue in 2013, nor were any savings observed in the MSSP. Neither ACO program showed significant differences in outcomes.[28] However, the authors also found little evidence of integration between behavioral and medical management. Instead, the majority of ACOs contracted out behavioral health services. Improving outcomes for individuals with mental health issues, they concluded, required that ACOs adopt evidence-based approaches associated with greater effectiveness in this population, such as integrated services.[28]

Even if ACOs are providing mental health services, far fewer are providing SUD services.[21,29] A survey of 635 substance abuse treatment centers found just 15% had a signed agreement to be included in an ACO, while just 6% and 4%, respectively, planned to be connected with an ACO or were currently negotiating to be connected.[21]

Publicly owned and private nonprofit SUD treatment facilities, as well as those in more competitive markets and those accredited by the Joint Commission, were most likely to have such contracts.[21] However, these contracts don't necessarily result in fully integrated services; they may only cover referral to behavioral health specialists. In addition, treatment centers in the Northeast were more likely than those in the Southeast and Midwest to sign contracts with an ACO, with those most likely located in states with 50 or more ACOs.[21] The authors concluded that the results of the survey "suggest that ACOs are not effectively integrating treatment and services for individuals with SUDs into medical settings." This, in turn, continues the fragmented, suboptimal, high-cost care received by this high-risk population, most of whom suffer from multiple chronic conditions.[21]

Yet, most ACOs understand the interrelationship between behavioral and physical health on overall outcomes and costs. An analysis of data from 90 Medicare ACOs between December 2012 and June 2015, including 72 site visits, found that nearly all of the ACO staff interviewed understood that behavioral health disorders contribute to overall health outcomes and spending and that most were working to better coordinate behavioral and physical health services.[33] They were working to integrate behavioral health and primary care, increase access to social workers, and enhance referral networks. Some embedded primary care providers in behavioral health facilities and included pharmacists and community resource specialists on treatment teams. One ACO even developed a mental health "center of excellence" for primary care referrals of complex patients who required significant behavioral and physical health services.[33] However, the study also found significant barriers to greater integration of behavioral health in an ACO, including a lack of behavioral health care providers, access to data, and sustainable financing models.[33]

Successfully Integrating Behavioral and Physical Health Services in an ACO

Successful integration of behavioral and physical health services in an ACO should focus on 5 areas: financial incentives, data sharing, legislative changes, quality measures, and alignment with existing initiatives.[33]

Financial Incentives

Financial incentives in any healthcare delivery system must be aligned with expected outcomes. Thus, the value of integrating behavioral and physical health services is low under a fee-for-service system, which pays for the episode of care provided regardless of outcomes and provides no reimbursement for the additional time and effort required to coordinate care.[33] The value is much higher, however, under a capitated system in which providers are essentially paid for keeping their population as healthy as possible.

Thus, value-based reimbursement models have entered the behavioral health sphere in the hope of spurring greater integration and improved outcomes. For instance, Minnesota's Medicaid program capitates Hennepin Health ACO for behavioral and medical services, which encourages greater coordination between providers.[34]

Capitation is but one reimbursement model. States may also require that ACOs share savings with behavioral health providers or leave it up to the ACO itself to compensate behavioral health providers. For example, Maine includes behavioral health services within the total cost of care (TCOC) calculations for its ACOs, leaving it up to the organizations to determine how to financially compensate the behavioral health provider. Given that the TCOC impacts the organizations' receipt of shared savings, this is designed to promote greater accountability across settings.[34]

Massachusetts embeds behavioral health services within its 3-tier payment system: comprehensive PMPM payments for an optional set of behavioral health services; quality incentive payments based on 23 quality measures, including 4 related to behavioral health; and shared savings payments based on cost savings on non–primary care services, including behavioral health. The higher the level, the higher the potential compensation.[34]

Data Sharing

Successful ACOs use robust information technology systems to collect and analyze data on their patients. These systems are typically tied into scheduling and revenue cycle systems to provide a holistic view of the state of the practice and patient population at any given time.[34] However, medical providers have been upgrading their information technology, particularly their EHR systems, for years thanks to the Health Information Technology for Economic and Clinical Health (HITECH) Act, which offered incentives for the development and meaningful use of such systems. The act, however, excluded mental and behavioral health providers and treatment facilities from this incentive program.[34] Thus, behavioral health providers are far behind their physical health counterparts in the collection and use of data.[34]

This could change if the Behavioral Health Information Technology Act and other legislations pass that are currently pending in Congress. The Behavioral Health Information Technology Act would extend incentives for meaningful use of EHRs to psychologists and mental health professionals who provide clinical care at psychiatric hospitals, mental health treatment facilities, and substance abuse treatment facilities.[35] In addition, the Office of the National Coordinator of Health Information Technology has released grants through the State Innovation Models Initiative to enhance IT integration into behavioral health.[36] ACOs could also require that their behavioral health providers participate in a joint EHR system and even offset some of the costs.

The lexicon for behavioral health diagnoses that is typically used for structured, coded information in health IT is also lacking. These structured data are required for the type of data analysis and clinical decision support necessary for successful population health management.[36] Just as challenging is the lack of interoperability among existing health information systems and the lack of behavioral health data fields in medical EHRs or physical health fields within behavioral health EHRs. Some states are beginning to provide support for more integrated systems, however, while larger ACOs may have the resources to modify existing systems to facilitate greater coordination.[34]

Legislative Changes

Legislative changes in the federal regulation that prohibits sharing patient information related to alcohol and drug treatment without additional patient consent (beyond the standard HIPAA form) are needed. Without these data, ACOs are unable to provide the level of analytics required to manage the health of a population and identify patients for targeted outreach.[33]

Billing issues also require changes. Just 28 state Medicaid systems allow providers to bill for primary care and behavioral health services on the same day even though there is no federal restriction. This creates a significant barrier to integrated and coordinated care.[34] Some legislative actions may seem minimal, but they can send a powerful message. For instance, in Arizona, it took legislative action to strike down a law that required separate waiting rooms for patients receiving mental health services and those receiving medical care.[37]

States should also encourage the training of additional behavioral health care specialists. A survey of 90 Medicare ACOs found that a scarcity of mental health professionals posted a significant barrier to the greater integration of behavioral and physical health. The ACOs cited poor Medicare reimbursement as one reason for the low number of providers willing to see Medicare patients.[33] Another survey of 2900 primary care providers found that 67% reported difficulties connecting their patients with behavioral health specialists because of a shortage of providers, as well as insurance barriers.[38] The survey was conducted in 2009, before the full impact of the Affordable Care Act and expanded access to insurance occurred. We do not yet know if this expansion changed access to providers or if benefits featuring narrow networks, behavioral health carve-outs, and high patient cost share blunted the benefit of this access.

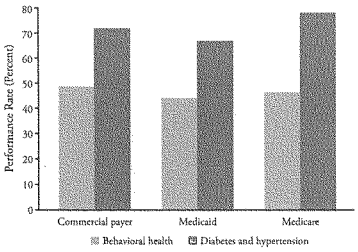
Quality Measures

Quality measures play an integral part in the effort to improve delivery of behavioral and physical healthcare services, ensure appropriate access, and align incentives under value-based reimbursement.[39] Although large national databases show 510 quality measures that address behavioral health, just 5% to 10% are included in major quality reporting programs, such as the Inpatient Psychiatric Facility Quality Reporting Program, the Physician Quality Reporting System, the National Quality Forum, and quality measures for Medicare and Medicaid programs maintained by the Centers for Medicare & Medicaid Services.[39,40]

Indeed, until recently, just 1 of 33 quality measures required for Medicare ACOs, depression screening, was directly related to behavioral health.[41] Yet, the depression screening is much more of a comprehensive primary care measure than measuring behavioral health performance. New measures for 2017 add rates of depression remission and response to treatment at 12 months. Measures involving screening for and treatment of SUDs are under consideration. In addition, several measures, such as shared decision making, medication reconciliation, and patient ratings of physicians, also apply.[42]

Adherence to behavioral health-related quality measures is poor, however, with reports demonstrating that patients receive recommended care based on quality initiatives about half the time. Conversely, recommended care is provided about two-thirds of the time for other chronic conditions, including diabetes and cardiovascular disease (Figure 2[39]).[39]

Figure 2. Average Performance Rates on Healthcare Effectiveness Data and Information Set Quality Measures for Behavioral Health Conditions vs Diabetes and Hypertension, by Payer, 2014[39]



Source: Copyrighted and published by Project HOPE/Health Affairs as Pincus HA, Scholle SH, Spaeth-Rublee B, Hepner KA, Brown J. Quality measures for mental health and substance use: gaps, opportunities, and challenges. *Health Aff (Millwood).* 2016;35(6):1000-1008. doi: 10.1377/hlthaff.2016.0027. The published article is archived and available online at www.healthaffairs.org.

In a recent article in Health Affairs, Pincus et al highlighted 5 key areas for improvement in the realm of behavioral health quality measures[39]:

- Expanding outcomes measurements built around the concept of "recovery" and including patients and families in their development.
- Developing structural approaches to enhance the capacity of organizations and providers to provide effective, quality care. This could include accreditation, certification, recognition, and payment programs, such as Medicaid Health Homes and the National Committee for Quality Assurance's patient-centered medical home and specialty recognition programs, which incentivize outcome-focused care.
- Encouraging the integration of behavioral and physical health services, as described earlier in this article.
- Expanding quality measures related to the use of effective patient-centered psychosocial interventions, such as talk therapy.
- Adding quality measures around the management of SUDs.

Table 3[34] highlights state efforts in these areas.[34]

Alignment With Existing Initiatives

Integrating behavioral and physical health services should build

Table 3. Behavioral Health–Related Measures Used in Medicaid Accountable Care Organization (ACO) Metrics in Select States[34]

Program, State	Behavioral Health–Related Measures
Accountable Communities (*Maine*)	Shared savings are contingent on performance on 18 measures, including the following 2 related to behavioral health services: • Rate of initiation and engagement of alcohol and other drug dependence treatment; and • Rate of follow-up within 7 days of hospitalization for mental illness
Primary Care Payment Reform Initiative (*Massachusetts*)	Providers are eligible to receive an annual incentive payment based on their performance on 23 quality measures, including the following 4 behavioral health-related measures: • Rate of depression screening; • Rate of follow up after hospitalization for mental illness; • Rate of initiation of alcohol/drug dependence treatment; and • Attention-deficit/hyperactivity disorder medication management for children
Integrated Health Partnerships (*Minnesota*)	Shared savings is calculated based on a weighted score that includes performance on 8 clinical quality measures, including: • Depression remission at 6 months
Coordinated Care Organizations (*Oregon*)	Within a global budget framework, coordinated care organizations are required to track: • Screening and follow-up for members diagnosed with clinical depression
Medicaid ACO Shared Savings Pilot (*Vermont*)	Providers who demonstrate successful integration and improve behavioral and physical health care in the following 2 measures will be eligible for increased shared savings (based on total cost of care calculations): • Rate of depression screening by 18 years of age; and • Rate of follow-up within 7 days of hospitalization for mental illness

Source: Brown D, McGinnis T. Considerations for integrating behavioral health services within Medicaid accountable care organizations. Center for Health Care Strategies website. http://www.chcs.org/media/ACO-LC-BH-Integration-Paper-07091411.pdf. Published July 2014.

on existing programs within ACOs. For instance, some ACOs already employ social workers and other behavioral health specialists for short-term support. New York state is working with existing "health home" programs, which provide care for complex patients, to grow them into ACOs and is providing grants to behavioral health providers to encourage them to better collaborate with health homes. Those health homes are already required to support care management across physical and behavioral health services and create links to community support and housing.[34]

ACOs should also investigate the numerous state and federal grants available for behavioral health integration. For instance, the SAMHSA-HRSA Center for Integrated Health Solutions has awarded more than $26.2 million in grants to 100 community-based behavioral health organizations to support integration of primary care services into these settings.[34]

A 2010 report from the Agency for Healthcare Research and Quality highlights several essential measures needed to facilitate an integrated mental health model in the primary care setting[16]:

- Normalize mental health into mainstream medical practice. This requires cultural shifts to move away from the stigma of behavioral health problems and recognize these conditions as chronic health conditions no different from diabetes and asthma. It also requires redesigning workflows and providing physicians with the technical and leadership skills they require for full integration.
- Integrate reimbursement mechanisms. This includes eliminating separate coding and billing procedures.
- Create a roadmap for implementation. This includes research that identifies the most effective and cost-effective primary care models for this population and the development of decision support tools that identify patients who require integrated services.
- Create and/or disseminate the tools providers need. This requires guidance and technical assistance for implementing integrated care, research, and valid screening, diagnostic, and monitoring instruments.

CONCLUSIONS

One in 3 individuals in this country has a behavioral health disorder, whether a mental illness, SUD, or both. These patients garner healthcare costs far higher than those without such disorders, experience greater morbidity and earlier mortality, and are more likely to experience comorbid physical health conditions. They also receive substandard care for their behavioral health disorders and experience difficulties accessing primary care for their physical health disorders. The traditional separation between behavioral and physical health services in the medical field contributes to these access and quality issues.

Integrating behavioral and physical health services within an ACO offers a significant opportunity to address both of these problems, as well as improves outcomes and reduces costs. However, ACOs, which have traditionally focused on physical health conditions, have been slow to incorporate behavioral health within their population health focus. Barriers include a lack of quality incentives, behavioral health providers, and a robust IT infrastructure.

The value-based reimbursement model under which ACOs operate, however, should incentivize these organizations to better address behavioral health conditions in order to improve the overall health of their population. However, payers need to ensure that financial incentives are aligned to encourage this by including behavioral health outcomes and responsibilities within any capitation and/or shared savings plans. They should also support the development of interoperative information systems and legislative changes that encourage the full integration of behavioral and physical health services.

Additional Resources

The following references provide more information about integrated primary and behavioral health care:

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CE Posttest Questions

1. **Most accountable care organizations (ACOs) surveyed in recent years:**
   - A. Offer fully integrated behavioral health care
   - B. Subcontract behavioral health care services to other providers
   - C. Have taken on risk for the provision of behavioral health care services
   - D. Have hired onsite psychiatrists and psychologists

2. **ACOs are uniquely suited to manage behavioral health conditions because they:**
   - A. Operate under value-based reimbursement systems
   - B. Are located in urban areas
   - C. See patients with chronic medical conditions
   - D. Typically employ behavioral health practitioners

3. **Which of the following is true regarding the outcomes of behavioral health and current ACO models?**
   - A. One-third of the population currently receives no treatment.
   - B. There has been an overall improvement in positive outcomes and lower cost as a result of primary care addressing behavioral health issues.
   - C. There has been a vast improvement in coordination of care between primary care and behavioral health care.
   - D. Over 90% of the US population has no access to behavioral health services.

4. **Improving access to behavioral healthcare through ACOs requires:**
   - A. Having primary care providers provide more behavioral health care
   - B. Greater use of quality measures related to behavioral health provision and outcomes
   - C. Centralizing behavioral health services for efficiency
   - D. Putting more responsibility for behavioral health visits on the patients.

5. **Pioneer ACOs showed:**
   - A. Sustained reduction in behavioral health savings
   - B. A 1-time reduction in behavioral health savings
   - C. Tight integration between primary care and behavioral health
   - D. Improved clinical outcomes

6. **Behavioral health providers are less likely to use an electronic health record (EHR) due to:**
   - A. EHRs not being useful in behavioral health
   - B. Lack of integration into an ACO
   - C. Being excluded from the Health Information Technology for Economic and Clinical Health Act
   - D. Concerns about HIPAA

Sample Posttest

7. **Quality measures used by Centers for Medicare & Medicaid Services (CMS) to measure ACO performance had:**
   A. A robust number of behavioral health performance measures
   B. A mix of outcome and process behavioral health measures
   C. 1 measure aimed at depression screening
   D. Multiple measures related to substance abuse

8. **Improvements in outcomes and cost has been demonstrated in which of the following models:**
   A. Co-located
   B. Coordinated
   C. Primary Care
   D. Integrated

9. **Existing initiatives that can be leveraged to help integration of behavioral health services include:**
   A. New York state's health home programs
   B. CMS' s behavioral health ACO program
   C. Commercial payer behavioral health carve-outs
   D. Reduction of hospital readmission rates

10. **Tighter integration strategies for behavioral health include all of the following, except:**
    A. Removing physical barriers, such as placing behavioral health providers in primary care clinics
    B. Adding behavioral health into a risk arrangement, such as capitation, to force primary care attention to behavioral health
    C. Increasing access to behavioral health providers
    D. Reducing reimbursement for behavioral health services

11. **The Substance Abuse and Mental Health Services Administration-Health Resources and Services Administration (SAMHSA-HRSA) Center for Integrated Health Solutions lists 6 levels of integrated care. At which level are most ACOs today?**
    A. Level 1
    B. Level 2
    C. Level 3
    D. Level 4

12. **Exemplary ACO behavioral health models focus on which of the following to reduce costs and improve outcomes?**
    A. Data sharing and identifying those at risk for behavioral health disorders.
    B. Chronic care management of behavioral health similar to that of physical chronic conditions
    C. Outsourcing behavioral health service removing burden from primary care providers
    D. Forcing efforts on substance use disorders

Sample Posttest

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Drug Interactions of Clinical Importance among the Opioids, Methadone and Buprenorphine, and other Frequently Prescribed Medications: A Review

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Abstract

Drug interactions are a leading cause of morbidity and mortality. Methadone and buprenorphine are frequently prescribed for the treatment of opioid addiction. Patients needing treatment with these medications often have co-occurring medical and mental illnesses that require medication treatment. The abuse of illicit substances is also common in opioid-addicted individuals. These clinical realities place patients being treated with methadone and buprenorphine at risk for potentially toxic drug interactions. A substantial literature has accumulated on drug interactions between either methadone or buprenorphine with other medications when ingested concomitantly by humans. This review summarizes current literature in this area.

The World Health Organization reports that drug interactions are a leading cause of morbidity and mortality.[1] This finding extends to medications used in the treatment of substance use disorders and pharmacotherapies utilized for treatment of medical or mental illnesses, as well as for abused substances—including alcohol, licit, and illicit substances. Furthermore, there has been a dramatic increase in deaths related to methadone use, both for the treatment of pain and illicit use, in the United States in recent years. Drug interactions have been implicated in many of these deaths.[2] In this paper, we will review the existing literature on drug interactions principally between opioids used in the treatment of opioid dependence, methadone and buprenorphine, and other medications with a focus on clinically relevant drug interactions in humans. Interactions between cocaine, alcohol, and other substances will also be summarized.

Clinical Pharmacology of Drug Interactions

Drug interactions can occur through several mechanisms. One or more mechanisms may be involved in the expression of a clinically significant drug interaction. The primary mechanisms of drug interactions include effects of drugs on hepatic metabolism of pharmaceuticals including effects on cytochrome P450 (CYP) enzymes or effects on glucuronidation, medication effects on the function of the drug transporter, P-glycoprotein, and effects on absorption of drugs.[3] Pharmacodynamic interactions are also important. For

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example, some drugs when taken in combination exhibit synergism that can increase drug effects resulting in toxicity.

The opioid medications, methadone and buprenorphine are extensively metabolized by human liver. Specifically CYP3A4 plays a significant role in the metabolism of methadone, and buprenorphine.[4-6] Other CYP enzymes play a role in opioid metabolism including 2B6, CYP2C19, CYP2C9 and CYP2D6[7] for methadone, and 2C8 for buprenorphine.[8] Drug interactions mediated by CYP 450 enzymes can be associated with the potential for significant adverse events.

Perhaps the best studied mechanism for drug interactions is seen with medications that inhibit the function of hepatic metabolic enzymes. Laboratory assays are well-developed and provide insights on the inhibitory effect of a specific compound on major liver CYP enzymes, particularly CYP3A4. The Food and Drug Administration (FDA) has classified CYP3A4 inhibitors as strong, moderate or weak, based on the increase in exposure they cause in sensitive CYP3A4 substrates (See Table 1 below). With buprenorphine, a CYP3A4 substrate, systemic exposure increase is noted following concomitant administration with ketoconazole, a strong CYP3A4 inhibitor. Drug interactions with other CYP3A4 inhibitors, listed in the Table 1, below may cause an increase in systemic levels or pharmacodynamic effects of buprenorphine.

Although assays that can reliably show induction of CYP enzymes exist, these assays are unable to predict drug interactions when the compounds inhibit some CYP enzymes while inducing other CYP enzymes. In such situations, we often learn of inducing properties of a drug through clinical observations. For example, HIV antiretroviral (ARV) medications such as ritonavir, nelfinavir, and nevirapine, are known to inhibit CYP3A4; however, they are shown to reduce the plasma levels of methadone, possibly due to induction of other CYP enzymes involved in its metabolic clearance.[9,10] Glucuronidation of many drugs directly results in their elimination. Glucuronidation can also be a late step in the metabolism of drugs which undergo a series of metabolic steps with intermediates produced as a result of metabolism by CYP enzymes. Glucuronidation renders a metabolite water soluble so that it can then be excreted. An example of a clinically significant drug interaction mediated by inhibition of glucuronidation is that of the effect of methadone on zidovudine elimination. Methadone can inhibit zidovudine glucuronidation resulting in increased concentrations that, in some cases, may produce zidovudine toxicity.[11]

Some drug interactions occur as a result of the production of a pharmacologically active metabolite as in the case of simultaneous cocaine and alcohol consumption which results in the formation of cocaethylene, a cocaine-like compound that can contribute to toxicities associated with the abuse of these substances.[12] Altered absorption can also produce clinically significant drug interactions as when an opioid such as methadone slows gastrointestinal mobility exposing a drug sensitive to acidic pH to prolonged time in the stomach resulting in increased degradation. This has been observed when methadone-maintained patients were administered the ARV medication, stavudine, resulting in sub-therapeutic stavudine concentrations.[13] This could result in ineffective treatment of HIV disease in patients receiving both medications.

Pharmacodynamic interactions can result when two or more drugs with the capability of producing similar pharmacological effects in an individual are ingested in the same time frame resulting in significant adverse effects. For example, when buprenorphine and benzodiazepines (e.g.: alprazolam) have been injected together, deaths have resulted that are thought to be related to depression of the central nervous system (CNS) with a resulting decrease in respiration.[14] Although buprenorphine when given alone has been shown to

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have a ceiling effect at which higher doses do not produce further opioid agonist effects,[15] when injected with benzodiazepines, it is possible that high plasma concentrations of two drugs with sedating and respiratory depression properties occur resulting in a potentially life-threatening drug interaction.[16]

It can be difficult to determine what mechanism(s) are responsible for adverse drug interactions. Controlled studies in humans that include simultaneous administration of medications and measurement of plasma drug concentrations are important to understanding the pharmacokinetic and pharmacodynamic drug interactions important in the treatment of common medical and mental disorders. In the following sections, important drug interactions that have been described will be briefly reviewed.

Drug Interactions of Clinical Significance in Substance Use Disorders

Drug Interactions Between Medications Used to Treat Substance Use Disorders and Other Medical Illnesses

HIV Disease—Historically, approximately 25% of new HIV cases in the U.S. have been attributed to injection drug use The HIV epidemic has had a significant component attributable to injection drug use and high risk practices with 25% of new HIV cases in the U.S. historically being secondary to injection drug use.[17] These high risk practices include the sharing of needles and syringes as well as other paraphernalia used in the preparation of drugs for injection. The majority of injection drug users are addicted to heroin or opium. There are several medical treatments available for opioid dependent patients. These include medical withdrawal from opioids and maintenance treatment with methadone or buprenorphine. Medical withdrawal from opioids has been shown to have a high relapse rate.[18] For those with HIV disease, where relapse places these patients at risk for resumption of injection drug use, its associated high risk practices, and non-adherence to HIV ARV therapy, opioid maintenance therapy is recommended. US FDA-approved therapies for opioid maintenance therapy include methadone, l-acetyl-methadol (not currently manufactured in the U.S.), and buprenorphine, the most recently approved medication for the treatment of opioid dependence. Buprenorphine is co-formulated with naloxone, an opioid antagonist (as buprenorphine/naloxone or Suboxone) for the purposes of decreasing the likelihood of abuse or diversion of the medication.[19] It is important to be aware of clinically significant drug interactions that may occur between opioids and medications used to treat HIV disease because of the high prevalence of HIV in opioid dependent patients. This population represents a significant risk for personal harm and harm to others should they relapse to opioid use and continue high risk injection drug use and sexual practices. For that reason, much research has been devoted to determining the presence of clinically significant drug interactions between opioids and ARV medications.

The first ARV medication to be approved by the FDA for the treatment of HIV infection was zidovudine (AZT).[20] At that time, as currently, most opioid-dependent patients with HIV disease were maintained on methadone. Some methadone-maintained patients with HIV disease who were started on AZT therapy for HIV infection were noted to develop symptoms that appeared to be consistent with opioid withdrawal including muscle and joint pain, dysphoria, insomnia, and depression.[21] In a human laboratory study which examined the direct interaction of methadone and AZT, it was found that methadone treatment was associated with a 41% increase in exposure to AZT in opioid-dependent patients with HIV disease which was attributed to inhibition of AZT glucuronidation and a general opioid effect of slowed gastrointestinal transit that could result in increased absorption of AZT.[11]

The results of this study led to another question: did interactions between methadone and AZT characterize interactions between AZT and other opioid therapies? To test this

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question, another study was conducted in which the interaction of AZT with either buprenorphine, LAAM, or naltrexone was examined.[22] The hypothesis for this study, based on the findings of the interactions between methadone and AZT was that medications that are antagonists at the mu opioid receptor, such as naltrexone, would have no effect on AZT concentrations, while mu opioid agonists such as buprenorphine or LAAM would increase AZT concentrations. In fact, what was observed were non-clinically significant decreases in AZT concentrations in patients treated with buprenorphine or LAAM; the opposite of that observed with methadone. These findings indicated that the observation for methadone was not representative of what would occur in the context of other opioids in combination with ARV therapies.

To date, a number of frequently utilized ARV therapies have been examined in combination with methadone and other opioid therapies. These drug interactions are summarized in Table 2. Selected important drug interactions are summarized below.

Interactions between methadone and several HIV therapies demonstrate the potential for adverse drug effects that can occur when absorption of a drug is altered. Methadone is a full mu opioid receptor agonist. A general effect of such drugs is to slow gastrointestinal mobility. Methadone has been associated with significant decreases in HIV medications that are sensitive to the acidic environment of the stomach. Didanosine (DDI or Videx) (in tablet formulation) and stavudine (d4T) are two non-nucleoside reverse transcriptase inhibitors (NRTIs) that may produce sub-therapeutic plasma concentrations of methadone when administered to methadone-maintained individuals.[13] Didanosine is now available in an enteric-coated formulation to prevent excess degradation in the stomach. This formulation has been shown to be associated with therapeutic plasma concentrations in both methadone-maintained[23] and buprenorphine-maintained individuals.[24]

Adverse events related to inhibition of the clearance of opioid medications have the potential to produce opioid toxicity including altered cognition and decreased respiration. Delavirdine is a non-nucleoside reverse transcriptase inhibitor that inhibits the function of CYP 450 3A4.[25] Administration of delavirdine to methadone or LAAM-maintained patients results in significantly elevated opioid concentrations and delayed clearance, although in a drug interaction study, no clinically significant adverse events were observed.[26] This finding might be related to the short period of time in which the medications were co-administered, with greater risk for those who taking such medications on a long-term basis. Buprenorphine has been associated with cognitive dysfunction in patients with HIV who received treatment with the protease inhibitors, atazanavir (Reyataz)/ritonavir.[27] A subsequent study to determine if a drug interaction could have been responsible for the observed cognitive dysfunction showed that atazanavir alone and in combination with ritonavir was associated with substantial increases in buprenorphine exposure and delayed clearance.[28] While no cognitive dysfunction was observed during the drug interaction study, several participants complained of increased drowsiness that abated after cessation of atazanavir/ritonavir.

Of equal concern are the drug interactions that result in diminished concentrations of opioid therapies. For example, co-administration of a medication that induces methadone metabolism could result in a reduction of plasma methadone concentrations in a methadone-maintained patient leading to the potential development of opiate withdrawal symptoms. The onset of opiate withdrawal may be associated with abuse of opioids or other illicit substances and resumption of high risk behaviors related to drug abuse with risk for HIV transmission. HIV ARV medications producing the induction of CYP 450 3A4 associated with opiate withdrawal have been reported. The NNRTIs efavirenz and nevirapine, as well as the protease inhibitor combination drug lopinavir/ritonavir, have been linked to opiate withdrawal in methadone-maintained patients.[29-33] Interestingly, these medications when

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given to buprenorphine-maintained individuals were not associated with the onset of opiate withdrawal despite marked reductions in buprenorphine plasma concentrations.[34-36] Buprenorphine has a metabolite, norbuprenorphine, that is formed when buprenorphine undergoes dealkylation by CYP 3A4.[37] Norbuprenorphine is also a mu opioid agonist. This may be one reason that withdrawal does not occur even with induction of buprenorphine metabolism. Further, buprenorphine is a partial mu opioid agonist with a high affinity for and slow dissociation from the mu opioid receptor which may protect buprenorphine-maintained individuals from opiate withdrawal.[19]

The use of ARV medications in those who also require opioid therapy for treatment of opioid addiction can be challenging with methadone. However, to date, none of the adverse drug interactions that have been observed between methadone and ARVs have been observed in buprenorphine-maintained individuals. With the exception of atazanavir/ritonavir which substantially increases buprenorphine and norbuprenorphine plasma concentrations with possible cognitive effects, there have been no other reports of toxic interactions between buprenorphine and ARVs. Further, buprenorphine has not been shown to significantly alter plasma concentrations of ARVs and therefore, buprenorphine/naloxone treatment appears to be less likely to be associated with adverse drug effects in combination with ARVs. These findings may be useful to clinicians who must treat both HIV disease and opioid dependence in the same patient.

What are the practical implications of drug interactions between opioid therapies and HIV medications? If a patient with co-occurring HIV/AIDS and opioid dependence is already methadone-maintained and on a stable, therapeutic dose, it is not recommended that the patient be converted to buprenorphine treatment. The necessary tapering of methadone to achieve buprenorphine induction could potentially destabilize the patient. Rather, clinicians with such patients should be aware of major drug interactions that may occur between ARV and methadone and adjust medication doses accordingly. If a patient is new to opioid therapy or wishes to be readmitted to opioid therapy and HIV/AIDS is a consideration, buprenorphine may be preferable as appears that it will have fewer clinically significant interactions with ARV.

Tuberculosis—Tuberculosis is a common opportunistic infection often seen in those with immunosuppressed states such as HIV/AIDS. Tuberculosis can also occur independently and is seen more frequently in individuals addicted to heroin. Medications used to treat tuberculosis can have significant interactions with methadone. The best known of these interactions is that of the effect of rifampin, a first-line agent used in combination with isoniazid for the treatment of tuberculosis infection, to induce methadone metabolism.[38] Rifampin has been associated with significant opiate withdrawal symptoms in methadone-maintained patients. Some patients receiving buprenorphine also develop opiate withdrawal symptoms when treated with rifampin, however at this time, the final data is still pending.[39] Rifabutin can be substituted for rifampin in those requiring tuberculosis treatment who are also receiving methadone treatment. This same finding is likely to be true for buprenorphine-treated patients, although this has not yet been examined. While rifabutin can also induce CYP 3A4, it appears not to produce the withdrawal symptoms rifampin does.[40] Rifampin is also used as a treatment for methicillin-resistant staphylococcus aureus (MRSA). This increasingly common infection also occurs in methadone-treated patients who will similarly require substitution of rifampin with rifabutin in this clinical circumstance. Isoniazid is a CYP 3A4 inhibitor,[41] but has not been associated with adverse events in opioid-maintained patients to date, perhaps because any effect to inhibit opioid metabolism is opposed by the concomitantly administered rifampin in patients with tuberculosis and receiving chronic opioid therapy.

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Hepatitis C—Hepatitis C virus (HCV) is a frequent infection in opioid-addicted patients with the reported rate of HCV in injection drug users in the United States to be estimated at approximately 33%.[42] Injection drug use remains the most common cause of HCV in the U.S., with over 60% of all new infections occurring as a result of injection drug use.[43] The standard of care for pharmacotherapy of HCV is the use of a combined regimen consisting of pegylated interferon and ribavirin. These medications have a high rate of adverse symptoms and side effects associated with their use including depression, anxiety, malaise, myalgia, fatigue, and anemia (ribavirin).[44] The documentation of these symptoms being experienced by opioid-dependent patients on methadone therapy as opiate withdrawal symptoms led to studies to examine whether there was a pharmacokinetic drug interaction between methadone and interferon. To date, two studies have been reported in the literature and both have shown no significant drug interactions between methadone and interferon.[45,46] No studies of drug interactions between ribavirin and methadone have been completed at this time.

Other Infections—There are four antibiotic treatments, specifically antifungal and antibacterial therapies that cause potentially clinically significant drug interactions with methadone as a result of inhibition of CYP 450 3A4 which can increase methadone concentrations. Both the antifungal medications fluconazole[47] and voriconizole[48] are inhibitors of this enzyme and might increase methadone plasma concentrations when administered concomitantly. Similarly, ciprofloxacin inhibits CYP450 3A4 and there has been a case report of life-threatening opioid toxicity when this medication was given to a methadone-maintained individual.[49] Biaxin is also an inhibitor of CYP450 3A4[50] and may increase methadone concentrations. Because buprenorphine is a substrate of CYP450 3A4, its plasma concentrations would likely be increased in the presence of any of these antibiotics as well. However, the ceiling effect for opioid agonist effects of buprenorphine could diminish any potential opioid toxicity.

Mental Illness—The lifetime rate of co-occurring mental illness in those with opioid dependence has been estimated to be as high as 50%.[51] As a result, many patients with opioid addiction will require treatment with psychotropic medications at some time. While exhaustive work examining drug interactions between opioids and medications commonly used to treat mental illness has not been undertaken, there are some findings that can be summarized in this review.

Antidepressants—Affective disorders, particularly major depression are common in opioid dependent patients. Current rates for depression of up to 25% and lifetime rates of 50% have been reported for this population.[52] Depressive symptoms will often resolve with methadone or buprenorphine treatment, but a significant minority of patients will require treatment with antidepressant medications.

The serotonin reuptake inhibitors exert a variety of effects on the cytochrome P450 enzyme system. Both fluoxetine and fluvoxamine have been examined in vitro for evidence of potential for drug interactions with methadone and buprenorphine. Both fluoxetine and fluvoxamine (with fluvoxamine being more potent than fluoxetine) inhibit CYP450 3A4 and 2D6. In vitro studies showed both antidepressants to be associated with decreased metabolism of methadone and buprenorphine.[53] Fluoxetine has not been associated with clinically important increases in methadone.[54] Importantly, administration of fluvoxamine has been reported to result in significantly increased methadone plasma concentrations in a series of 5 patients. Further, discontinuation of fluvoxamine was associated with the onset of opiate withdrawal.[55] Opiate withdrawal is a risk in any patient experiencing increased methadone exposure as a result of concomitant administration of a medication that inhibits

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methadone metabolism. Discontinuation of the concomitant medication will result in resumption of normal methadone metabolism which could decrease methadone plasma concentrations to the point that the patient experiences opiate withdrawal. This subsequent opiate withdrawal may lead to non-adherence to the treatment regimen and increased use of illicit substances, underscoring the importance of clinician awareness of the potential for such interactions. Other serotonin reuptake inhibitors including sertraline[56] and citalopram[57] have not been associated with adverse drug interactions with methadone or buprenorphine. However, both sertraline and citalopram have been associated with inhibition of CYP450 2D6. Since methadone metabolism is contributed to by CYP450 2D6, it is possible that methadone concentrations could increase in a patient receiving one of these antidepressants in combination with methadone. Although no clinical reports of serotonin syndrome have been reported in conjunction with methadone treatment and treatment with serotonin reuptake inhibitors, it is a consideration should those receiving concomitant therapies develop symptoms of neuromuscular hyperactivity including tremor, clonus, myoclonus, and hyperreflexia. Other symptoms of serotonin syndrome include rigidity, autonomic hyperactivity (diaphoresis, fever, tachycardia and tachypnea) as well as altered mental status characterized by agitation, excitement and confusion.[58]

Other antidepressant medications have not been reported to have significant interactions with methadone or buprenorphine. Mirtazepine has no reported interactions with these opioids. Duloxetine, an antidepressant medication also approved for treatment of neuropathic pain particularly in patients with diabetes, a common co-morbid medical condition in patients with opioid dependence, is a substrate of CYP450 2D6. Methadone has been reported to not only be a substrate of this enzyme, but also has some ability to inhibit its function. As such, methadone could potentially lead to increased duloxetine exposure;[59] however a formal drug interaction study has not been conducted. Amitriptyline has been shown to inhibit both CYP450 3A4 and 2D6.[60] As such it could be associated with increases in plasma methadone concentrations, although no clinically important adverse events have been reported. However, the use of amitriptylene as either an antidepressant or for the treatment of pain syndromes warrants clinician awareness of the potential for drug interactions between amitriptylene and methadone.

St. John's wort is an over-the-counter herbal remedy purported to have antidepressant properties. Its use is widespread and represents a potential for adverse drug interactions. This medication is known to induce both CYP450 3A4 and P-glycoprotein which can result in increased metabolism and elimination of methadone and buprenorphine.[61] The large number of clinically significant adverse events that have been reported between St. John's wort and other medications underscore the need to query patients about the use of over-the-counter remedies, herbal, and nutriceutical use when other medications are prescribed for concomitant medical conditions.

Antipsychotics—There are few reports of antipsychotic medications having adverse drug interactions with opioids. Some of the older neuroleptic medications would not be expected to have clinically significant pharmacokinetic drug interactions with opioids because their major metabolic pathways are not shared by methadone or buprenorphine. Pharmacodynamic interactions might occur, however, as a result of increased sedation or cognitive dysfunction that could be experienced when these medications are given concomitantly. There is a report of increased plasma methadone concentrations in those treated with quetiapine. This interaction results from quetiapine's ability to inhibit CYP450 2D6 as well as to inhibit P-glycoprotein.[62] There have been no reports of adverse events related to methadone toxicity in the literature resulting from this interaction, however the impact on two mechanisms of methadone clearance could be of potential clinical importance. No clinically significant pharmacokinetic drug interactions have been reported

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for methadone or buprenorphine when administered concomitantly with risperidone, clozapine, aripiprazole, olanzepine, or ziprasodone.

Anxiolytics—The use and abuse of anxiolytic medications, benzodiazepines and sedative-hypnotics by those with opioid addiction and being treated with buprenorphine or methadone is common. The anxiolytics share common pharmacological properties of sedation and when abused, altered cognition. In combination with methadone or buprenorphine, these drugs have potential for significant harm. Opioids such as methadone and, to a lesser extent, buprenorphine as a result of its partial agonist effect, can decrease respiration through agonist action at mu receptors in the medullary respiratory center. Benzodiazepines (and alcohol) act synergistically in that these drugs facilitate inhibition at gamma-aminobutyric acid (GABA) receptors and alcohol decreases the excitatory effect of glutamate at N-methyl-D-aspartic acid (NMDA) receptors. These mechanisms may help to explain fatal overdose in the presence of opioids and/or benzodiazepines and alcohol.[63] Diazepam has been shown not to be associated with altered methadone plasma concentrations.[64] However, significant pharmacodynamic interactions have been reported between diazepam and methadone as well as diazepam and buprenorphine.[65,66] Diazepam has been associated with increased sedation and impaired performance on psychological tests. Fatalities have been reported when methadone and alprazolam were co-ingested.[67] In these cases, methadone concentrations in blood were not in the toxic range indicating that a pharmacodynamic interaction between methadone and alprazolam played a role in the toxicity. Buprenorphine has also been associated with deaths when ingested by the intravenous route in combination with benzodiazepines.[68,69] This is also thought to be a pharmacodynamic interaction resulting in fatal respiratory depression. The impairment associated with combined methadone or buprenorphine use with benzodiazepines as well as the morbidity and mortality that has been linked to co-ingestion of these drugs indicates that caution should be used in prescribing benzodiazepines to those receiving methadone or buprenorphine treatment of opioid dependence. Further, clinicians should monitor for evidence of benzodiazepine abuse substance-related disorders resulting from benzodiazepine abuse should be treated in these patients.

Anticonvulsants—Anticonvulsant medications are commonly prescribed to patients treated with methadone or buprenorphine to treat either seizure disorders or mental illnesses including bipolar disorder and schizoaffective disorder. Several anticonvulsants have clinically significant drug interactions with methadone. Carbamazepine, phenytoin, and phenobarbital are all inducers of CYP450 3A4 and have been associated with opiate withdrawal when administered to methadone-maintained patients.[70] Larger doses of methadone have been required in patients treated with anticonvulsants that induce methadone metabolism. Whether such drug interactions occur in buprenorphine-treated patients has not been evaluated, but induction of buprenorphine metabolism is likely to occur since it is a substrate of CYP450 3A4.

Newer anticonvulsant medications do not have the same broad spectrum effects on CYP450 enzymes or drug interactions with opioids. Oxcarbazepine, lamotrigene, and topiramate have not been reported to have adverse drug interactions with methadone or buprenorphine. These anticonvulsants are likely to be better choices for clinical use in opioid-maintained patients.

Psychostimulant Medications—Psychostimulant medications frequently prescribed for attention deficit hyperactivity disorder, night shift work or narcolepsy include amphetamines, methylphenidate, pemoline, or modafinil. Psychostimulant medications have not been reported to produce adverse drug interactions in methadone or buprenorphine-treated patients.

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Antihistamines—Antihistamine drugs are commonly prescribed for a variety of medical symptoms. CYP450 2D6 contributes to the metabolism of some of the antihistamine medications promethazine, diphenhydramine and chlorpheniramine. In addition, some antihistamines such as promethazine and diphenhydramine may inhibit CYP450 2D6.[71] Methadone is a substrate of and can also inhibit CYP450 2D6 as well. While clinical reports of adverse events related to pharmacokinetic and pharmacodynamic interactions are not in the literature, these medications have the characteristics that might result in adverse interactions. This could result from direct pharmacokinetic interactions as well as a synergistic effect of use of the opioids in combination with an antihistamine.

Other Potential Drug Interactions Based on Methadone Effect on CYP 2D6—Methadone can inhibit CYP450 2D6 and has been reported to alter the pharmacokinetics of the antidepressant desipramine, a substrate of CYP 2D6.[72] Methadone has been reported to be associated with increased desipramine levels.[73] Other tricyclic antidepressants (imipramine), antipsychotics (risperidone, other phenothiazines), analgesics (codeine), antiarrhythmics (flecainide) and some beta blockers are also substrates of CYP 2D6 and may have the potential for adverse drug interactions based on increased plasma concentrations.[72] Dextromethorphan, a substrate of CYP 450 2D6, has been associated with delirium in a patient receiving methadone.[74] The adverse events abated with cessation of dextromethorphan and were attributed to the effect of methadone on dextromethorphan clearance.

Other Medical Diseases: Cardiac and Pulmonary—Opioid addicted patients often develop co-occurring medical illnesses. Some of the more common medical illnesses seen in opioid-dependent patients are those associated with the cardiovascular and pulmonary systems. A few commonly prescribed medications include digoxin, quinidine, verapamil, cholesterol-lowering statin drugs, heparin, and theophylline. Adverse interactions between these medications and either methadone or buprenorphine are not found in the clinical literature. Aspirin, a very frequently utilized medication for pain and for its anticoagulant properties is metabolized by a serum esterase which is inhibited by methadone.[75] No adverse drug interactions between methadone and aspirin have been reported, but the possibility of accumulation of aspirin in methadone-maintenance treatment is a possibility that should be considered in the appropriate clinical situation.

Interactions between Opioids and Other Abused Substances

Psychostimulants: Cocaine and Methamphetamine

Recently, it has been found that cocaine can significantly diminish buprenorphine concentrations.[76] This may be the result of cocaine having an effect on inducing buprenorphine metabolism through induction of CYP450 3A4[77] or through induction of P-glycoprotein.[78] Another possibility is that given that buprenorphine is administered via the sublingual route, vasoconstriction produced by cocaine metabolite might reduce buprenorphine absorption.[79] There is clinical data that supports these findings in that patients enrolled in a clinical trial receiving buprenorphine treatment and using cocaine had fewer opioid-negative urines ($p=.02$) and lower rates of retention in treatment ($p=.04$).[80] Cocaine use has a similar, but less dramatic effect on methadone concentrations.[81] This lesser effect may be related to the findings that methadone is metabolized by several CYP 450 enzymes, as compared to buprenorphine which is primarily metabolized by CYP 3A4. Methamphetamine has not been associated with adverse drug interactions in combination with either methadone or buprenorphine.

Stimulants used to treat attention deficit hyperactivity disorder (ADHD) include methylphenidate, amphetamine, and pemoline. To date, no clinically important drug

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interactions have been reported between methadone or buprenorphine and these medications. It is worth noting, however, that stimulants have been used with opioid medications to obtain a desired euphoria that results from the opposing actions of the opioids (sedation) with stimulant effects of drugs (e.g.: cocaine) resulting in what has been termed a "speedball."[82,83] Clinicians should be aware of this and use caution in prescribing stimulant medications in those receiving opioid therapy.

Alcohol

A pharmacodynamic interaction has been reported to occur between alcohol and methadone. Severe adverse events including deaths have occurred in patients who co-ingest these substances,[84] although a direct effect on pharmacokinetics of methadone has not been found, but alcohol appears to be eliminated more rapidly in those receiving methadone.[85] Clinical reports of adverse events related to alcohol ingestion in buprenorphine treated patients has not been reported to date, but a pharmacodynamic interaction similar to that which has been reported with benzodiazepines seems likely (see above). Interestingly, no drug interaction of clinical significance has been detected between methadone and disulfiram[85] These findings highlight the need to treat co-occurring alcohol disorders in opioid addicted patients receiving opioid agonist therapy.

Consequences of Drug Interactions

There are several important consequences of drug interactions that occur between opioids used in the treatment of opioid dependence and other drugs. Drugs that induce the metabolism of opioids or drugs that induce P-glycoprotein resulting in opioid efflux can produce opiate withdrawal symptoms if plasma concentrations become sub-therapeutic. Should this occur, patients may not adhere to the medication to which they attribute the opiate withdrawal symptoms. Non-adherence can have significant consequences in worsening of disease. For HIV disease, non-adherence can result in viral mutations with the development of resistance to currently available antiretroviral medications increasing the likelihood of disease progression in patients and the likelihood of viral transmission to those with whom they are in intimate contact. In addition, the development of opiate withdrawal can contribute to relapse to illicit drug use in order to relieve the adverse symptoms. Illicit drug use and intoxication is associated with an increased risk of overdose and unsafe practices such as injection drug use. These practices can place the patient at risk for the complications of injection drug use such as abscesses, cellulitis, endocarditis, and osteomyelitis.

Another concern when drug interactions occur that increase opioid concentrations is that of opioid toxicity. Cognitive dysfunction and decreased respiration can be life threatening. Methadone has been associated with cardiac conduction delays, prolongation of the QT interval, and arrhythmia that can be fatal through its ability to block HERG (human cardiac ether à go-go–related gene) potassium channels.[86] This effect is dose-related; therefore as methadone plasma concentrations increase, patients are at increased risk for developing arrhythmia.[87] Patients can also be at risk when they receive medications that induce methadone metabolism resulting in the need for an increase in methadone dose. However, if the medication that is causing induction of metabolism is discontinued, methadone concentrations will rise, possibly to toxic levels, unless the methadone dose is tapered to that on which the patient was stable before starting the medication. A case report describes such a clinical event where a patient developed Torsades de Pointes after stopping lopinavir/ritonavir and failure to reduce the methadone dose which had been increased due to opiate withdrawal associated with administration of the protease inhibitor combination.[88] Buprenorphine has not been shown to prolong the cardiac QT interval[89] and may be a better choice for opioid-addicted patients needing medication treatments likely to increase

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methadone exposure. Further, patient selection for either methadone or buprenorphine treatment based on identification of cardiac risk factors, family history, medical history of cardiac disease or history of arrhythmia, or the finding of a prolonged QT interval prior to starting opioid therapy can be helpful in diminishing the likelihood of this complication.

Another important aspect of understanding drug interactions between opioids and other medications is that of optimally matching treatments to patients. It can be difficult for patients to adhere to prescribed medication regimens. The occurrence of adverse symptoms when medications are given together contributes to non-adherence. Because patients may not want to divulge their lack of adherence to a regimen associated with adverse effects, there can be consequences related to worsening of the conditions which the medications were meant to improve. Anticipation of adverse events when medications known to have interactions are to be given can improve adherence. Patients should be counseled about the possible interactions including the time to expected adverse effects should they occur and the treating clinician should be prepared to make adjustments to the medication regimen should a drug interaction occur. Drugs that induce the metabolism of a drug require new enzyme production so that the onset of opiate withdrawal generally occurs after about 7 days. Inhibitors can delay metabolism with onset of drug administration so that increases in opioid exposure can occur soon after initiating the medications. The same is true for pharmacodynamic interactions that occur at the time of the drug use. While knowledge of drug interactions may be helpful in selecting medications; the fact that a drug interaction may occur should not exclude the use of a medication; nor can opioid doses be adjusted in anticipation of a drug interaction. Not all patients will develop drug interactions. The occurrenee is related to doses of medications (e.g.: those with lower methadone plasma concentrations are more likely to develop opiate withdrawal in the presence of an inducer), the clinical pharmacology of the drug(s), and individual genetics that determine CYP450 enzyme activity.

Finally, the existence of these interactions between methadone and buprenorphine and myriad other medications they may be receiving, underscores how critical it is for clinicians who are caring for patients receiving opioid agonist treatment to routinely query their patients regarding medications they are receiving for treatment of other medical conditions. In addition, given the potential interactions between methadone and buprenorphine and substances of abuse, in order to optimize treatment outcomes, they must discuss with patients the use or mis-use of other substances that may interact with their methadone or buprenorphine. Providing guidance to clinicians with data on these real or potential drug interactions will allow them to better manage their patients' overall medical care by increasing their general awareness of interactions between opioids and HIV antiretrovirals and other medications thereby improving outcomes (avoiding suboptimal levels of medications) and also minimizing the likelihood of adverse events (avoiding toxicity and overdose).

Future Research Needs

There remains much to be learned about drug interactions between opioids used in the treatment of opioid dependence and other drugs. Most medications in combination with opioids have not been directly studied in humans. In vitro studies indicating the likelihood of drug interactions are not always predictive of what will occur in people. The ongoing study of frequently prescribed medications with opioids will help to enhance clinical outcomes and to increase safety with medication treatments in this high risk and challenging population.

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Table 1

Classification of CYP3A inhibitors*

Strong CYP3A inhibitors (Cause ≥ 5-fold increase in AUC of sensitive CYP3A substrate)	Moderate CYP3A inhibitors (Cause ≥ 2 but <5-fold increase in AUC of sensitive CYP3A substrate)	Weak CYP3A inhibitors (Cause ≥ 1.25 but <2-fold increase in AUC of sensitive CYP3A substrate)
atazanavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, lopinavir/ritonavir, saquinavir/ritonavir, telithromycin	aprepitant, diltiazem, erythromycin, fluconazole, fosamprenavir, grapefruit juice, verapamil	cimetidine

Adapted from source at http://www.fda.gov/cder/drug/drugInteractions/default.htm.

*Reference: US Food and Drug Administration. Draft Guidance for Industry: Drug Interaction Studies—Study Design, Data Analysis and Implications for Dosing and Labeling, 2006.

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Table 2
Drug Interactions Between Methadone or Buprenorphine and other Medications

HIV Medications	Methadone	Buprenorphine
AZT	Increase in AZT concentrations; possible AZT toxicity[11]	No clinically significant interaction[22]
Didanosine (in tablet form)	Significant decrease in didanosine concentrations.[13]	
Stavudine	Significant decrease in stavudine concentrations.[13]	
Delavirdine	Increased methadone (and LAAM) concentrations; no cognitive impairment[26]	Increased buprenorphine concentrations; no cognitive impairment
Atazanavir	Not associated with increased levels of methadone[90]	Significant increases in buprenorphine and report of cognitive dysfunction[25]
Darunavir	Opiate withdrawal may occur[91]	
Efavirenz	Opiate withdrawal may occur[29-33]	No clinically significant interaction[34-36]
Fosamprenavir	Data suggest that the PK interaction is not clinically relevant; however, patients should be monitored for opiate withdrawal symptoms[92]	
Nelfinavir	Methadone levels are decreased. Opiate withdrawal may occur[93]	
Nevirapine	Opiate withdrawal may occur[29-33]	No clinically significant interaction[34-36]
Lopinavir/ritonavir	Opiate withdrawal may occur[29-33]	No clinically significant interaction[34-36]
Tuberculosis Medications		
Rifampin	Opiate withdrawal may occur[39]	Opiate withdrawal may occur[39]
Rifabutin	No clinically significant interaction[40]	Not studied
Hepatitis C		
Interferon	No clinically significant interaction[45,46]	
Ribavirin	Not studied	
Other Infections		
Fluconazole	Increased methadone plasma concentrations[47]	
Voriconizole	Increased methadone plasma concentrations[48]	
Ciprofloxacin	Increased methadone plasma concentrations[49]	
Biaxin	Increased methadone plasma concentrations[50]	
Antidepressants		
Fluoxetine	Not associated with increased levels of methadone[54]	
Fluvoxamine	May cause increased methadone plasma levels and discontinuation has been associated with onset of opioid withdrawal[55]	
Sertraline	No associated adverse drug interaction[56]	No clinically significant interaction[56]
Citalopram	No clinically significant interaction[58]	No clinically significant interaction[58]
Mirtazepine	No clinically significant interaction	

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HIV Medicatinns	Methadone	Buprenorphine
Duloxetine	Potentially lead to increased duloxetine exposure[59]	
Amitriptylene	Could be associated with increases in plasma methadone concentrations[60]	
St. John's Wort	Increased metabolism and elimination of methadone[61]	Increased metabolism and elimination of buprenorphine[61]
Desipramine	Associated with increased desipramine levels[73]	
Dextromethorphan	Associated with delirium[74]	
Antipsychotics		
Quetiapine	Increased plasma methadone concentrations[62]	
Risperidone	No clinically significant interaction	No clinically significant interaction
Clozapine	No clinically significant interaction	No clinically significant interaction
Aripiprazole	No clinically significant interaction	No clinically significant interaction
Olanzepine	No clinically significant interaction	No clinically significant interaction
Ziprasodone	No clinically significant interaction	No clinically significant interaction
Anxiolytics		
Diazepam	Associated with increased sedation and impaired performance on psychological tests[65,66]	
Alprazolam	Fatalities have been associated[67]	
Anticonvulsants		
Carbamazepine	Associated with opiate withdrawal[70]	Not studied
Phenytoin	Associated with opiate withdrawal[70]	Not studied
Phenobarbital	Associated with opiate withdrawal[70]	Not studied
Oxcarbazepine	No clinically significant interaction	No clinically significant interaction
Lamotrigene	No clinically significant interaction	No clinically significant interaction
Topiramate	No clinically significant interaction	No clinically significant interaction
Psychostimulant Medications		
Methylphenidate	No clinically significant interaction	No clinically significant interaction
Pemoline	No clinically significant interaction	No clinically significant interaction
Modafinil	No clinically significant interaction	No clinically significant interaction
Antihistamines		
Promethazine	May have synergistic depressant effect[71]	
Diphenhydramine	May have synergistic depressant effect[71]	
Cardiac and Pulmonary Disease Medications		
Digoxin	Not studied	Not studied

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HIV Medications	Methadone	Buprenorphine
Quinidine	Not studied	Not studied
Verapamil	Not studied	Not studied
Heparin	Not studied	Not studied
Theophylline	Not studied	Not studied
Aspirin	No clinically significant interaction	
Psychostimulants		
Cocaine	Decrease in trough methadone concentrations[81]	Increased metabolism and diminished plasma concentrations[76-79]
Methamphetamine	No clinically significant interaction	
Alcohol	Severe adverse events including death (84), Alcohol appears to be eliminated more frequently[85]	Not studied

were not developed by large drug manufacturers but were acquired through purchase of the biotech firms that discovered them. These, in turn, are often spinoffs based on the discoveries of NIH-funded university research laboratories. For example, Gilead Sciences did not invent its blockbuster treatment for hepatitis C, sofosbuvir (Sovaldi), which it priced at $1,000 per pill. Rather, it acquired the product from a small company founded by the drug's inventor, a faculty member at Emory University, much of whose work on the usefulness of nucleoside viral inhibitors was federally funded. Gilead paid $11 billion in late 2011 for the rights to market Sovaldi, an amount it totally recouped in its first year of sales after approval of the drug in late 2013.

An audio interview with Dr. Avorn is available at NEJM.org

We need an accurate determination of all the costs that go into the creation of a new drug, to inform ongoing discussions about how best to foster such development and the most reasonable way of paying for truly innovative medications — especially given the proliferation of "specialty" drugs that can cost patients and payers as much as $300,000 per year. These analyses will in turn require a broad-based and transparent reckoning of the costs of all the research and development that lead up to the creation of a new drug. Such a comprehensive accounting could well lead to policy decisions focused less on the need to replenish the capital of pharmaceutical companies and more on preserving the taxpayer-supported scientific sources of new drug discovery on which so many therapeutic advances depend.

Disclosure forms provided by the author are available with the full text of this article at NEJM.org.

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Protection or Harm? Suppressing Substance-Use Data

Austin B. Frakt, Ph.D., and Nicholas Bagley, J.D.

What if it were impossible to closely study a disease affecting 1 in 11 Americans over 11 years of age — a disease that's associated with more than 60,000 deaths in the United States each year, that tears families apart, and that costs society hundreds of billions of dollars?[1] What if the affected population included vulnerable and underserved patients and those more likely than most Americans to have costly and deadly communicable diseases, including HIV–AIDS? What if we could not thoroughly evaluate policies designed to reduce costs or improve care for such patients?

These questions are not rhetorical. In an unannounced break with long-standing practice, the Centers for Medicare and Medicaid Services (CMS) began in late 2013 to withhold from research data sets any Medicare or Medicaid claim with a substance-use–disorder diagnosis or related procedure code. This move — the result of privacy-protection concerns — affects about 4.5% of inpatient Medicare claims and about 8% of inpatient Medicaid claims from key research files (see table), impeding a wide range of research evaluating policies and practices intended to improve care for patients with substance-use disorders.

The timing could not be worse. Just as states and federal agencies are implementing policies to address epidemic opioid abuse and coincident with the arrival of new and costly drugs for hepatitis C — a disease that disproportionately affects drug users — we are flying blind.

The affected data sources include Medicare and Medicaid Research Identifiable Files, which

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Percentages of Claims That Were Suppressed because of Substance-Use–Disorder Diagnoses or Procedure Codes, 2007–2010.*

Year	Medicare			Medicaid	
	Part A Inpatient	Part A Outpatient	Part B	Inpatient	Outpatient
2007	4.6	0.4	0.3	7.3	1.3
2008	4.3	0.5	0.3	7.1	1.4
2009	4.4	0.5	0.4	7.1	1.4
2010	4.6	0.6	0.4	8.2	1.5

* Data are from the Research Data Assistance Center, University of Minnesota.

contain beneficiary ZIP Codes, dates of birth and death, and in some cases Social Security numbers. For tasks common to most health services research — such as combining patient-level data across systems (e.g., Medicare, Medicaid, and the Veterans Health Administrarion [VHA]), associating them with community or market factors (e.g., provider density or type of health insurance plans available), or studying mortality as an outcome — these are essential variables.

For decades, CMS has released data on claims related to substance-use disorders to allow researchers to study health systems and medical practice. One early example of such work is a study based on 1991 Medicare claims data that showed that few elderly patients received follow-up outpatient mental health care after being discharged with a substance-use–disorder diagnosis. Patients who received prompt follow-up care were less likely to die, a finding that could not have been obtained without information on patients' precise date of death.[2] More recently, a 2010 study used 2003–2004 Medicare claims data linked by Social Security number to records from the VHA to assess the extent to which patients with substance-use disorders relied on the VHA for care.[3] Substance-use disorders are among the diagnoses that have been included in the Dartmouth Atlas analyses of geographic variation in Medicare spending — which rely on ZIP Code identifiers — going back to at least 1998. To our knowledge, no patients have been harmed because of data breaches associated with studies such as these.

CMS has justified the data suppression by pointing to privacy regulations that prescribe the stringent conditions under which information related to the treatment of substance-use disorders may be shared.[4] These regulations, which are overseen by the Substance Abuse and Mental Health Services Administration (SAMHSA), already frustrate accountable care organizations and health-information exchanges, since their elaborate consent requirements make it difficult or impossible to share patient data related to substance-use disorders. As a result, many organizations exclude such information from their systems, undercutting efforts to improve care and efficiency.

For researchers, the problem is more acute. Although the privacy regulations authorize providers to disclose data on substance-use disorders for research purposes, they prohibit third-party payers — including CMS — from doing so. In 1976, when the regulations were first adopted, this prohibition was not a substantial impediment to research. Before computers came into widespread use, researchers could not look to insurers or CMS to provide large claims-based data sets. Even if they could, crunching those data would have been exceedingly difficult.

But the world has changed. Access to reliable Medicare and Medicaid data has long offered researchers a window into U.S health care.[2,3] Indeed, given the unwillingness of private insurers to share their data, Medicare and Medicaid data often provide our only way of gathering information about medical practice, patient outcomes, and costs. The very importance of the data may explain why CMS has long overlooked the prohibition on disclosure.

In 2013, however, SAMHSA advised CMS that the privacy regulations require suppression of claims related to substance-use disorders. The agency's sudden insistence on this point is puzzling. The law that the privacy regulations are intended to implement states that identifiable data on substance-use disorders "may be disclosed," even without patient consent, "to qualified personnel for the purpose of conducting scientific research." Banning CMS from sharing such data with researchers is difficult to square with that statutory exemption.

Nonetheless, in November

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2013, CMS began scrubbing Medicare data of claims related to substance-use disorders. It did the same for Medicaid data in early 2014. No notice was given to the research community about the policy change. Most of our colleagues have been shocked to learn of it; many others probably remain unaware of the change.

The suppression has skewed Medicaid data more than Medicare data, a disparity that reflects differences between the populations served by the two programs (see table, and the Supplementary Appendix, available with the full text of this article at NEJM.org). In both programs, inpatient claims are much more likely to be affected than outpatient claims.

CMS has begun scrubbing Medicare and Medicaid data of claims related to substance-use disorders. No notice was given to the research community about the policy change.

In the vast majority of cases, claims are suppressed because the patients have secondary diagnoses of substance-use disorders. That raises an additional concern: many of the withheld data pertain to admissions for services that address not substance-use disorders but rather conditions that may be exacerbated by substance abuse. In other words, the data suppression extends well beyond its intended domain.

The effects of the CMS actions are thus much broader than they might initially seem. Clearly, it is now infeasible to conduct any study of patients with substance-use disorders based on Research Identifiable Files. But studies of conditions disproportionately affecting such patients — such as hepatitis C or HIV — will also be hampered. Moreover, any study relying on those files cannot make full diagnosis-based risk adjustments that include substance-use–disorder diagnoses. And because the data have been altered in a systematic, nonrandom manner — with suppression affecting different populations, age groups, regions, and providers to different degrees — the results of many studies that have no apparent connection to substance use will be biased.

And to what end? Without question, protecting patient confidentiality is essential, especially when it comes to potentially stigmatizing diagnoses and treatments. But there is no evidence that researchers — who, under current rules, must adhere to strict data-protection protocols, backed by criminal penalties — cannot appropriately secure research data. And most Americans want their health data to be available for research.[5] At the same time, data suppression and access limitations remove from scrutiny a great deal of taxpayer-financed care.

We believe that the federal government's short-sighted policy will harm the very people it was meant to protect. We encourage SAMHSA and CMS, in dialogue with researchers and providers, to restore access to data that are necessary to improving care for patients with substance-use disorders.

The views expressed in this article are those of the authors and do not necessarily reflect the positions or policies of the Department of Veterans Affairs, Boston University, the University of Michigan, or the Institute for Healthcare Policy and Innovation.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From the Veterans Affairs Boston Healthcare System, Department of Veterans Affairs, and Boston University — both in Boston (A.B.F.); and the University of Michigan Law School and the Institute for Healthcare Policy and Innovation, University of Michigan, Ann Arbor (N.B.).

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October 12, 2017

Ten Steps the Federal Government Should Take Now to Reverse the Opioid Addiction Epidemic

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The United States is in the midst of the worst drug addiction epidemic in its history. Prescriptions for and deaths from opioids both quadrupled between 1995 and 2010. By 2015, an estimated 92 million individuals in the United States were prescribed an opioid and there were more than 33 000 deaths from an opioid-involved overdose.[1]

There are no simple solutions to ending this epidemic. Effective programs need to address 2 separate priorities: (1) prevention of addiction among people not currently addicted, and (2) treatment and risk reduction to prevent overdose and death among the millions of individuals in the United States now addicted. In this Viewpoint, we suggest 10 steps that could accelerate progress; national declarations, state-specific emergency declarations, or both could potentially facilitate implementation of these steps.[2]

Preventing Opioid Addiction and Overdoses

1. Improve surveillance of possible opioid addiction. No current information systems enable real-time assessment of the numbers, patterns, or trends of new opioid addiction. This makes it impossible to determine the trajectory of the epidemic, identify areas in which opioid addiction is worsening and intervene, and learn lessons from areas in which incidence is decreasing. By using Prescription Drug Monitoring Program (PDMP) and other data systems to identify trends and patterns of possible new addiction (eg, newly filled prescriptions for ≥30 days), aggregate data could be used in real time to identify factors associated with addiction. New cases of opioid use disorder may be declining, while deaths among heroin users may be increasing due to

spread of illicitly synthesized fentanyl; however, it is not possible to know until the incidence of opioid addiction is tracked.

2. Improve reporting of and response to opioid-related overdoses and fatalities. Real-time data on overdoses from syndromic and other surveillance systems can enable rapid response to changing patterns of opioid use. The timeliness and specificity of testing for drugs involved in opioid-related fatality reports differ from state to state. More reliable information on the specific drugs involved in deaths would better inform public health and law enforcement interventions. Substantial improvements in the quality and timeliness of medical examiner and coroner work, including access to data from PDMPs, could greatly improve data timeliness and completeness. Improved training and increased funding of coroners and medical examiners could facilitate more accurate and timely identification of drugs involved in overdose deaths. Fatal and nonfatal overdoses involving prescribed medications should trigger an automatic report to the patient's health care professionals to facilitate appropriate medical response and to state medical boards, and people who have survived an overdose could be linked to treatment. This feedback could foster more cautious prescribing and improve regulation of prescribing practices.

3. Promote more cautious prescribing for acute pain. Opioids are essential medicines to treat severe pain after surgery or serious injury, but they are too frequently prescribed for pain that could be treated with nonsteroidal anti-inflammatory medications (eg, molar extractions in adolescents). When opioid use is unavoidable, dosage should be as low and duration as brief as possible[3]; physiological dependence on and tolerance to opioids can develop in as little as 1 week. Patients taking short courses of opioid medication may experience withdrawal symptoms, including worsening of pain upon discontinuation; this may lead to continued use. According to a recent study, 1 in 5 patients who had been prescribed opioids for 10 days became long-term users.[4] Another study found that the quantity of pills prescribed for postsurgical acute pain could be reduced 53% and that less than 1% of patients required refills.[5] The Centers for Disease Control and Prevention (CDC) recommends that when opioids are prescribed for acute pain, "[t]hree days or less will often be sufficient; more than 7 days will rarely be needed."[3] The US Food and Drug Administration (FDA) should revise opioid labels to be consistent with the CDC recommendation. Adding duration of use to opioid labels would send a clear message to prescribers and patients that risks increase when opioid use continues past 3 days.

4. Change labeling for chronic pain and greatly restrict or eliminate marketing of opioids for this indication. The risks of opioids are likely greater than the benefits for common chronic conditions (eg, low back pain, fibromyalgia). However, patients with chronic non-cancer-related pain have been the target market for opioid manufacturers and account for much of the increase in opioid consumption in the United States during the past 20 years. The FDA should narrow on-label indications and halt marketing of opioids for low back pain and other conditions for which risks of use outweigh potential benefit. This could help to discourage clinicians from initiating long-term opioids, but would not prohibit clinicians from continuing off-label prescribing of opioids to stable patients with chronic pain. Compassionate care for patients with chronic pain is not jeopardized by more cautious prescribing.

5. Increase insurance coverage of and access to nonopioid and nonpharmacological management of pain. Chronic pain is a serious and potentially disabling problem for millions of people in the United States. Opioids are likely less effective and certainly more dangerous than other modalities of chronic pain management. The Centers for Medicare & Medicaid Services should ensure full reimbursement for nonprescription analgesics, such as acetaminophen and nonsteroidal anti-inflammatory drugs, for Medicare Part D and Medicaid beneficiaries. This

would remove a financial disincentive for patients to use these medications. Easier access to and low or no copayments for physical therapy and other nonpharmacological pain management modalities could potentially reduce medication use and improve patient functionality and outcomes.

6. Interrupt the supply of heroin and illicitly produced synthetic opioids and improve coordination between legal and public health authorities. Interdiction is critically important to increase the cost and reduce accessibility of opioids. As with tobacco and alcohol, if heroin and illicitly produced synthetic opioids such as fentanyl are more expensive and more difficult to obtain, use should decrease.[6,7] The legal system can also implement programs such as treatment as an alternative to incarceration, and correctional facilities can provide opioid agonist treatment for addicted inmates during detention and linkage to treatment services on release. These interventions are more likely than criminal sentences for low-level drug users to reduce both illicit opioid use and related crime.

Treatment and Harm Reduction for Current Users

7. Identify possible opioid addiction early and link individuals to treatment. Early identification and treatment of opioid-addicted individuals reduces the risk of overdose, psychosocial deterioration, transition to injection opioid use, and medical complications. Medically assisted treatment (eg, methadone, buprenorphine) should be routinely offered in primary care, emergency departments, and hospital inpatient services to increase treatment uptake, as well as in the criminal justice system, with careful attention to continuity on discharge. States receiving federal funding for their PDMPs should be incentivized or required to mandate prescriber checking of and timely data provision to PDMPs for all opioid prescriptions of more than 3 days' duration, and state health officials should identify opioid-addicted patients as early as possible and facilitate referral to treatment. The federal privacy law known as 42 CFR Part 2 (Confidentiality of Substance Use Disorder Patient Records) should be amended so that opioid addiction can be treated like other medical conditions, improving patient safety and continuity of care.

8. Expand low-threshold access to opioid agonist treatment, particularly with methadone and buprenorphine. A substantial proportion of patients who would benefit from buprenorphine or methadone treatment will receive this treatment only if it becomes more attractive and accessible than either prescription or illicit opioids. In France, opioid overdose deaths decreased 79% six years after widespread prescribing of buprenorphine.[8] Barriers to accessing buprenorphine in the United States include federal limits on the number of patients a clinician can treat, a required 8-hour training course, and inadequate integration of buprenorphine into primary care treatment. Access to buprenorphine could be expanded if the federal government removed regulatory barriers and required all federally qualified health centers to offer buprenorphine treatment. It seems illogical and perhaps ironic that buprenorphine, the one opioid that appears to be safer than commonly prescribed opioid analgesics and heroin, is the only one with such barriers to prescription.

9. Implement harm reduction measures for current users, including access to clean syringes and naloxone. Access to clean syringes can prevent injection-related infectious diseases, and access to naloxone can reduce fatal overdoses. The federal government should continue to assist state and county efforts to make naloxone and clean syringes more widely available, and

the FDA should accelerate its efforts to help drug manufacturers pursue approval of an over-the-counter naloxone product.

10. Consider removing ultra-high-dosage-unit opioid analgesics from the market. Formulations of opioids that exceed 90 morphine milligram equivalents per day when taken as directed are dangerous and should be removed from the market. For example, a patient directed to take 1 oxycodone 80-mg tablet twice a day is consuming the equivalent of 240 mg of morphine, far exceeding a dosage associated with a greatly increased risk of death. Because only 1 pill is taken at a time, the patient and prescriber may not appreciate that this is an extremely high dose. An individual who takes a single pill that is unused or diverted from a prescription supply could experience a fatal overdose. Opioids are available in liquid preparations, patches, sublingual forms, and suppositories for patients who have difficulty swallowing extra pills.

The opioid addiction epidemic has worsened over the course of a generation and will not end overnight. Rapid implementation of the 10 steps outlined here could enable tracking and reduction of both new opioid addiction and fatal overdoses. The opioid epidemic is largely iatrogenic, and the health care system has a responsibility to support actions such as those outlined here that could prevent addiction and save lives.

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MacKenzie: Mental, behavioral health crisis deserves attention

Gwen MacKenzie is senior vice president of Ascension Healthcare and ministry market executive of Ascension Michigan. Published 5:30 a.m. ET Dec. 17, 2017

(Photo: submitted photo)

Behavioral disorders and mental illness are nearly ubiquitous in our society. According to the National Alliance on Mental Illness, more than 43 million adults experience mental illness each year. In 2013-14, 336,000 Michigan adults had serious mental illness. From 1999-2015, deaths in Michigan from drugs quadrupled to 1,981.

Ascension Michigan's emergency departments have seen a 400% increase in behavioral health patients in the past 4 years. The United States and Michigan are struggling with a mental and behavioral health crisis, and it demands a national discussion that is transparent and honest.

Ascension Michigan has one of the most sophisticated inpatient treatment facilities in the state – the Brighton Center for Recovery. Yet, the demand for mental and behavioral health services in Michigan far outstrips supply. It is not uncommon to experience a 3-4 month wait for an appointment with a psychiatrist, if you are in an area of the state that has psychiatrists.

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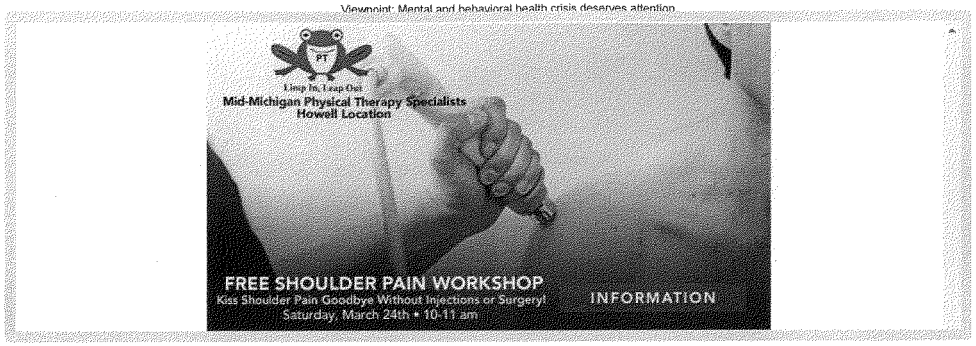

Sadly, according to the Substance Abuse and Mental Health Services Administration, nearly 60 percent of adults with a mental illness don't receive mental health services. Failure to intervene to help these individuals results in far more pain for them and much higher costs for society, which means that we need increased investment in these services now.

As Congress and state legislatures continue to struggle with the appropriate response to the crisis, they must take several crucial steps immediately in the areas of coverage, access, and care integration. Enforcement authorities must enforce the Mental Health Parity and Addiction Equity Act (MHPAEA) more robustly.

The MHPAEA broadly requires parity between coverage for mental and physical health ailments. Some health plans may use subtle mechanisms to make mental health and substance use treatment less available than treatment for physical conditions.

They may deny initial access to care, limit the length of treatment, or use "carve outs" for mental and behavioral health. Payment rates can be so low that it deters providers from taking insurance. Because the MHPAEA is enforced by multiple agencies depending on the nature of the insurance, those agencies should coordinate enforcement and become more aggressive.

Access to providers in Michigan and nationally is a serious problem. To address the need for care in the context of this shortage, systems like Ascension Michigan developed telehealth capabilities to make services available to those in need. Yet, public and private payers will often make it difficult to obtain reimbursement for telehealth services even in the crisis areas of mental and behavioral health.

Medicare will reimburse for telehealth delivery in a rural area, but not in an urban area unless it has been declared a manpower shortage area. Because of the provider shortage, it is crucial that federal, state and private payers begin to provide payment for all mental and behavioral health services.

Many clinical experts endorse the integration of mental and behavioral health experts with primary care practitioners to identify mental and behavioral issues as early as possible. To facilitate this integration, Congress needs to make crucial adjustments to the patient protections offered by 42 CFR Part 2.

Those who suffer from mental health and substance use disorders need significant privacy protection often because of the unfair stigmatization stemming from ignorance that surrounds those victimized by these conditions. Yet, the privacy requirements in 42 CFR Part 2 set requirements limiting the use and disclosure of patients' substance use records make it profoundly difficult to provide team-based care.

The inability to share information between substance abuse provider and primary care physician undermines the holistic care that patients need. Ascension Michigan supports the recommendations of the Partnership to Amend 42 CFR Part 2 to balance the need for privacy and integrated care for those suffering from mental and behavioral health disorders.

Mental and behavioral health disorders are often progressive: delaying treatment only makes matters worse for the individual, his or her family, and the rest of society. The costs of poor or delayed mental and behavioral healthcare have impacts far beyond the health system, affecting the areas of criminal justice and social services. And these costs often are incurred without addressing or treating the underlying causes.

As Ascension Michigan works to expand our behavioral and mental health services to address these national gaps of care and coverage, we need the public policy changes described above, as well as increased reimbursement and funding to facilitate our efforts to serve these most vulnerable patients.

We owe it to the thousands of Michiganders who experience mental illnesses and substance use disorders, and their families, to provide affordable healthcare access and coverage.

Gwen MacKenzie is senior vice president of Ascension Healthcare and ministry market executive of Ascension Michigan.

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OPINION | HEALTH

A Seven-Step Plan for Ending the Opioid Crisis

More treatment. Stronger oversight. And above all, bolder leadership.

By Michael R. Bloomberg
January 10, 2018, 5:00 AM EST

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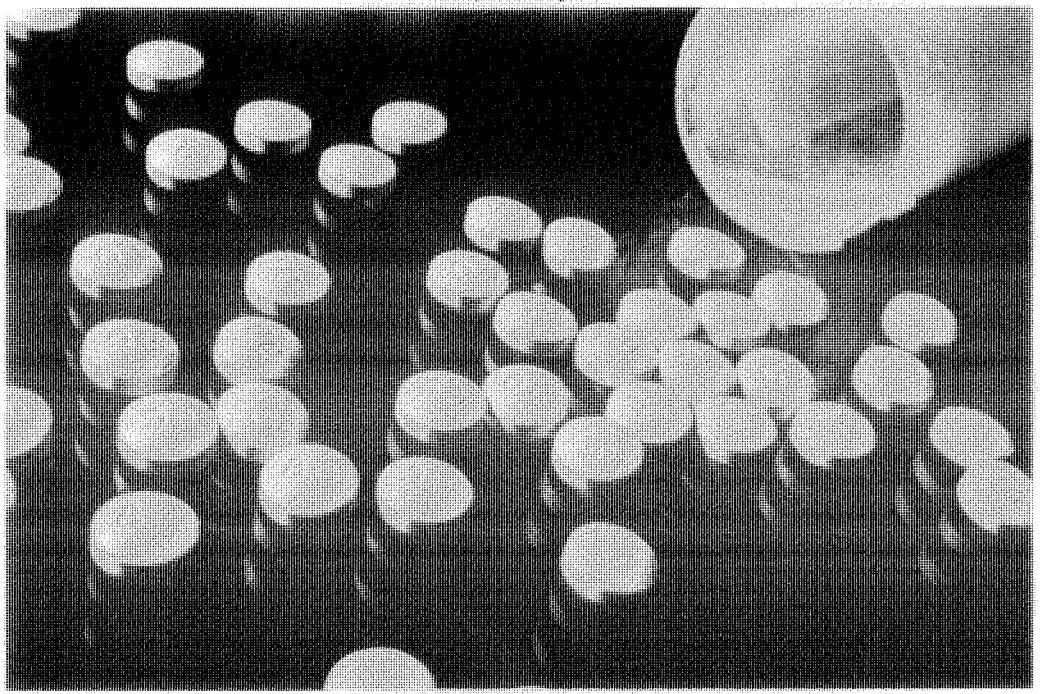

Time to clean up. *Photographer: Liz O. Baylen/Los Angeles Times*

The opioid epidemic is now a full-blown national crisis, yet the federal government continues to dawdle. President Donald Trump declared opioid addiction a public health emergency, and he talks a tough game. But he has not taken forceful action.

If he will not lead, Congress must -- and now, before the crisis grows even worse.

How America's Opioid Crisis Spiraled Out of Control

Opioid overdose deaths rose 28 percent in 2016, to 42,000 men, women and children. Some 2.6 million more Americans are addicted to opioids, and communities in every region of the country are suffering from the resulting trauma. Largely as a result, life expectancy declined in 2016 for a second straight year -- something that has not happened since the early 1960s.

QuickTake
Heroin and Opioids
<https://www.bloomberg.com/quicktake/heroin>

This is a solvable problem, and through philanthropy <https://www.jhsph.edu/about/bloomberg-american-health-initiative/index.html> we can make some progress. But real success requires much bolder leadership -- and a far greater sense of urgency -- from both elected officials and industry leaders.

We must stop doctors from over-prescribing opioids, especially when non-addictive pain medications (such as ibuprofen or acetaminophen) would be just as effective. Steps have been taken to educate doctors and to curtail prescriptions for opioids (such as Oxycontin, Percocet and Vicodin), and the prescription rate has fallen from its peak in 2010. But it remains three times what it was in 1999 -- and four times what it is in Europe.

More aggressive action is needed. The Food and Drug Administration should allow only doctors who complete specialized education in pain management to prescribe opioids for more than a few days, a move FDA Commissioner Scott Gottlieb is considering. Some states have limited the size of certain opioid prescriptions -- all should do so. To avoid the need for bans or other draconian measures, which would harm people suffering the most severe chronic pain (including many who are terminally ill), the medical profession must do more to rein in prescriptions and create effective monitoring programs.

Insurers and pharmacy benefit managers must better oversee opioid prescriptions. CVS Caremark has moved to limit coverage for opioid prescriptions. Others should follow its lead. These companies exist to help people lead better, healthier lives, and they should not be complicit actors in an addiction and overdose epidemic.

We must hold pharmaceutical companies accountable for the supply of prescription opioids. Like gun manufacturers that continue to supply dealers with a history of selling to traffickers, pharmaceutical companies and their distributors have a history of turning a blind eye to pill mills. Local governments have filed nearly 200 lawsuits against manufacturers and

distributors. They deserve their day in court, but we cannot pin our hopes on the outcome. The federal government must do more to monitor the supply of the drugs and crack down on companies that skirt the law.

We must start treating those with addiction disorders when they come in contact with emergency rooms, hospitals and clinics. Too often, those who overdose are not offered long-term treatment -- a regimen of buprenorphine, methadone or naltrexone -- because the hospitals they are taken to do not provide it. Many walk out the door looking for their next hit, with fatal consequences. More funding is needed for treatment -- and it may be that further state intervention is needed, too. Massachusetts Governor Charlie Baker has proposed requiring overdose patients to be sent to treatment centers for up to three days in hopes of convincing them to accept longer-term treatment. Drastic times require drastic measures.

We must stop stigmatizing the medications that have been proven <http://www.nejm.org/doi/full/10.1056/NEJMsr1706626> **to help people recover.** Many politicians wrongly believe that providing methadone or other opioid-based treatment to people allows them to get high. In fact, when used as part of treatment programs, these medications address the symptoms of cravings and physical withdrawal without providing the euphoria of illicit drug use.

The stigmatization of medication is especially problematic for our criminal justice system. Each year, about one-third of heroin users spend time locked up, yet the federal government, and the vast majority of states and localities, do not offer them

medication-assisted treatment while they are behind bars. That treatment, when linked to addiction services after release, boosts the odds of putting their lives back together and reduces the likelihood that they will return to crime.

The federal government should incentivize cities and states to offer treatment to inmates, as New York City and a handful of other localities do. In addition, police need new strategies to respond to heroin and fentanyl, a deadly synthetic opioid. These include providing ready doses of naloxone (Narcan) to reverse overdoses, and offering paths to treatment for all users.

We must develop better data. Existing statistics on misuse and overdose are out of date and often inaccurate. In many communities, relevant data is gathered only when people are arrested, or when they die from overdoses -- or not at all. Better information of all kinds could help communities, states and the federal government monitor the scope of the crisis and target interventions more effectively.

We must do more to block the importation of heroin -- and of fentanyl, much of which originates in China. President Trump declared that this would be "a top priority" of his meeting with President Xi Jinping -- "He will do something about it," Trump said prior to the meeting. We have yet to hear what, if any, new commitments he secured. Nor will building a wall along the Mexican border stop the drugs from entering the U.S., despite the president's belief that it will have a "great impact" on the problem. Government by symbolism -- whether building a wall or declaring an emergency -- doesn't solve real problems.

All of these steps come with a cost, but little effort has been made to quantify it. Local and state agencies bear most of the burden of this crisis, but no one has yet analyzed the extent of the assistance they need. That should be done before coming up with a price tag. Senate Democrats have proposed spending $25 billion without first detailing a plan. If money is to be spent effectively, it must be attached to a comprehensive plan of attack.

The number of opioid deaths for 2017 is likely to set a record. Yet it's business as usual in Washington. In 2018, the American people must demand more -- from all their elected officials.

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March 19, 2018

The Honorable Michael Burgess
Chair, House Energy & Commerce
Health Subcommittee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Gene Green
Ranking Member, House Energy &
Commerce Health Subcommittee
2125 Rayburn House Office Building
Washington, DC 20515

Dear Representatives:

The American Academy of Neurology (AAN), the world's largest association of neurologists representing more than 34,000 professionals, is strongly committed to improving the care and outcomes of persons with neurologic illness.

One in six people live with a brain or nervous system condition, including Alzheimer's disease, Parkinson's disease, stroke, epilepsy, traumatic brain injury, ALS, multiple sclerosis, and headache. Many of these complex conditions are associated with chronic pain. The National Institutes of Health (NIH) estimates that more than 11 percent of adults in the US experiences chronic pain, and pain affects more Americans than diabetes, heart disease, and cancer combined. The opioid crisis is a symptom of the pain problem in the United States.

We thank you for scheduling a hearing to examine many potential solutions to the opioid crisis. Issues surrounding the crisis often revolve around abuse and treatment needs of those who use opioids, as it should. The AAN strongly supports:

- Research to understand pain, the impact of opioids on the developing and recovering brain, and the gaps in current addiction and recovery services.
- Interoperability of electronic health records and prescription monitoring programs, including electronic prior authorization to promote responsible prescribing.
- Science-based standardized resources for prescribers, pharmacists, and patients to make safe and informed medication decisions.

Specifically, the NIH is an ideal venue to begin the process of understanding the effects of pain medication on the brain that will lead to better treatment alternatives for physicians. The AAN encourages you to provide significant flexibility and resources to NIH to study these effects and develop non-opioid, non-addictive pain treatments. NIH Director Francis Collins, MD, PhD, put it well in October 2017 when he said, "Our mission to end the opioid crisis will not be successful until we can provide patients with better options for the treatment of pain, which touches 25 million Americans every day."

One example would be to support the Advancing Cutting Edge (ACE) Research Act, H.R. 5002, which would provide the NIH with new, flexible authorities to conduct innovative research and spur urgently needed research on new, non-addictive pain medications.

The AAN and America's neurologists look forward to working with you to curb the opioid epidemic and bring safer, more effective treatments to those suffering from chronic pain.

Sincerely,

Ralph L. Sacco, MD, MS, FAHA, FAAN
President, American Academy of Neurology

CC: Representative Debbie Dingell

Representative Fred Upton

Written Testimony
Of
The American College of Obstetricians and Gynecologists
Submitted by:
Hal C. Lawrence, III, MD, FACOG
Before the
House Committee on Energy and Commerce
Subcommittee on Health
Regarding
Combating the Opioid Crisis: Prevention and Public Health Solutions
March 21, 2018

Chairman Burgess, Ranking Member Green, and distinguished Members of the House Energy and Commerce Subcommittee on Health, thank you for the opportunity to submit written testimony in response to your February 28, 2018 hearing titled "Combating the Opioid Crisis: Prevention and Public Health Solutions." The American College of Obstetricians and Gynecologists (ACOG), representing more than 58,000 physicians and partners dedicated to advancing women's health, appreciates the Committee's attention to this important issue. I hope you will view ACOG as a resource and trusted partner as you continue to examine strategies to combat the ongoing opioid crisis.

I am the Executive Vice President and Chief Executive Officer at ACOG and in this capacity am keenly aware of the increase in opioid use disorder and overdose and its impact on the women we serve and their families. My testimony will focus on the need for greater access to evidence-based treatment for pregnant and parenting women and the need for responses to opioid use during pregnancy to remain in the public health space.

Health professionals, public health advocates, and bipartisan policymakers recognize that the United States is in the midst of a major opioid epidemic. The incidence of opioid use disorder (OUD) has risen dramatically over the past few years, including among women of reproductive age and pregnant and parenting women. According to the HHS Office of Women's Health, the number of women dying from overdose of prescription drugs rose 471 percent between 1999 and 2015, compared to 218 percent for men, and heroin deaths among women increased at more than twice the rate of men.[i] In rural areas, where the opioid crisis has hit hardest, pregnant women and women experiencing intimate partner violence are among populations with higher prevalence of misuse of prescription pain relievers.[ii]

Unsurprisingly, the high prevalence of OUD among reproductive age women means more women are using opioids while pregnant. This is also reflected in the rising incidence of neonatal abstinence syndrome (NAS), an expected and treatable medical condition associated with drug withdrawal in newborns exposed to opioids, including medication-assisted treatment, or other drugs in utero. The unplanned pregnancy rate among women with OUD is 86 percent, a number that far surpasses the national average of 45 percent, making clear the need for increased access to contraception among women with OUD. [iii] Untreated OUD during

pregnancy is associated with significant obstetric morbidity and mortality.[iv] Tragically, overdose and suicide are now the leading causes of maternal mortality in a growing number of states.[v,vi,vii]

During pregnancy, most women who use substances, including opioids, are motivated to change unhealthy behaviors and quit or cut back. Those who cannot stop using have a substance use disorder. In other words, continued substance use in pregnancy is a characteristic of addiction, a chronic, relapsing brain disease.

Evidence-based treatment for pregnant and breastfeeding women with OUD includes the use of medication-assisted treatment (MAT) such as methadone and buprenorphine. MAT is the recommended therapy for treating pregnant women with opioid use disorder, and is preferable to medically-supervised withdrawal, which is associated with higher relapse rates and poorer outcomes, including accidental overdose and obstetric complications. Use of MAT also improves adherence to prenatal care and addiction treatment programs. MAT, together with prenatal care, has been demonstrated to reduce the risk of obstetric complications among pregnant women with OUD.[viii]

Threats of incarceration, immediate loss of child custody, and other potential punishments drive pregnant and parenting women away from vital prenatal care and substance use disorder treatment. Research has found that **non-punitive public health approaches to treatment result in better outcomes for both moms and babies**. Immediately postpartum, women who bond with their babies, including via skin-to-skin care and breastfeeding, are more likely to stay in treatment and connected to the health care system. Further, breastfeeding is associated with decreased severity of NAS symptoms and reduced length of hospital stay for the newborn.[ix] Substance use disorder treatment that supports the family as a unit has proven effective for maintaining maternal sobriety and child well-being.

In 2015, the Government Accountability Office (GAO) report titled *Prenatal Drug Use and Newborn Health: Federal Efforts Need Better Planning and Coordination* found that "the program gap most frequently cited was the lack of available treatment programs for pregnant women..."[x] In 2017, the GAO report titled *Newborn Health: Federal Action Needed to Address Neonatal Abstinence Syndrome* again cited barriers faced by pregnant women with OUD, including "the stigma faced by women who use opioids during pregnancy" and "limited coordination of care for mothers and infants with NAS," making it "difficult for families to get the resources or support they need."[xi]

As the Committee considers policies to address the ongoing opioid epidemic, we urge you to consider the following:

- The need for urgent action to address the rising maternal mortality rate in the United States. States with maternal mortality review committees (MMRCs) bring together multi-disciplinary health care professionals to review individual maternal deaths and recommend policy solutions to prevent them in the future. MMRCs are critical tools to

understanding maternal deaths, including those linked to opioid overdose, and identifying opportunities for prevention. **Advance H.R. 1318, the Preventing Maternal Deaths Act**, introduced by Reps. Herrera Beutler (R-WA), DeGette (D-CO), and Costello (R-PA) to assist states with the creation or expansion of MMRCs.

- **Support testing of new models to improve access to treatment for pregnant and parenting women with OUD, including telemedicine pilots**. Treatment gaps remain, despite continued efforts to increase the availability of programs tailored to the unique needs of pregnant and parenting women. Innovative models can help ensure treatment is effective and responsive to women's complex responsibilities, often as the primary or sole caregivers for their families. In addition:
    - **Ensure Section 501 of the Comprehensive Addiction and Recovery Act (CARA; Public Law 114-198) receives adequate funding to improve access for all women seeking treatment.** Section 501 authorized funds for treatment programs tailored specifically for pregnant and parenting women with OUD.
    - **Ensure full implementation of the Protecting Our Infants Act: Final Strategy, created pursuant to Public Law 114-91**. The Strategy, released by HHS in 2017, made several recommendations to address gaps in research; gaps, overlaps, or duplication in relevant federal programs; and coordination of federal efforts to address NAS with recommendations regarding maternal and child prevention, treatment, and services. The October 2017 GAO report made one recommendation: to implement the Strategy.[xii] However, HHS is clear that "full implementation will be contingent upon funding."[xiii]

- Critical gaps in public and private insurance coverage lead to gaps in care or discontinuation of treatment. Women receiving pregnancy coverage through Medicaid or the Children's Health Insurance Program (CHIP) may lose their access to MAT weeks after giving birth, during a particularly vulnerable time when relapse risk increases if treatment is not continued. **Explore coverage policies that ensure continued access to treatment for women postpartum.**

- **Preserve Medicaid's financing structure and ensure continued and sufficient federal funding to support Medicaid expansion as currently available**. Proposals to reduce federal Medicaid expenditures by shifting costs to states or reducing enrollment or services will limit access to care for low-income women of reproductive age, including pregnant and parenting women, with OUD. Approximately 42.6 percent of births in the U.S. are financed by Medicaid, Medicaid covers the care of 80 percent of infants diagnosed with NAS,[xiv,xv] and approximately 25 percent of Americans with OUD are Medicaid beneficiaries.[xvi] Any changes to the Medicaid financing structure and/or Medicaid expansion will negatively impact access to care for this vulnerable population.

- Facilitate better collaboration between health care providers and the child welfare system in responding to the rise of opioid use disorder among pregnant and parenting women and NAS. This epidemic is increasingly leading to children being placed in kinship

care or foster care homes. State child welfare agencies do not currently have the resources necessary to address the impact of this epidemic on families. Obstetric care providers have an ethical responsibility to their pregnant and parenting patients with substance use disorder to discourage the separation of parents from their children solely based on substance use disorder, either suspected or confirmed.[xvii] Our shared priority is that infants born to families struggling with OUD have safe homes, and that the family unit is preserved when possible.

- Section 503 of CARA added requirements for states to develop infant plans of safe care in instances when an infant experiences NAS following opioid exposure in utero. Unfortunately, those requirements came without resources for implementation or clear guidance, and has the potential to unintentionally lump together women who use illicit substances with those in active treatment or with a current prescription from a licensed health care provider. **States need additional guidance, funds, and resources from the federal government to ensure infant safety and to keep families intact when appropriate.**
- States are encountering barriers to providing affected families the services they need to heal. If we are to truly help children impacted by this epidemic achieve their potential, we must apply a treatment-focused public health approach. Unfortunately, our current system is too often a punitive one that leaves pregnant and parenting women less likely to seek treatment and incentivizes placing children in foster care when they could safely remain at home with the appropriate treatment and support services. **Ensure full implementation of the Family First Prevention Services Act** (Division E, Title VII of the Bipartisan Budget Act; Public Law 115-123) to expand access to treatment services for vulnerable families while helping them stay together and heal.

- Improve access to primary care and the full range of contraceptive options for women with private insurance with opioid use disorder. With a high unplanned pregnancy rate among women with opioid use disorder, to reduce the rate of NAS we must increase access to care for women, including access contraception with no cost-sharing. **Advance H.R. 4082, the Protect Access to Birth Control Act** introduced by Rep. DeGette to ensure continued access to coverage for women with private insurance.

- **Ensure continued access to women's preventive care and the full range of contraceptives for Medicaid beneficiaries,** including women of reproductive age with OUD, to drive down the high rate of unplanned pregnancies in this group as well as the rate of babies born with NAS. Reject legislative and administrative efforts to condition payment for health care services on factors other than medical and legal qualifications and standards. Congress should not deny federal funds, including reimbursement for covered services provided to Medicaid beneficiaries, to providers, programs, and health care facilities in cases where a provider is qualified to perform those services.

- **Improve access to the full range of contraceptives for Medicare beneficiaries**, including women of reproductive age with OUD. Medicare does not currently cover contraception

for the purposes of preventing pregnancy, despite the fact that more than 900,000 women ages 18-44 receive insurance coverage through Medicare.[xviii]

- **Continue to promote research into pharmacological and nonpharmacological treatments** for both pregnant and breastfeeding women with opioid use disorder; non-opioid pharmacotherapies for pain management for women, including pregnant women; and both pharmacological and nonpharmacological treatments for newborns with NAS.

- **Address barriers to accessing non-pharmacological pain relief**, including transportation and childcare options for women seeking treatment for pain. In addition, the Committee should ensure that acute and chronic pain management with opioids are not denied to women of reproductive age, including pregnant and parenting women, out of concern for NAS when they are otherwise recommended.[xix]

- Expand access to MAT for women of reproductive age, including pregnant and parenting women, by enabling certified nurse-midwives (CNMs) to prescribe buprenorphine. In an ongoing effort to provide the best care for women suffering from OUD, ACOG offers buprenorphine training courses tailored to women's unique health needs for obstetrician-gynecologists and other health care providers. Treating, prescribing, and referring for MAT services are all within the scope of practice for CNMs. **Advance H.R. 3692, the Addiction Treatment Access Improvement Act**, introduced by Reps. Tonko (D-NY) and Lujan (D-NM), to expand the qualified providers able to prescribe MAT.

- **Reject proposals to legislate prescriber practices.** Addressing this ongoing epidemic will require dedication and partnership between policymakers, health care providers, and the public. Mandating prescribing practices and provider education requirements in federal legislation is an inappropriate political interference in the practice of medicine. Instead, efforts to engage prescribers should focus on collaborative provider partnerships with the federal government through multi-stakeholder efforts to increase public awareness, and provider training and education.

Thank you again for the opportunity to submit written testimony, and for your thoughtful approach to this issue. We look forward to working closely with you as you consider additional strategies to address the impact of the ongoing opioid crisis. I hope that you will consider ACOG a trusted partner in this space and will let us know if we can provide any additional assistance.

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March 21, 2018

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Re: 2018 Substance Use Disorder Treatment, Prevention, and Recovery Package

Dear Chairman Burgess and Ranking Member Green,

On behalf of the American Society of Addiction Medicine (ASAM), the nation's oldest and largest medical specialty society representing more than 5,100 physicians and allied health professionals who specialize in the prevention and treatment of addiction, we are writing to offer legislative comments and recommendations as the House Energy and Commerce Subcommittee on Health works on a comprehensive, legislative response to our nation's opioid overdose and addiction crisis.

As you know, the cost of substance misuse, and untreated and ineffectively treated addiction in the United States is staggering, both in economic terms and in terms of human lives lost. During the twelve-month period ending January 2017, the Centers for Disease Control and Prevention estimates there were approximately 64,000 drug overdose deaths.[i] Recently, the White House Council of Economic Advisers announced that the cost of the opioid crisis, alone, approached $504 billion in 2015.[ii] And while opioid-related overdose deaths may dominate national headlines, the associated costs are a fraction of the total societal cost of substance misuse and addiction. Each year alcohol misuse leads to approximately 88,000 deaths in America.[iii] Cigarette smoking contributes to another 480,000.[iv] These costs, however, could be dramatically reduced by utilizing effective substance misuse prevention practices and programs and by addressing untreated, and ineffectively treated, addiction in this country.

Given these alarming statistics, we appreciate your leadership regarding the possible passage of legislation aimed at addressing our country's crisis of addiction involving opioid use. President Donald J. Trump's direction to declare the opioid epidemic a nationwide public health

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emergency on October 26, 2017 was a historic first step, but turning the tide on the current crisis and preventing future crises related to substance misuse and addiction require a new approach to the delivery of substance use prevention, addiction treatment, and recovery support services. Considering all the lives we have lost and all the lives we still risk losing, the time for transformational change is now. Thus, ASAM respectfully offers these comments for your consideration as you embark on the hard work that lies ahead.

Advancing Cutting-Edge (ACE) Research Act (H.R. 5002/S. 2046)

The ACE Research Act would facilitate additional research into treatments for public health epidemics such as the opioid addiction crisis by providing the National Institutes of Health (NIH) with new tools and flexibility to approve high-impact, cutting-edge research. Patients with addiction and patients with chronic pain, like all patients, should have available to them a robust and varied array of treatment options, as no one treatment modality is appropriate or therapeutic for everyone. We support research and the development of non-addictive pain treatment options and additional therapies to treat addiction. These new treatments could not only help save lives but help prevent addiction from taking hold in the first place. ASAM supports the ACE Research Act and recommends that Congress incorporate it into a future legislative package to address the opioid addiction epidemic.

The Addiction Treatment Access Improvement Act (H.R. 3692/S. 2317) / Amendment in the Nature of a Substitute to H.R. 3692

To make a meaningful and sustainable impact on the current opioid overdose epidemic, it is imperative that we build a robust treatment workforce. There are simply too few physicians and other clinicians with the requisite knowledge to meet the needs of the estimated 20.1 million Americans suffering from untreated substance use disorders. The Addiction Treatment Access Improvement Act makes great strides in doing so by codifying the Final Rule issued by the Department of Health and Human Services (HHS) in July 2016 that raised the DATA 2000 patient limit for certain physicians to 275 patients, eliminating the sunset date for nurse practitioners' (NPs) and physician assistants' (PAs) prescribing authority for buprenorphine, and expanding the definition of 'qualifying practitioner' to include nurse anesthetists, clinical nurse specialists, and nurse midwives.

These changes would increase the number of the clinicians to meet the needs of patients who are seeking treatment for their addiction but are unable to find a practitioner who can treat them. It is essential that we increase the treatment workforce, and we urge Congress to include these provisions (or the provisions in the substitute amendment that would also shorten the timeframe to reach the 100-patient limit in certain circumstances) in any legislative package moving forward.

Substance Use Disorder Workforce Loan Repayment Act (H.R. 5102/S. 2524)

In addition to expanding and codifying the eligibility of existing treatment providers, it is imperative that our country make strategic investments to incentivize clinicians to work in programs and practices that specialize in the treatment of addiction. To accomplish this goal, the Substance Use Disorder Workforce Loan Repayment Act helps clinicians who pursue full-time substance use disorder treatment jobs in high-need geographic areas repay their student loans. Many parts of the United States, and particularly rural areas, suffer from a lack of treatment providers. ASAM supports the goals of this bill and its efforts to incentivize clinicians to work in

substance use disorder treatment programs in these high-need areas and urges Congress to include it in any future legislative package to address the opioid epidemic.

The Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse (RESULTS) Act (H.R. 5272)

ASAM is pleased that the House Energy and Commerce Subcommittee on Health is holding a hearing that includes the RESULTS Act of 2018. The RESULTS Act would require grant, loan, and other recipients of funds from the Department of Health and Human Services for a mental health or substance use disorder prevention or treatment program to use evidence-based practices. We also support research and the development of new and innovative treatments for substance use disorders that will contribute to the body of knowledge that is needed for emergent or innovative programs and activities to become evidence-based.

There are many misconceptions about the disease of addiction, and we need a culture change in this country to drive patients to the treatment options that have been proven to be effective at reducing relapse and overdose deaths and supporting patients in remission and recovery. When it comes to opioid addiction, the most effective treatment options we have involve the use of medications in combination with specific psychosocial interventions to support remission and recovery. When we say, "Treatment works," we're not referring to every approach that claims to be treatment. We are physicians and other clinicians who specialize in the treatment of addiction. We're referring to those interventions that have scientific evidence to support their effectiveness.

The RESULTS Act would raise the clinical standard to a level that we demand from all other forms of medicine—to use clinical methods and practices based on evidence—and ASAM is proud to support that goal.

Preventing Overdoses While in Emergency Rooms Act (H.R. 5176)

With the rise in the use of potent synthetic opioids such as fentanyl and carfentanil, the rates of opioid overdoses and emergency department visits due to opioid overdose have increased significantly. Data from CDC's Enhanced State Opioid Overdose Surveillance (ESOOS) program showed opioid overdose rates increased an average of 35% in the 16 states reporting from July 2016 through September 2017. Eight states reported substantial increases (25% or greater) in opioid overdose emergency department visits.[v]

People who are admitted to a hospital for a drug overdose and discharged without treatment are at elevated risk to relapse and overdose again. H.R. 5176, the Preventing Overdoses While in Emergency Rooms Act, works to prevent that from happening by authorizing the Secretary of the Department of Health and Human Services to create grants for health care sites with emergency departments to develop protocols for discharging patients who have presented with a drug overdose and enhance the integration and coordination of care and treatment options for individuals with substance use disorders after discharge.

Addiction is a chronic brain disease and evidence shows that treatment is effective at achieving and sustaining remission and recovery. It is past due that we stop discharging patients from emergency rooms without treating their addiction. ASAM is proud to support the Preventing Overdoses While in Emergency Rooms Act and urges Congress to include it in any legislative package to address the needs of patients who have overdosed.

The Comprehensive Opioid Recovery Centers Act of 2018 (H.R. 5327)

Treatment of the disease of addiction, without also addressing associated social externalities such as homelessness, will result in poorer outcomes. The Comprehensive Opioid Recovery Center Act would help to fill this gap in wrap-around care and services, by creating competitive grants to entities to establish or operate comprehensive opioid recovery centers. This policy would accomplish the two-fold objective of increasing access to treatment and ensuring that the treatment is comprehensive - offering a full continuum of clinical, vocational, and educational services to meet the needs of patients. In addition, the grants would prioritize entities in a state or Indian country with high per capita drug overdose mortality rates, so the resources are focused in areas that need it most.

As you consider this legislation, ASAM offers these additional comments:

- Selected centers should be required to ensure that intake and ongoing evaluations meet the clinical needs of patients, including by offering assessments for services and level of care recommendations through independent, research-validated verification processes for reviewing patient placement in addiction treatment settings;
- Independent program evaluators should be required to evaluate program effectiveness; and
- Selected centers should be required to report on a set of pre-identified performance measures.

ASAM applauds this legislation which would make great strides in increasing access to comprehensive treatment and urges Congress to include it in any upcoming legislative package to address the opioid epidemic.

The Treatment, Education, and Community Help to Combat Addiction Act of 2018 (H.R. 5261)

This legislation would amend the Public Health Service Act to provide for regional centers of excellence to enhance and improve how health professionals are educated in pain management and substance use disorder through development, evaluation, and distribution of evidence-based curriculum for health care professional schools. ASAM has recommended for years that medical, nursing, dental, pharmacy and other clinical schools increase curriculum time devoted to addiction screening and treatment, safe prescribing and pain management. We would also encourage you to consider supporting future proposals which would establish an additional pathway for physicians who have had comprehensive training in medical school treating and managing opiate-dependent patients to apply for a DATA 2000 waiver.

We welcome this legislation and urge Congress to include it in any upcoming legislative package to address the opioid epidemic.

Confidentiality and 42 CFR Part 2

The federal regulations governing the confidentiality of drug and alcohol treatment and prevention records, 42 CFR Part 2 (Part 2), set requirements limiting the use and disclosure of

patients' substance use records from certain substance use treatment programs. Obtaining multiple consents from the patient is challenging and creates barriers to whole-person, integrated approaches to care, which are part of our current health care framework. Part 2 regulations may lead to a physician treating a patient and writing prescriptions for opioid pain medication for that individual without knowing the person has a substance use disorder. Separation of a patient's addiction record from the rest of that person's medical record creates several problems and hinders patients from receiving safe, effective, high-quality substance use treatment and coordinated care.

The advent of integrated health systems and electronic medical records has improved the safety, quality, and coordination of care for patients with any other health condition. Part 2 requirements prevent patients with addiction from sharing in these benefits, even though electronic exchanges of other health information are governed by strict privacy and security standards set by the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act.

ASAM holds patients' privacy rights in the highest regards but recognizes the barriers that Part 2 currently presents to coordinated, safe, and high-quality medical care cause significant harm, and that thoughtful changes to the law are necessary to mitigate this harm while protecting patients' privacy. Thus, we support changes that would align Part 2 with HIPAA's consent requirements for the purposes of treatment, payment, and healthcare operations. Such a change would allow for the sharing of patients' addiction treatment records within the healthcare system under HIPAA's well-established and modern privacy and security protections, while leaving in place Part 2's prohibition on disclosure of records outside the healthcare system. Moreover, we also welcome changes that would strengthen protections against the use of addiction treatment records in criminal proceedings, a further improvement to Part 2 that we see as essential to protect patients in treatment for substance use disorder.

CARA 2.0 Act of 2018 (H.R. 5311/S. 2456)

We appreciate the leadership of all the CARA 2.0 Act sponsors in filing this major legislative package aimed at addressing the opioid addiction crisis in our country. With that, we would like to respectfully provide comments and recommendations to you on provisions of the CARA 2.0 legislation for your consideration.

Section 3. Three Day Limit on Opioid for Acute Pain.

We appreciate the desire to help reverse the exponential increases in opioid misuse, addiction, and death by limiting initial prescriptions for opioids to three days or less while exempting certain conditions such as chronic pain care and pain being treated as part of palliative care. While this goal is important, a "hard" three-day limit in federal statute is inconsistent with evidence-based guidelines such as the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain (the "CDC Guideline").

According to Recommendation 6 of the CDC Guideline, "[w]hen opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed."[vi] Further, the applicable CDC Guideline narrative reads as follows:

> Experts thought, based on clinical experience regarding anticipated duration of pain severe enough to require an opioid, that in most cases of acute pain not related to surgery or trauma, a ≤3 days' supply of opioids will be sufficient . . . Some experts thought that because some types of acute pain might require more than 3 days of opioid treatment, it would be appropriate to recommend a range of ≤3–5 days or ≤3–7 days when opioids are needed. Some experts thought that a range including 7 days was too long given the expected course of severe acute pain for most acute pain syndromes seen in primary care.[vii]

Considering the foregoing, we highlight three observations for your consideration. First, unlike the CDC Guideline, Section 3 of CARA 2.0 is not limited to primary care prescribers. Second, patients with acute pain related to surgery or trauma and for whom three days or less can be insufficient, may have to incur financial costs and bear logistical burdens to obtain additional medically-appropriate opioid medication. Further, such a 3-day limitation would inevitably and disproportionately impact patients with lower incomes and patients living in rural areas located many miles from their prescribers. Third, violating a federal statute can carry significant legal ramifications for prescribers trying to treat acute pain appropriately as compared to deviating from a voluntary guideline, such as the CDC Guideline. Therefore, ASAM strongly recommends that any statutory acute pain limitation passed by Congress incorporate more flexibility for prescribers to meet the medical needs of all their patients and should more closely align with the recommendations of the CDC Guideline.

Section 4. First Responder Training.

This section would provide funds primarily to make naloxone available to first responders to train and provide resources for carrying and administering naloxone. While we know state and local governments would certainly welcome federal assistance for naloxone training and distribution given the increasing cost of naloxone in this country, we urge you to consider enacting policy interventions which would allow the federal government to bulk purchase naloxone at discounted prices to increase access to this life-saving medication. Our nation's Vaccines for Children Program may be an existing model Congress could rapidly replicate to increase naloxone access for first responders, public health departments, and community organizations.[viii] Such a program, coupled with investments aimed at enhancing the Centers of Disease Control and Prevention's surveillance capabilities for identifying overdose clusters and infectious disease outbreaks, could go a long way in preventing the spread of infectious diseases and death.

Section 6. Building Communities of Recovery.

ASAM supports additional investments in recovery support services for people trying to achieve long-term remission and recovery from the disease of addiction. However, we strongly caution against any statutory language which states that addiction recovery support services can be "in lieu of addiction treatment." Nearly 90% of Americans with addiction do not receive treatment and 80% of individuals with opioid addiction are not treated.[ix] [x] As many families know all too well, remission and recovery from addiction involving opioid use is often only preceded by evidence-based medical treatment. To put it simply, there is no remission or recovery if you are dead.

Therefore, our nation must come to terms with the difficult reality in which we find ourselves: the current addiction treatment gap will never be closed with the current addiction treatment

workforce. While we want you to support additional investments in recovery support services, we urge you also to prioritize federal funding for Accreditation Council for Graduate Medical Education (ACGME)- accredited addiction medicine and addiction psychiatry fellowship positions and a loan repayment program for students who enter the substance use disorder treatment workforce.[xi] Additionally, please consider revising the Public Health Service (PHS) Act to include addiction medicine specialists in the definition of "behavioral and mental health professionals" within the National Health Service Corps.

Section 7. Medication-Assisted Treatment for Recovery from Addiction.

ASAM applauds the efforts in Section 7 of CARA 2.0 that would expand access to medication-assisted treatment for remission and recovery from addiction. As previously noted, it is imperative that we build a robust treatment workforce, and this section would make great strides in doing so by eliminating the sunset date for nurse practitioners' (NPs) and physician assistants' (PAs) prescribing authority under DATA 2000 and expanding the definition of 'qualifying practitioner' to include nurse anesthetists, clinical nurse specialists, and nurse midwives. This section would also give individual states the option to waive the limit on the number of patients a physician can treat so long as the state directs its applicable state regulatory body to adopt evidence-based prescribing guidelines for the use of medication to treat addiction involving opioid use, such as ASAM *National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use*. This policy change would help accomplish the two-fold objective of increasing access to and the quality of the prescribing medications for the treatment of addiction involving opioid use.

We also welcome the opportunity to work with you and the CARA 2.0 sponsors to improve the innovative "Offer 2 Types of Medication-Assisted Treatment" minimum requirement in Section 7(d) of CARA 2.0. For example, we would recommend that such minimum, two-medication requirement for medications to treat opioid use disorder only apply to residential treatment providers, prisons, and jails[xii] that receive federal funds for a program or activity offering addiction treatment to people with opioid use disorder, especially if a residential provider is receiving Medicaid funding due to a waiver or repeal of the Institutes for Mental Diseases (IMD) Exclusion within the Medicaid program. We would want to avoid any policy intervention which could result in an unintended consequence of decreasing access to life-saving medications prescribed by individual prescribers treating patients whose health care is federally-subsidized.

Section 13. Require the Use *of Prescription Drug Monitoring Programs (PDMP).*

ASAM believes that prescription drug monitoring programs (PDMPs) are an important tool to inform safe prescribing. From 2014 to 2016, there was a 121 percent increase in the number of queries by health professionals to state PDMP databases.[xiii] As a result, we applaud the creative policy innovations outlined in this section - namely that prescribers or their designees be required to query the PDMP upon initial prescription of a controlled medication and quarterly thereafter if treatment continues. Further, requiring proactive reports, increased timeliness of data entry, and de-identified data sets for research and evaluation are also welcomed policy changes. However, requiring state agencies to provide reports to law enforcement agencies and licensing boards "describing any prescribing practitioner that repeatedly fall [*sic*] outside of expected norms or standard practices for the prescribing practitioner's field" is troubling as it could have an unintended chilling effect on appropriate prescribing, particularly with respect to disclosures to law enforcement outside of a court-supervised process. PDMP information should be considered what it is: personal health information, and, therefore, should be protected from release like other personal health information.

In addition, we would be remiss not to urge you to fund research and evaluation programs that study best practices for integrating PDMPs into EHRs and clinician workflow in a meaningful, user-friendly manner. While PDMPs now exist in almost every state and practitioners are increasing their use of them, the lack of integration with electronic health records continues to inhibit the effective use of these clinical support tools. Further, in addition to improving and integrating these programs, ASAM recommends that Congress urge the Department of Health and Human Services to support the development of training for primary care providers to know how to engage a patient whose PDMP report indicates he or she may be inappropriately accessing controlled substances. Without such training, many clinicians might simply dismiss patients from their practice without an assessment for substance use disorder or referral to treatment, if indicated. These clinicians are missing an important opportunity to engage patients in treatment and should be equipped to use the PDMP report as a conversation-starter with patients at risk of addiction or overdose death.

Telemedicine

As stated in a testimony on behalf of ASAM before the House Energy and Commerce Subcommittee on Health, telemedicine provides significant opportunities to reach more patients in urban and rural communities. However, the current restrictions on internet prescribing under the Ryan Haight Act and the seven, specific "practice of telemedicine" exceptions it provides for are of limited utility for expanding access to treatment with buprenorphine for addiction involving opioid use via telemedicine. As you know, the Ryan Haight Act generally requires an "in-person medical evaluation" in the physical presence of the prescribing clinician for the prescription to be considered valid.

The "practice of telemedicine" exceptions to this requirement provide for circumstances in which the patient is being treated by, and physically located in, a DEA-registered hospital or clinic, or in which the patient is being treated by and in the physical presence of another DEA-registered practitioner. It generally does not allow for circumstances in which a patient may have received a medical evaluation by another qualified practitioner but is not physically present in a DEA-registered hospital or clinic or with another DEA-registered practitioner. While *The ASAM's Standards of Care*[xiv] and *The ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use*[xv] make it clear that patients presenting for treatment of addiction involving opioid use should receive a physical examination by a qualified and appropriately licensed healthcare professional as part of a comprehensive assessment process, they specifically allow for this examination to be conducted by a healthcare professional other than the prescriber, as long as the prescriber "ensure[s] that a current physical examination is contained within the patient medical record before a patient is started on a new medication for the treatment of his/her addiction."

ASAM recommends that Congress pass legislation to revise the Ryan Haight Act to include an additional exception to the requirement for an in-person physical exam by the prescribing clinician to allow for a current physical exam to be conducted by another appropriately licensed healthcare professional and documented in the patient's medical record. Additionally, ASAM recommends limiting this exception to the in-person physical exam requirement for patients who will be treated with buprenorphine for opioid addiction only to those physicians who hold "additional certification" or who practice in a "qualified practice setting" per the definitions in the 2016 SAMSHA rule that raised the DATA-2000 prescribing limit.

Additional Recommendations

On March 8, 2018, the Senate HELP Committee held a hearing titled "The Opioid Crisis: Leadership and Innovation in the States." Hearing participants discussed recommendations from Governors across the U.S. expressed at the National Governors Association annual winter meeting. Toward the conclusion of that hearing, Chairman Alexander highlighted the problem of an "unevenness" in addiction treatment program quality across the country. We would be honored to have the opportunity to meet with Congressional leaders to discuss, in greater detail, possible federal action that could start incentivizing states to continue building out an addiction treatment infrastructure that can consistently deliver quality care for people suffering with addiction.

We know well that as the field of addiction treatment works to integrate more fully with traditional medical care, it is imperative that it "catch up" with other medical specialties in terms of clinical guideline development and quality measurement. Federal efforts to promote high-quality addiction treatment could include support for the following:

- Development and dissemination of clinical practice guidelines for addiction treatment, such as the ASAM *National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use* and of science-based patient guides, such as the *Opioid Addiction Treatment: A Guide for Patients, Families and Friends*, that include information on assessment, treatment overview (including treatment plans, patient participation, and counseling), and all the medications available to treatment opioid use and overdose;

- Establishment and maintenance of addiction treatment programs that ensure intake and ongoing evaluations meet the clinical needs of patients by offering assessments for all substance use disorder services and level of care recommendations through an independent, research-validated verification process for reviewing patient placement in addiction treatment settings; and

- Implementation of, and related technical assistance for, nationally-recognized and research-validated treatment center certification programs that can provide patients, families, and payers with a reliable indicator that providers are delivering a certain level of care.

Efforts such as these are critically needed to help improve the overall quality of addiction treatment provided in our nation and assure those who are seeking and paying for treatment that they are receiving medically appropriate and high-quality care.

Thank you for the opportunity to make recommendations and offer additional tools that may be helpful to combat this public health emergency. We look forward to working with you to build upon the progress already made and help lay the foundation for a future in which long-term remission and recovery from addiction is not only possible, but probable. If you have any questions or concerns, please contact Kelly Corredor, ASAM's Director of Advocacy and Government Relations, at kcorredor@asam.org or at 301-547-4111.

Sincerely,

Kelly J. Clark

Kelly J. Clark, MD, MBA, DFASAM
President, American Society of Addiction Medicine

cc: The Honorable Greg Walden
The Honorable Frank Pallone

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[i] Provisional Counts of Drug Overdose Deaths, as of 8/6/2017; https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf

[ii] *White House: Opioid Crisis Cost US Economy $504 Billion in 2015*; https://www.voanews.com/a/us-opioid-crisis-white-house-report/4126121.html. [Accessed on 2017 November 27].

[iii] Stahre, M., Roeber, J., Kanny, D., Brewer , R. D., & Zhang, X. (2014). Contribution of excessive alcohol consumption to deaths and years of potential life lost in the United States. *Preventing Chronic Disease, 11*(E109).

[iv] U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014 [accessed 2017 Nov 29].

[v] Centers for Disease Control and Prevention. CDC Vital Signs, March 2018. https://www.cdc.gov/vitalsigns/pdf/2018-03-vitalsigns.pdf. Updated March 6, 2018. Accessed March 15, 2018.

[vi] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1

[vii] Id.

[viii] Vaccines for Children (VPC) Program. Retrieved from https://www.cdc.gov/vaccines/programs/vfc/index.html

[ix] Legal Action Center. (2015). Confronting an Epidemic: The Case for Eliminating Barriers to Medication Assisted Treatment of Heroin and Opioid Addiction. Washington, D.C: Legal Action Center. Available at http://lac.org/wp-content/uploads/2014/07/LAC-The-Case-for-Eliminating-Barriers-to-Medication-Assisted-Treatment.pdf

[x] Saloner PhD, Karthikeyan MPP. Changes in Substance Abuse Treatment Use Among Individuals with Opioid Use Disorders in the United States, 2004-2013. *The Journal of the American Medical Association*. 2015;314(14):1515-1517

[xi] By way of further background, in 2016, addiction medicine was recognized as an American Board of Medical Specialties (ABMS) subspecialty under the American Board of Preventive Medicine (ABPM). The first ABMS addiction medicine board exam was offered in October 2017. While the board exam will be open to any American physician with a primary ABMS board certification until 2022, after that time, physicians will need to complete a year-long fellowship program to be qualified to sit for the exam. In five short years, the number of accredited and funded addiction medicine fellowship programs and slots will be the limiting factor in determining how many addiction medicine specialists can receive board certification.

It is critical that all stakeholders work to maximize funded addiction medicine fellowship opportunities before their number begins to limit qualified examinees.

[xii] Green TC, Clarke J, Brinkley-Rubinstein L, Marshall BDL, Alexander-Scott N, Boss R, Rich JD. Post incarceration Fatal Overdoses After Implementing Medications for Addiction Treatment in a Statewide Correctional System. *JAMA Psychiatry*. Published online February 14, 2018. doi:10.1001/jamapsychiatry.2017.4614.

[xiii] Based on AMA survey and responses from 44 state PDMP administrators. https://www.ama-assn.org/sites/default/files/media-browser/public/physicians/patient-care/opioid-task-force-progress-report.pdf

[xiv] American Society of Addiction Medicine. The ASAM Standards of Care for the Addiction Specialist Physician. 2014. Available at: https://www.asam.org/docs/default-source/practice-support/quality-improvement/asam-standards-of-care.pdf?sfvrsn=338068c2_10

[xv] Kampman K and Jarvis M. American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. J Addict Med 2015;9: 1–10.

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AdvancedMD
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Allscripts
Amazing Charts
Aprima Medical Software
Bizmatics
Cerner Corporation
ChartLogic, A Division of Medsphere Systems
CureMD Corporation
eClinicalWorks, LLC
eMDs
EndoSoft
Epic
Evident
Flatiron Health
Foothold Technology
GE Healthcare Digital
Greenway Health
Harris Healthcare Group
Lumeris
MacPractice
MEDHOST
MEDITECH
Modernizing Medicine
Netsmart
NexTech
NextGen Healthcare
Practice Fusion
Sevocity, A Division of Conceptual Mindworks
SRS Health
STI Computer Services
Välant Medical Solutions
Varian Medical Systems
Wellsoft Corporation

March 21, 2018

The Honorable Morgan Griffith
House Committee on Energy & Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Dear Representative Griffith,

On behalf of the members of the Electronic Health Record (EHR) Association, we thank you for your leadership in drafting an amendment to the Comprehensive Addiction & Recovery Act (CARA) 2.0 of 2018 to further recognize and prioritize the many ways in which health information technology and other digital solutions can play an important role in tackling the nation's unfortunate opioid and opiate epidemic.

The EHR Association's more than 30 member companies serve the majority of hospitals and ambulatory care providers across the United States. Our core objectives focus on collaborative efforts to improve the quality and efficiency of care through the use of these important technologies, and we recently formed an Opioid Crisis Task Force to examine how to best utilize EHR systems' data and capabilities as a tool in nationwide efforts to fight opioid abuse.

Information technology, such as EHRs, information exchange solutions, and Prescription Drug Monitoring Programs (PDMPs) are already playing a role in tackling the opioid crisis and have tremendous potential to do much more. As represented in your discussion draft, our solutions can be used to identify problematic prescribing patterns, patients already addicted, and patients at high risk of becoming addicted.

Further, our technologies play a critical role in:

- Exchanging information between clinicians to alert to "drug shopping" behaviors
- Integrating with the numerous and disparate PDMPs
- Providing tools to support ePrescribing of Controlled Substances (ePCS) approaches being implemented by states
- Supporting physicians through clinical decision support tools in developing comprehensive approaches to pain management as they look beyond prescriptions to help their patients

Policy actions by Congress and the Administration that support maximization of technology or the removal of obstacles to success are critical, and we thank you for identifying several key opportunities within your draft.

Over the last several months, we have worked not only within our own Association but also in partnership with other healthcare stakeholders to identify ways in which EHRs and other health IT can be helpful in this fight; we would be happy to share with your staff what we have learned and some of our ideas for moving forward productively. Please contact Leigh Burchell, VP of Policy and Government Affairs at Allscripts and Chair of the EHRA Opioid Crisis Task Force, at leigh.burchell@allscripts.com or Sarah Willis-Garcia, EHRA Program Manager, at swillis@himss.org.

Sincerely,

Sasha TerMaat
Chair, EHR Association
Epic

Cherie Holmes-Henry
Vice Chair, EHR Association
NextGen Healthcare

HIMSS EHR Association Executive Committee

Hans J. Buitendijk
Cerner Corporation

Nadeem Dhanani, MD, MPH
Modernizing Medicine

David Heller
Greenway Health

Rick Reeves, RPh
Evident

About the EHR Association
Established in 2004, the Electronic Health Record (EHR) Association is comprised of more than 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.

CC:
The Honorable Greg Walden
The Honorable Frank Pallone, Jr.
The Honorable Michael Burgess, M.D.
The Honorable Gene Green

19 March 2018

Thank you, Chairman Walden, Ranking Member Pallone, Subcommittee Chairman Burgess, and distinguished Members of the Committee on Energy and Commerce for holding the "Combating the Opioid Crisis: Prevention and Public Health Solutions" hearing.

My name is Keith Pardieck a biologist and a Town Council member; I am writing to you as a private citizen. During 2016, as a newly elected town council member, I immediately lead an effort to form a town-based Opioid Abuse Awareness Committee which I co-Chair to focus attention on the opioid crisis in the towns of Chesapeake Beach and North Beach, Maryland. With support of community members, we formed the Twin Beach Opioid Abuse Awareness Committee. The committee is a diverse coalition of residents and organizations. Our mission is educating community members about prevention, recovery, and counseling services related to drug addiction. We focus on mitigating the emotional and physical harm caused by Opioid Abuse Disorder. Our committee received the 2017 Prevention Services Community Connection Award from the Calvert County Health Department for outstanding efforts to raise community consciousness and connect those in need with existing prevention and recovery resources.

Based on my experience, I recommend support and passage of the "Comprehensive Opioid Recovery Centers Act of 2018" bill, introduced by Mr. Guthrie to amend title V of the Public Health Service Act to establish a grant program to create comprehensive opioid recovery centers for the following reasons:

- Friends and families of those afflicted by Opioid Use Disorder, and many first responders, consistently cite lack of available and affordable recovery service providers (especially those who provide evidence-based, long-term services) as a barrier to effective treatment.

- Hurdles to effective treatment need to be removed wherever and whenever possible. When a person suffering from opioid addiction finally resolves to seek

help, that help needs to be immediately accessible because they may otherwise have no tomorrow.

- In Calvert County, Maryland 33 people died of overdoses in 2017, a 17.8% increase over 2016 yet treatment resources remain insufficient. More recovery resources are needed to stem the tide of this epidemic. Detox is not enough. Failure to treat the underlying causes through long-term support dooms most to a cycle of relapse and eventual death. We need more resources made available for long-term recovery support as indicated in this proposed legislation, especially as described on page 4, line 19 through page 5, line 19.

Thank you again,

Keith L. Pardieck
7792 C Street
Chesapeake Beach, MD 20732

Statement

Of

The National Association of Chain Drug Stores

For

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

On

"Combating the Opioid Crisis:
Prevention and Public Health Solutions"

March 21, 2018
9:00 a.m.

2123 Rayburn House Office Building

National Association of Chain Drug Stores (NACDS)
1776 Wilson Blvd., Suite 200
Arlington, VA 22209
703-549-3001
www.nacds.org

Introduction

The National Association of Chain Drug Stores (NACDS) thanks Chairman Burgess, Ranking Member Greene and the members of the Subcommittee on Health for your continued commitment to identifying and developing holistic policies and strategies to curb prescription opioid abuse and diversion. The chain pharmacy community welcomes the opportunity to partner with lawmakers and other stakeholders for this purpose. As healthcare providers on the frontlines of patient care who play a critical role in helping the public take their medications safely and effectively, the chain pharmacy community is keenly aware of complexities associated with this epidemic. We thank you for the opportunity to provide recommendations on policy changes to prevent the abuse and diversion of prescription opioid medications.

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS' chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.2 million individuals, including 179,000 pharmacists. They fill over 2.9 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 850 supplier partners and over 60 international members representing 22 countries. For more information, visit www.NACDS.org.

A Nationwide Solution to Enhance Prescription Drug Monitoring Programs

NACDS supports the important role of prescription drug monitoring programs (PDMPs) to help prevent drug abuse and diversion. Over the years, states have established PDMPs as a tool to provide critical information to prescribers and dispensers. However, many states have implemented their own approaches to designing and managing PDMPs, resulting in disparate data and access requirements. These challenges are compounded by inconsistent interconnectivity between different state programs and the lack complete data sets among many PDMPs. On top of this, it is difficult for healthcare providers to access PDMP data that is not integrated into their existing health IT and workflow. Altogether, these challenges impede optimal use of PDMPs.

Experts have pointed toward eight best practices for increasing provider utilization of PDMPs.[1,2] Evidence suggests that physicians do not use PDMPs consistently, or at all, due to a lack of data timeliness to show real-time prescribing data in their workflow and lack of health IT integration with electronic medical records (EMRs). NACDS supports health IT initiatives that equip providers with real-time data within EMRs. Improvement of health IT integration to combat the opioid crisis also requires use of electronic controlled substance prescriptions. Working in tandem with e-prescribing technology would help to ensure that prescribers receive immediate, in-workflow information at the point-of-prescribing, thus eliminating the need to access another

[1] Pew Charitable Trusts, Dec. 2016.
[2] Duke Margolis Center for Health Policy, Feb. 15, 2018.

system or database. Moreover, this would help ensure that any federal or state opioid prescribing limits are followed.

As a result of the present functionality and interoperability challenges, NACDS is calling on stakeholders to work together to develop and implement a nationwide PDMP solution to harmonize state PDMPs. Such a system should be built in tandem with efforts that require e-prescribing for controlled substances in an effort to provide timely, in-workflow analyses of real time data with actionable point of care guidance for prescribers and dispensers.

A nationwide PDMP solution could take many forms, pulling information from several data sources including: clinical data extracted from insurers, PBMs, and state PDMPs; and aggregated data via a commercial market solution. Additionally, controlled substances prescribing information could be included within electronic medical records. NACDS would support a nationwide solution through any of those vehicles, provided that the solution included the following principles:

1. The most effective use of PDMP data is in ensuring appropriateness of controlled substance use when the prescriber is issuing a prescription for a patient. Towards that end, it is important for prescribers to have real-time, actionable data at the point of care to better inform their prescribing decisions. We recommend that PDMPs be utilized by pharmacies as a secondary safeguard, in addition to the prescriber's review. In exercise of their professional judgment, pharmacists can take necessary actions to investigate and attempt to resolve any concerns identified as a result of a PDMP query, as part of the process of determining whether or not to fill controlled substance prescriptions.

2. Data is accessible to prescribers, dispensers, and supporting staff (e.g. automatic and free registration into PDMP);

3. Compile data exclusively on controlled substances; stay focused on main mission; and

4. Sufficiently protect proprietary data rights of participating stakeholders.

NACDS strongly supports the development of a nationwide PDMP solution that includes the previously mentioned principles; however, we are agnostic to the specific format of the solution. In other words, this solution could be supported and housed within a federal agency (e.g. ONC, ONDCP or FDA) or it could be built and delivered entirely outside government through commercial market forces. Depending on the solution that moves forward, it could build upon existing state PDMP data or pull data from other sources – we are open to the most reasonable solution that harmonizes existing gaps and inconsistencies. NACDS looks forward to working with key stakeholders to discuss the development and implementation of a nationwide PDMP.

NACDS encourages the support of Congress for legislation that would help to facilitate a nationwide PDMP solution. We were encouraged to learn that at today's hearing, the Subcommittee on Health will be considering a discussion draft of "A Bill to Enhance and Improve State-run Prescription Drug Monitoring Programs." While we have some concerns with this specific legislation, we are supportive of many of the broader approaches outlined in this bill to leverage innovative technology solutions, provide healthcare providers with

actionable information and data, and overall improve the functionality of PDMPs. We welcome the opportunity to work with lawmakers to advance legislation that would include these concepts in alignment with the important principles for a nationwide PDMP solution outlined above.

Take Back and Disposal of Consumer's Unused Controlled Substances

Chain pharmacies support patient access to safe and effective methods for disposal of unwanted opioids. To further such access, NACDS supports policies that accommodate pharmacy participation in a variety of DEA authorized options for opioid disposal programs. For example, NACDS member pharmacies participate in and support the following programs: take-back kiosks in pharmacies, mail-back envelopes made available by manufacturers or pharmacies, community drug take-back events hosted at pharmacies, in-home disposal products, take-back kiosks at law enforcement locations, and vouchers to patients to obtain mail-back envelopes from manufacturers or pharmacies. For NACDS members, the key to effective opioid disposal policy is public policy which allows pharmacies to choose from a variety of program options. With such flexibility, pharmacies can choose which opioid disposal program best fits their customer needs and is best suited for their patient population.

NACDS supports a collaborative approach to opioid drug disposal. This a team effort across the supply chain. Accordingly, NACDS member pharmacies seek to collaborate with other supply chain stakeholders to promote safe and effective consumer opioid disposal, including working with manufacturers to implement opioid disposal solutions. More specifically, NACDS supports programs that require manufacturers to fund and make available to pharmacies mail-back envelopes for distribution to patients, upon request, when those patients fill opioid prescriptions. A program of manufacturer-funded mail-back envelopes for unused opioid drugs recognizes that the entire drug supply chain has a role in drug disposal.

Notably, the FDA has recently shown support for manufacturer-driven opioid disposal solutions. Last month, the FDA provided a policy document to the full Energy and Commerce Committee in which FDA called upon manufacturers to establish programs for the return or destruction of unused opioids.[3] NACDS fully supports FDA's policy position and we applaud FDA for recognizing the supply chain collaboration required for effective consumer disposal of opioids. Accordingly, we urge this Subcommittee to also support drug disposal strategies focused on manufacturer leadership in opioid disposal.

In addition to a commitment to offer patients a variety of opioid disposal options, NACDS members are also committed to participating in education programs directed at patients for how to safely and effectively dispose of their unused opioids. To that end, NACDS encourages Congress to fund, develop, and promote programs that provide opioid disposal

[3] "FDA Asks E&C For New Authority On Opioid Evaluation, Seizure; Suggests Requirements On Manufacturers;" *Inside Health Policy*, https://insidehealthpolicy.com/daily-news/fda-asks-ec-new-authority-opioid-evaluation-seizure-suggests-requirements-manufacturers, accessed February 9, 2018; Referencing FDA policy document provided to the House Energy and Commerce Committee.

educational materials to consumers through pharmacies. The programs and the educational materials should focus on opioids, including the dangers of misuse and the potential for addiction to opioids, treatment resources available, and the proper way to dispose of unused opioids. These educational materials should be posted on websites operated by the federal government and be made available to pharmacies to provide to patients filling opioid prescriptions, with each pharmacy determining the best method for making those materials available to its patient population in a written and/or electronic format.

Conclusion

NACDS thanks the Subcommittee for consideration of our comments. We look forward to working with policymakers and stakeholders on these important issues.

NATIONAL COALITION ON HEALTH CARE

Working Together for an Affordable Future

March 12, 2018

Honorable Katherine Clark
1415 Longworth House Office Building
Washington, DC 20515

Honorable Markwayne Mullin
1113 Longworth House Office Building
Washington, DC 20515

Dear Representatives Clark and Mullin:

The National Coalition on Health Care (NCHC) is a coalition of health care stakeholder organizations committed to promoting an affordable, high-quality health system in the United States. As the nation's oldest and most diverse group working to achieve comprehensive health reform, we represent more than 100 member organizations, including health care providers, purchasers, payers, and consumers. Collectively, our organizations represent—as employees, members, or congregants—more than 100 million Americans.

As you know, Opioid Use Disorder (OUD) and Substance Use Disorders (SUDs) are exacting an enormous toll on the American population in both lives and economics. This crisis is complex, and the public policy response must be multifaceted. Providers, payers, and public programs are re-examining their practices and policies related to CDC guidelines regarding opioid use—specifically that opioids should not be routine or first-line treatments for chronic pain, and prescriptions should be at the lowest effective dose for the shortest possible time.

Unfortunately, our current policies on permitting paper prescriptions opens the door to abuse, diversion, and fraud. Tracking prescriptions and prescribing patterns is a necessary part of preventing the growth of this avoidable public health emergency. That is why the Coalition is pleased to support H.R. 3528, *Every Prescription Conveyed Securely Act*, because it requires prescriptions for controlled substances in the Medicare Part D program to be issued electronically. This legislation is a key component to modernizing our prescribing policies to prevent misuse of opioids as we battle a nationwide epidemic.

NCHC looks forward to working with you to advance this important legislation. If NCHC can be of any assistance, please contact NCHC's Policy Team, Larry McNeely at lmcneely@nchc.org or Emily Haas ehaas@nchc.org

Sincerely,

John Rother
President and CEO
National Coalition on Health Care

NATIONAL COALITION ON HEALTH CARE

Working Together for an Affordable Future

March 20, 2018

The Honorable Paul Tonko
U.S. House of Representatives
Washington, DC 20515

The Honorable Elise Stefanik
U.S. House of Representatives
Washington, DC 20515

The Honorable Ben Ray Lujan
U.S. House of Representatives
Washington, DC 20515

The Honorable David McKinley
U.S. House of Representatives
Washington, DC 20515

Dear Representative Tonko, Representative Lujan, Representative Stefanik, and Representative McKinley:

I write to express the National Coalition on Health Care's (NCHC) support for HR 3692, the Addiction Treatment Access Improvement Act.

NCHC is a nonpartisan, nonprofit organization representing more than 80 participating organizations, including medical societies, businesses, unions, health care providers, faith-based associations, pension and health funds, insurers, and groups representing consumers, patients, women, minorities, and persons with disabilities. The Coalition is committed to advancing - through research and analysis, education, outreach, and informed advocacy – an affordable, high-value health care system for patients and consumers, payers, employers, and taxpayers.

Opioid Use Disorder (OUD) and other Substance Use Disorders (SUDs) are exacting an enormous toll in lives and in increased economic burden. The National Institute of Drug Abuse estimates that 64,000 Americans lost their lives to drug overdoses alone in 2016. According to the Altarum Institute, the combined economic costs of substance abuse since 2001 have exceeded $1 trillion, inclusive of health spending as well as lost wages and productivity.

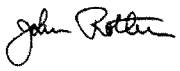
Yet as of today, the specialty behavioral health infrastructure and workforce is not large enough to successfully address this challenge. Prevention, screening, assessment, and treatment for substance use disorders, and other behavioral health conditions, must be fully integrated with the

rest of health care – particularly primary care. To effectively combat this epidemic, the United States must mobilize the full range of health care professionals.

HR 3692 would make meaningful progress towards this goal. It makes permanent the broad buprenorphine prescribing authority for Nurse Practitioners and Physician Assistants that was enacted as part of the Comprehensive Addiction Recovery Act of 2016. This legislation further expands that authority to Certified Nurse Midwives, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists and eases restrictions on the number of patients that can be treated by qualified practitioners.

At a time when opioid use and substance use disorders seriously threaten the nation's health, we must bring all qualified health professionals fully into this fight. Please do not hesitate to contact NCHC's Policy Director Larry McNeely at lmcneely@nchc.org if you have questions regarding this letter or related issues.

Yours truly,



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February 14, 2018

The Honorable Steve Stivers
United States House of Representatives
1022 Longworth HOB
Washington, D.C. 20515

Dear Congressman Stivers,

This letter is in strong support of your proposed legislation entitled, "Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse Act of 2018". Your bill seeks to develop evidence-building activities to inform policymaking within federal agencies. The passage of this legislation will be a big national win for advancing evidence-based practice and policy, enhancing the quality of healthcare, and improving the health outcomes of Americans.

The United States spends more money on healthcare than any western world country, it ranks 37th in health outcomes. One key reason for this ranking is that many healthcare systems, public health departments, and clinicians across the United States do not consistently use the evidence generated from science to implement evidence-based practices and inform policies. Instead, care and programs are often based on tradition (for example, "that's the way we do it here") or on outdated, non-science-based information. Findings from a strong body of research indicates that evidence-based or science-based healthcare and programming enhances the quality and safety of care, reduces healthcare costs, and improves population health outcomes. However, it often takes years or even decades to translate findings from science into real world clinical settings and health policy to improve outcomes. Embracing evidence-based practice cultures and policies is long overdue in America and in our healthcare systems. Healthcare environments are under enormous pressure. Healthcare costs continue to escalate and there is still a tendency to deliver too much care instead of the right evidence-based care.

In virtually any other field, science and research dictate decision-making and practice. In healthcare, inertia is so powerful that it often overwhelms scientific evidence. To change the practice and change the results, we have to change the culture to one in which evidence-based practice and evidence-based policy-making is the norm. This important legislation is urgently needed in our country to improve the health outcomes of Americans.

Thank you for introducing this very needed legislation.

Warm regards,

Bernadette Melnyk

Bernadette Mazurek Melnyk, PhD, RN, CRNP, FAANP, FNAP, FAAN
Vice President for Health Promotion
University Chief Wellness Officer
Dean and Professor, College of Nursing
Professor of Pediatrics & Psychiatry, College of Medicine
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Testimony of United South and Eastern Tribes Sovereignty Protection Fund Submitted to the House Committee on Energy and Commerce Subcommittee on Health for the Record of the February 28, 2018 Hearing, *Combatting the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety*

March 14, 2018

On behalf of the United South and Eastern Tribes Sovereignty Protection Fund (USET SPF), we are pleased to provide the House Committee on Energy and Commerce Subcommittee on Health with testimony for the record of the hearing, "Combatting the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety," held on February 28, 2018.

USET SPF is a non-profit, inter-tribal organization representing 27 federally recognized Tribal Nations from Texas across to Florida and up to Maine[1]. Both individually, as well as collectively through USET SPF, our member Tribal Nations work to improve health care services for American Indians. Our member Tribal Nations operate in the Nashville Area of the Indian Health Service (IHS), which contains 36 IHS and Tribal health care facilities. Our citizens receive health care services both directly at IHS facilities, as well as in Tribally-operated facilities under contracts with IHS pursuant to the Indian Self-Determination and Education Assistance Act (ISDEAA), P.L. 93-638.

The opioid epidemic has had a devastating effect on USET SPF Tribal Nations and Tribal Nations across the country, who continue to experience the destructive effects of opioid addiction--often at higher rates than non-Indian communities. According to data from IHS, American Indians and Alaska Natives (AI/ANs) are more likely than any other race/ethnicity to have an illicit drug use disorder in the past year. In addition, according to the Centers for Disease Control and Prevention (CDC), AI/ANs are at the greatest risk for prescription opioid overdose confronting an opioid overdose rate of 8.4 per 100,000. Despite the disproportionate impact opioid addiction has had in Indian Country, Tribal Nations often do not have access to sufficient vital resources to address the damaging effects of opioid abuse and are frequently excluded from collaborative efforts, including state and local, when determining solutions to eradicate opioid abuse.

In addition, Tribal Nations continue to be overlooked during important Congressional hearings seeking to address the opioid epidemic, including the February 28th hearing within the Subcommittee on Health. In future hearings, USET SPF urges the Committee to ensure Tribal leaders and representatives are included as witnesses, as well as ensure the opioid issues facing Indian Country are brought to the forefront of every hearing. Further, USET SPF provides the below recommendations to the Committee to include Tribal

[1] USET SPF member Tribal Nations include: Alabama-Coushatta Tribe of Texas (TX), Aroostook Band of Micmac Indians (ME), Catawba Indian Nation (SC), Cayuga Nation (NY), Chitimacha Tribe of Louisiana (LA), Coushatta Tribe of Louisiana (LA), Eastern Band of Cherokee Indians (NC), Houlton Band of Maliseet Indians (ME), Jena Band of Choctaw Indians (LA), Mashantucket Pequot Indian Tribe (CT), Mashpee Wampanoag Tribe (MA), Miccosukee Tribe of Indians of Florida (FL), Mississippi Band of Choctaw Indians (MS), Mohegan Tribe of Indians of Connecticut (CT), Narragansett Indian Tribe (RI), Oneida Indian Nation (NY), Pamunkey Indian Tribe (VA), Passamaquoddy Tribe at Indian Township (ME), Passamaquoddy Tribe at Pleasant Point (ME), Penobscot Indian Nation (ME), Poarch Band of Creek Indians (AL), Saint Regis Mohawk Tribe (NY), Seminole Tribe of Florida (FL), Seneca Nation of Indians (NY), Shinnecock Indian Nation (NY), Tunica-Biloxi Tribe of Louisiana (LA), and the Wampanoag Tribe of Gay Head (Aquinnah) (MA).

Nations as full partners in the fight to end the opioid epidemic and to underscore Congress's federal trust responsibility to ensure Tribal Nations are adequately equipped with necessary resources.

Opioid Crisis in the USET SPF Region

Opioid abuse, deaths, and trafficking have reached epidemic levels in Indian Country. Based on reports from Tribal/IHS health facilities within the USET SPF region, our Tribal Epidemiology Center (TEC), and law enforcement agencies, USET SPF suspects that rates of AI/AN opioid overdose and addiction among our member Tribal Nations are likely much higher than national statistics and current data reveal. For the last 12 years, USET's TEC has been conducting a mortality analysis, and now has a limited amount of data that speaks to opioid abuse among our member Tribal Nations. From that data, we have learned that 9% of all deaths among USET SPF Tribal Nations were somehow related to substance abuse between 2002 and 2012. Almost one in five substance use deaths were attributable to opioids, including heroin, with the vast majority of opioid deaths, 93%, prescription drug related.

However, USET SPF has learned that available data does not paint a complete picture of the problem within our region, as data is limited to information that is currently accessible through the Indian Health System. USET SPF Tribal Nations, as well as Tribal Nations across the country, have a distinct lack of complete data regarding substance abuse. An overall lack of data within the Indian Health System has not only impeded Tribal Nations prevention and treatment efforts, but also efforts to advocate for increased federal funding. Improvements in data collection, expanded reporting, and unidirectional data sharing will help Congress and Tribal Nations get a clearer picture of the extent of opioid epidemic in Indian Country. USET SPF strongly recommends the Committee work in consultation with Tribal Nations on initiatives that would address challenges in acquiring comprehensive data within Indian Country through subsequent legislation.

Direct Opioid Funding for Tribal Nations

The federal government has a trust responsibility to ensure Tribal Nations have access to resources, financial and otherwise, to combat the opioid epidemic. Among these vital resources is access to direct federal funding for Tribal Nations. Though our data on this issue is incomplete, that which is available shows Indian Country, including USET SPF Tribal Nations, is among the communities affected most by this crisis. And yet, we remain without critical resources, including federal dollars. USET SPF urges the Committee to prioritize addressing this shortfall by working to ensure Tribal governments have access to direct funding.

Unfortunately, within Indian Country, many federal grant programs require funding to pass through the states before it can be delivered to Tribal Nations. Because of this, many Tribal communities have difficulty accessing federal funds, with many completely unable to access them in this manner. Further, when applying for these grants, states will often include Tribal population numbers in the overall state population used to determine each state's award. Yet, Tribal Nations are not provided with outreach for these programs and are left with minimal resources to address the opioid crisis in their communities. In order to ensure Tribal Nations are fully accessing these federal funds in the future, USET SPF recommends the Committee and Congress:

1. Consider implementing a funding model utilized by the Centers for Disease Control and Prevention's Good Health and Wellness in Indian Country which allows for a direct, separate funding mechanism specifically for both Tribal Nations and TECs. This model has proven to be successful.

2. Expand language within grant funding programs to specifically include Tribal Nations so that states cannot exclude them in grant funding disbursements.

Tribal Addiction and Recovery Act
As discussed above, despite Tribal advocacy, Tribal Nations are ineligible for a majority of funding delivered to state and local governments under the 21st Century Cures Act. Where Tribal Nations are eligible for funding, they are forced to compete with state and other entities for limited dollars. On March 1, 2018, Congressman Markwayne Mullin introduced H.R. 5140, the Tribal Addiction and Recovery (TARA) Act of 2018. The TARA Act would make Tribal Nations eligible to be direct grantees of federal opioid funding under the 21st Century Cures Act in their efforts to combat opioid abuse in their communities. In addition, H.R. 5140 would provide an increase in grant funding of $25 million to state and Tribal Nations under the State Response to the Opioid Abuse Crisis within the 21st Century Cures Act. USET SPF supports this legislation[2] and requests the House Energy and Commerce Committee ensure this bill receive an immediate hearing on this bill.

Tribal Engagement at all Levels of Government
USET SPF reminds the Committee that Tribal Nations are sovereign governments to which each member of Congress has a trust responsibility. This trust responsibility is carried out not just through funding, but through meaningful government-to-government consultation and coordination. Tribal Nations have also been experiencing the destructive effects of opioid abuse within our communities, and we must be included as full partners in the fight to end the epidemic at all levels of government.

As the federal, state, and local governments are working together to ensure a coordinated, comprehensive response, Tribal Nations are frequently excluded from these efforts. Failure to include Tribal Nations when seeking solutions to the opioid epidemic will result in major gaps in the ability of the United States to eradicate opioid addiction in this country. These gaps in coordination are detrimental not just from a healthcare and treatment perspective, but from a law enforcement perspective, as well. As the trustee to Tribal Nations and in pursuit of a more comprehensive response to this crisis, the federal government must facilitate and require collaboration between Tribal governments and other units of government. Outreach from the Committee, as well as future legislation, should promote and require this necessary intergovernmental collaboration.

Culturally Competent Treatment
The incorporation of traditional healing practices and a holistic approach to health care are fundamental to successful opioid treatment and aftercare programs in Indian Country. Culturally appropriate care has had positive, measurable success within Tribal communities, and the incorporation of traditional healing practices and holistic approaches to healthcare has become central to many Tribal treatment programs. Tribal communities have unique treatment needs when it comes to substance abuse disorders, as AI/ANs experience high levels of substance abuse disorders, with a strong link to historical trauma. Opioid addiction treatment in Indian Country, then, must be cognizant of this trauma, respectful of community factors, and utilize traditional health care practices. Additionally, opioid addiction treatment within Tribal communities must include adequate culturally appropriate aftercare programs to help prevent substance abuse relapse. These services must be accessible through the Indian Health Care Delivery System.

Even though culturally competent care has had success across Indian Country, treatment options that incorporate cultural healing aspects are oftentimes not available within or near Tribal communities due to a lack of resources. However, some USET SPF member Tribal Nations are engaging in innovative practices that have the potential to be replicated across Indian Country. For example, one Tribal Nation's treatment program incorporates a culturally-based recovery model that has had great success, including in preventing early relapse following treatment. Other best practices within USET SPF Tribal Nations include:

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[2] USET SPF Board of Directors supporting resolution attached.

- Extended, culturally-based recovery support in a sober living environment; and
- Trauma informed care training for health and behavioral health staff.

Other notable best practices and culturally healing modalities not currently being employed by USET SPF Tribal Nations include:

- Rapid entry into an acute care facility (detox/inpatient care); and
- Prevention and control interventions developed utilizing the Community Based Participatory Action model.

With additional funding and guidance, these best practices have the potential provide higher rates of recovery for our people. USET SPF encourages the Committee to explore how it might expand and promote these models through legislative action.

Tribal Healing to Wellness Courts
In addition to traditional healing practices, USET SPF urges this Committee and Congress to support innovative, culturally-appropriate Tribal restorative justice models through sustained funding. Established as alternatives to conventional sentencing for non-violent individual offenders, Tribal Healing to Wellness Courts promote long-term recovery through treatment, community healing resources, and the Tribal justice process by using a multi-disciplinary approach to achieve the physical and spiritual healing of participants.

For example, USET SPF member, the Penobscot Nation, has operated a Healing to Wellness Court (HTWC) since 2011. Any individual Penobscot Nation citizen who is charged with a non-violent crime can petition to participate in the HTWC program. Once accepted into the program, the individual must agree to enter a guilty plea for the crime charged against him/her, but his/her sentence is "deferred" to allow the individual to go through the program. Then, a comprehensive, holistic plan is developed in collaboration between 10 Tribal government departments to address the individual's treatment needs in four phases:

- Phase I: Introduction/Education. This phase is focused on detoxification and beginning treatment and generally lasts 180 days.
- Phase II: Personal Responsibility. This phase is focused on stabilization and treatment and generally lasts 120 days.
- Phase III: Cooperation/Accountability. This phase is focused on maintenance and treatment and generally lasts 120 days.
- Phase IV: Completion/Continuing Wellness. This phase is focused on graduation and aftercare and generally lasts 120 days.

Successful completion of the program results in a dismissal of the participant's guilty plea. Over two dozen individuals have gone into the program since 2011. Recidivism is extremely low. The biggest problem that the Penobscot Nation has is that they do not have sufficient resources to accommodate all the individuals who are interested in participating in the program. While, the program is funded mainly through the Bureau of Indian Affairs, with supplemental funding from the Indian Health Service, the Department of Justice, and the Department of Housing and Urban Development, this is administratively burdensome and unlikely to result in additional resources for the Court. Similarly, while some grants offered by the Substance Abuse and Mental Health Services Administration (SAMHSA) could possibly be used for this purpose, SAMHSA's application requirements and standards often serve to preclude smaller, less resourced Tribal Nations from applying. The recovery model offered by Tribal Healing to Wellness Courts should be supported by this Congress, as it seeks to incentivize long-term sobriety and reduce criminal recidivism among drug offenders. In order to accomplish this, USET SPF urges this Committee to consider dedicated, sustained funding for this infrastructure in Indian Country.

Telehealth for Opioid Treatment

As with other telehealth programs nationally, the limited number of existing telehealth programs within Indian Country are making dramatic improvements in Tribal communities when it comes to healthcare, including access to care, diagnoses, treatment, and expansion of local healthcare treatment options. As the Committee considers the benefits of telehealth to treat and prevent opioid addiction, it is imperative that the unique telehealth needs of Tribal Nations are reflected in subsequent legislation. Within the Nashville Area of IHS, there have been multiple initiatives to expand the use of telehealth. These initiatives have provided multiple telehealth services within IHS and Tribally-operated facilities. Expanding the use of telehealth for treating substance abuse would add a vital component in efforts to address the opioid epidemic in Tribal communities.

Though Tribal telehealth continues to make strides, these programs continue to fall behind when it comes to developing sustainable telehealth infrastructure or a telehealth program standard system wide due to limited, or in some cases, lack of existing infrastructure and bandwidth. It is crucial that as the Committee and Congress consider the expansion and promotion of telehealth services, that they do so keeping in mind that additional funding is needed to modernize the existing infrastructure and bandwidth capabilities. Granting funding solely for telehealth will not be beneficial if the infrastructure and bandwidth remains insufficient. Further, modernizing existing infrastructure and bandwidth capabilities must be accomplished in a manner that protects Tribal cultural property and sacred sites.

Conclusion

The destructive effects of opioid addiction continue to devastate Tribal communities. Therefore, it is critical that Tribal governments have access to all the resources necessary to address this crisis. As both the Health Subcommittee and full Energy and Commerce Committee move forward with further hearings and legislative action on combating the opioid crisis nationwide, the Committees must remember the federal trust obligation to and the sovereign status of Tribal Nations and make this a priority. Should you have any questions or require further information, please contact Ms. Liz Malerba, USET SPF Director of Policy and Legislative Affairs, at LMalerba@usetinc.org or 202-624-3550.

THE KENNEDY FORUM

The Honorable Patrick J. Kennedy
The Kennedy Forum
Testimony for hearing titled: "Combating the Opioid Crisis: Prevention and Public Health Solutions."
Subcommittee on Health
March 21, 2018 10:00 AM

Our country is in the midst of an opioid epidemic that is spiraling out of control and threatening our communities from coast to coast, in rural areas as well as in urban areas, with no regard to race, ethnicity, or social class status. Roughly 175 people will die today of a drug overdose. Another 175 people will die tomorrow. Another 175 people will die on Friday. That's the equivalent of a jumbo jet full of people dying every three days.

Of course, everyone in this room knows that, which is why this hearing was scheduled. There are so many different ways upon which we must act to solve this epidemic. As all of you have heard me say before, including during every meeting of the President's Commission on Combating Drug Addiction and the Opioid Crisis, we will never solve the crisis without fully implementing the Federal Parity Law. We are turning our backs on science if we don't do everything in our power to increase access to medication-assisted treatment (MAT), which is the most evidence-based form of treatment for addiction. We cannot adequately address the epidemic if we don't improve and better coordinate prescription drug monitoring programs (PDMPs). We will still see far too many inappropriate opioid prescriptions if there is no improvement in provider and prescriber education about substance use disorders and those at elevated risk.

However, maybe the most pressing threat to the safety and wellbeing of individuals who have been treated or are being treated for substance use disorder is a set of federal privacy regulations. Those regulations, found at 42 CFR Part 2, endanger people's lives every day and codify our country's shameful legacy of secrecy and silence when it comes to addressing addiction.

The current federal substance use disorder treatment privacy protections were created with the best intentions and were vitally important when they were written in 1974. However, the main function they serve now is to maintain and perpetuate a separate and unequal system for individuals facing addiction that puts their lives at risk. I would know because the privacy rules put me directly in the crosshairs of danger. When I injured my arm four years ago the doctor in the ER wrote me a prescription for percocet because she had no idea about my extensive addiction treatment history since it was not on my medical record. This is happening dozens if not hundreds of times each day across this country because of the federal substance use disorder treatment privacy stipulations. That's going to continue unless we change the underlying privacy statute, which is what HR 3545 does.

THE KENNEDY FORUM

What good is provider and prescriber education about opioids if the clinician can't see the full medical record? Someone could be the most well-educated doctor in the world about addiction, follow all the right protocols, ask the right questions, and still prescribe an opioid to someone who shouldn't have any opioids because the addiction treatment information was hidden behind a cloak of secrecy.

These privacy rules also threaten those in recovery who are prescribed certain MAT medications, like I was a number of years ago. For example, someone who is prescribed Suboxone should not be prescribed Ambien because it increases the risk of respiratory failure and death. But, if the doctor treating a person taking Suboxone with concurrent sleep issues can't see the substance use disorder treatment record, she is very likely to go ahead and prescribe Ambien and greatly increase the likelihood of tragedy.

There are legitimate concerns some may have about changing the federal privacy protections that this legislation makes sure to guard against.

Maybe treatment information could end up being shared with someone's employer? Still illegal under this legislation.

Maybe treatment information could end up being shared with a person's landlord? Still illegal under this legislation.

Maybe treatment information could end up being shared in a criminal case or in a divorce hearing? Still illegal under this legislation.

The way the legislation is now drafted, there is no way treatment information can be shared with the outside world unless someone is breaking the law. It's not like the bill is throwing all privacy requirements out the window. It's simply putting HIPAA protections in place instead of 42 CFR Part 2 but also making the protections even stronger than HIPAA when it comes to preventing information from being released to civil and criminal courts. This is a commonsense piece of legislation that will undeniably save lives, reduce suffering, prevent inappropriate prescribing, and still protect those with substance use disorder from facing discrimination and retribution.

There are many different solutions that Congress must pursue to address this epidemic but this one should be right at the top of the list. We can never solve this crisis if we keep addiction treatment information hidden away in a separate box and think that by doing that we're protecting anything other than continued chaos and misery.

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

April 20, 2018

Dr. Ken Martz
Special Projects Consultant
Gaudenzia, Inc.
106 West Main Street
Norristown, PA 19401

Dear Dr. Martz:

Thank you for appearing before the Subcommittee on Health on March 21, 2018, to testify at the hearing entitled "Combatting the Opioid Crisis: Prevention and Public Health Solutions."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on May 4, 2018. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.dareshori@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

May 1, 2018

Ken Martz, Psy.D., MBA
Gaudenzia Inc.
106 W. Main Street
Norristown, PA 19403

Michael Burgess
Chairman
Congress of the United States House of Representatives
Committee on Energy and Commerce, Subcommittee on Health
2125 Rayburn House Office Building
Washington, D.C. 20515
Majority (202) 225-2927 Minority (202) 225-3641

Re: Confidentiality of Substance Use Disorder Patient Records, Combatting the Opioid Crisis, Prevention and Public Health Solutions

We appreciate the opportunity to provide the requested clarification to the Committee on Energy and Commerce, Subcommittee on Health. As discussed in the Committee, virtually all of the cases I have seen can be addressed effectively while respecting the balaneing concern of confidentiality protections. An understanding of the reasons for confidentiality as well as the desired coordination can lead to an effective and balanced solution that protects the individual seeking care. Focus should remain on the impact to the majority of those affected, rather than rare or very uncommon situations.

In your followup request, you asked:

- So if the providers cannot see methadone in the PDMP and the patient does not disclose this information to them, how can they know if a patient is getting prescriptions for controlled substances and methadone and is potentially at risk for a dangerous drug interaction?

Context: Every change to the confidentiality regulation has unintended consequences, since it affects multiple types of patients. Based on the limited details provided, an adverse impact caused by unknown multiple prescriptions as described is quite uncommon. When offering a new prescription, this limited risk of unknown interactions must be weighed against the known risks as noted on the FDA label change for all long-lasting opioids stating:

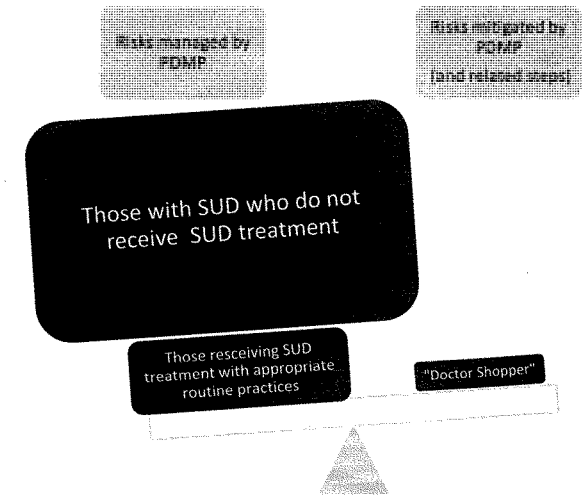
> "Because of the risks of addiction, abuse and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve [Trade name] for use in patients for whom alternative

treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain." (2013)

Scenario to explain the use of PDMP:

The follow-up question does not provide a sufficient detail of the concerning situation that is driving this particular effort. Therefore, accurately answer, I will describe a scenario in which an individual who is on methadone and seeks an additional prescription for opioids from another provider. This situation highlights the importance of the PDMP which may be used as an effective, although imperfect tool.

The illustration below demonstrates where this situation fits in the context of SUD.



Group 1) Majority scenario: Those with SUD who do not receive SUD treatment

The vast majority of those with SUD receive no SUD treatment whatsoever. Consequently, the PDMP accurately describes their medication history. Given the widespread

use and efforts at interstate sharing of data in this system it is perhaps the most complete source of information of this nature, although it is imperfect (it will not describe illicit use history).

Remember that SAMSHA reviewed and published two final rules in the past year and a half, after considering hundreds of detailed comments of information from the field over multiple revisions and review periods. They reiterated that 42CFR Part 2 would remain, and that its original purpose of "intended to insure that an alcohol or drug abuse patient in a federally assisted alcohol or drug abuse program is not made more vulnerable by reason of the availability of his or her patient record than an individual who has an alcohol or drug problem and who does not seek treatment.(42 CFR Part 2, §4.3 Purpose and Effect)". This conclusion is supported by their signature study; the annual National Survey of Drug Use and Health (NSDUH) that surveys over 90,000 Americans (the most recent was published September, 2017). The NSDUH study continues to find that two of the top reasons why individuals do not seek treatment are related to the fear of stigma. Specifically, they report concern of what others will think of them and fear of impacts on employment. They also find that among those who need treatment, approximately 90% do not receive it. Any considered changes to the system are weighed against the adverse impact to this majority.

While sharing of this confidential personal medical information is illegal under both HIPPA and 42 CFR, we know that adverse impact, and related discrimination is more common when personal data is more widely available. The current Cambridge Analytica situation has highlighted these risks, as well as the concern that disclosures today can lead to other unforeseen risks in the future. It is noteworthy that 42 CFR Part 2 is specific to the release of information from a Part 2 covered program. So despite its reputation, confidentiality does not impact sharing of personal data shared in other non-42 CFR settings (the majority of hospitals, doctor's offices etc.). One other key difference between 42 CFR and HIPPA is that 42 CFR requires the direct release of information from the patient, who thereby remains in control of the disclosure of their most personal guilt, fear, shame and trauma, while HIPPA permits sharing more broadly with a general release. These are the specific concerns of the majority of individuals with SUD, as illustrated by the NSDUH survey, and consequently must be central to any consideration since we can't help individuals who are so afraid of harm that they do not ever seek treatment.

Group 2: Those with SUD who are engaged in appropriate routine practice.

With routine practice, any physician asks the patient about their medical history, orders various lab tests, and seeks follow-up information from other treating physicians with a release from the patient. Similarly, it is routine that treatment providers in a Part 2 covered program monitor for changes in the medical history, check the PDMP, orders drug testing, and obtain signed releases for a variety of collaborators for coordination of care. The specific releases help to engage the patient in the treatment process. With these routine practices, there is coordinated care to prevent aberrant prescribing requests or associated drug interactions.

Group 3: "Doctor Shopping"

The third group of individuals include two subsets: those with a prior relationship with the prescribing physician and those without. In this scenario where both a general practitioner

and methadone clinic are working with a patient, there is already a release in place, as well as detailed information in the general practitioner's medical record due to the history. If a patient seeks additional prescriptions from this provider, the existing history will be glaring red flag, and simple follow-up phone call can maintain coordinated care. Even if a medication were prescribed, the methadone clinic could see the prescription change made by the general practitioner in the PDMP.

In the scenario of this patient going to a new general practitioner, what would they find when they check the PDMP? The Center for Disease Control finds that among those prescribed opioids, **there are an average of 3.5 opioid prescriptions per individual user** (CDC, 2017). Consequently, the prescriber would likely have reason to prescribe with caution (as indicated by the FDA warning label). When in any doubt (such as presenting risk factors or history), in the current environment of the opioid epidemic, it is good practice to order a drug screen prior to a new prescription of a controlled substance. This would help not only to protect against a drug interaction of prescribed medications, but also protect against interactions with other drugs obtained illicitly, which would be an expected risk in this subset.

Alternate Solution:

Rather than reducing confidentiality for millions of Americans, to potentially correct a concern in a serious but uncommon situation, emphasis should be placed on:

- The methadone provider offering adequate treatment and referring to more intensive care when the outpatient medication assisted treatment is inadequate to stabilize a patient.
- The methadone provider engaging in continued monitoring of PDMP to adjust the treatment plan.
- Insurance or other funders authorize and pay for adequate intensity and duration of SUD treatment, just like offering the proper dose and duration of an antibiotic.
- For some individuals, outpatient treatment is not adequate stabilization, so the removal of the Institute for Mental Disease (IMD) barrier to residential care is critical for these patients.
- The prescribing community use due caution with opioid prescribing, which would include checking the PDMP as well as drug testing prior to offering new prescriptions in patients that demonstrate risks.
- Use of effective best practices including routine releases of information and direct coordination of care rather than "access" to a record.
- Remembering that there is a struggling patient at the center of this. If we stop them from obtaining a prescription, they will go illicit sources instead. Therefore, the emphasis must be on improving their clinical care, rather than trying to simply "catch" a unique situation.

As discussed, the best solutions invariably are grounded in the effective relationship building with a patient directly, who will always know more than we will, since they know what was used illicitly.

In terms of outlining the context, there is one other group to consider, which is larger than any of those mentioned above; the recovery community. There are an estimated 23.5 million Americans in recovery from SUD. While some may have the financial means, and recovery support to share their personal information, many continue to avoid disclosing these past behaviors for fear of impact on their employment, housing, or other situations, years later. At the recent SAMHSA listening session on confidentiality, a testifier discussed how he continued to face challenges for a heart condition and pain management, many years after being labeled with SUD following a severe spinal cord injury. A recent New York Time exposé entitled *"Injecting Drugs Can Ruin a Heart. How Many Second Chances Should a User Get?"* discusses offering SUD treatment as a rationale to deny surgery:

> "Dr. Pollard has been lobbying hospital systems in Knoxville to provide addiction treatment for willing endocarditis patients, at least on a trial basis, after their surgery. If the hospitals offered it, he reasons, doctors would have more justification for turning away patients who refused and in the long run, hospitals would save money."

Taken together, the PDMP offers a means to mitigate the risk of drug interactions, identify aberrant drug seeking, and engage a patient in the proper SUD treatment, while protecting the civil rights of personally protected information from being spread unnecessarily.

If you have additional questions as they relate to the critical nature of confidentiality on the SUD treatment relationship, please let me know. Since the question posed relates directly to methadone, you might also seek input from the American Association for the Treatment of Opioid Disorders, the national association specializing in this area.

Again, thank you for your careful consideration in this complex issue that is so sensitive in the context of the current epidemic.

Sincerely,

Ken Martz, Psy.D.

Ken Martz, Psy.D., MBA, CAS
Licensed Psychologist
Gaudenzia Inc.

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
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Majority (202) 225–2927
Minority (202) 225–3641

April 20, 2018

Ms. Jessica Hulsey Nickel
Founder, President, and CEO
Addiction Policy Forum
718 7th Street, N.W.
Washington, DC 20001

Dear Ms. Nickel:

Thank you for appearing before the Subcommittee on Health on March 21, 2018, to testify at the hearing entitled "Combatting the Opioid Crisis: Prevention and Public Health Solutions."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on May 4, 2018. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.dareshori@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

Following Questions submitted by Brett Guthrie:

"Currently there are only three types of medications approved for the treatment of opioid use disorders (methadone, naltrexone and buprenorphine), yet according to a recent analysis in Health Affairs fewer than 3% of all licensed substance abuse treatment facilities in the country are able to offer all three. In other words, we have a lot of one-size-fits-all treatment programs."

1. What's wrong with our current, fragmented and siloed approach in the treatment of opioid use disorders?

Patients and families struggling with substance use disorders (SUDs) often do not know where to find high quality, evidence-based treatment. In a crisis, many turn to google, where search results display treatment programs that appear to be high quality due to their use of therapeutic buzzwords and expert marketing. But many of them do not provide treatment services that meet current standards of care, leaving patients and families in crisis incredibly vulnerable to predatory marketing schemes. Because our patient population, and arguably substantial sections of the field as a whole, are uneducated and/or misinformed about what evidence-based care for SUDs actually entails, quality of *marketing*, rather than *care*, tends to dictate which facilities people encounter and "trust" with loved ones.

There are countless examples of families taking out second mortgages or bankrupting themselves to pay for what they assumed to be excellent and critical care, only to learn later that they were misled by programs offering substandard treatment. When a person is struggling with a severe SUD, their loved ones often feel alone and afraid, and they will do whatever they can to find help. Unfortunately, because the current state of treatment in this country is so poor, many receive bad advice and take action that ends up hurting their loved ones rather than helping them.

Historically, the general health care system has not taken responsibility for treating addiction. SUD treatment has remained relatively isolated from innovations that have transformed modern medicine and led to increasingly integrated systems of care. Because addiction treatment exists in *a* silo, most medical students are inadequately trained to diagnose and treat SUD. As a result, general health care providers (primary care, emergency department physicians) often do not know where to refer people for high quality care. This means that even if they recognize the signs and symptoms of SUD in their patients, they do not know how to effectively respond to their needs. The few providers who are trained in evidence-based treatment for SUD commonly find themselves surrounded by an "addiction treatment desert" as so few facilities operating in the U.S. provide evidence-based care.

2. How do you believe the Comprehensive Opioid Recovery Centers, or "CORCs," would help to correct this problem?

CORCs would ensure that patients and families have access to trusted treatment programs offering the most current standards of care and provide evidence-based treatment for SUDs.

There are only three medications available to treat opioid use disorders and very few facilities provide all three. Each patient has a unique profile, defined by his or her circumstances, biology, environment, medical history, etc., that influence which medication will

be most effective. Patients should have access to all three medications, and the decision of whether to use medication, and which one, should be made with their doctor, based on an accurate understanding of the scientific evidence and the individual patient's needs and circumstances.

The Comprehensive Opioid Recovery Centers Act (CORC) of 2018 will help address these barriers through the development and promotion of integrated care models based on best practices, which will build a pathway toward the comprehensive health care infrastructure that must be achieved to ensure that everyone suffering with a substance use disorder has access to quality treatment. More importantly, the legislation would provide resources to operate these centers, which will provide the full spectrum of evidence-based treatment services including intake evaluations and regular assessments, all Food and Drug Administration (FDA)-approved treatments for substance use disorders, detoxification, counseling, residential rehabilitation, recovery support services, pharmacy and toxicology services, and interoperable electronic health information systems.

3. In your work with family members of people who unfortunately have lost their battle with addiction as a result of an opioid overdose, how common is it that their loved one completed treatment without being offered a range treatment options and the necessary support services?

Unfortunately, this is all too common. We have heard countless families, who have lost a loved one to this disease, reflect on the fact that they had no idea medications existed to treat opioid use disorder (OUD). It is devastating for these families to be left to grapple with the fact that their children were denied basic care, let alone the gold standard of treatment, and to wonder whether their child would still be alive if they had been armed with better information and access to evidence-based treatment.

4. One of the unique provisions of CORCs is the requirement that they provide job-training and job placement assistance. Why might this be an important component within a treatment center?

Job training, placement assistance and other wrap-around services are essential to help patients recover from addiction and rebuild their lives. When left untreated, SUDs tend to get worse over time. As the disease progresses, those struggling with a SUD often find it harder and harder to perform basic functions in their personal and professional lives. Loss of employment and difficulties performing at work are key indicators used by doctors to assess the severity of a patient's disorder.

Severe SUDs have profound effects on every aspect of a person's life, often leading to delays in education, gaps in job history and legal challenges, as well as problems with family and social relationships. In order to achieve and maintain long-term recovery, patients may need a diverse array of supports to rebuild their lives—including help finding stable housing, employment, recovery-supportive communities, repairing interpersonal relationships, etc. There are many things that employers can do to help address addiction in the workplace and better assume their role as a critical point of intervention for those struggling with substance use. Job

training and job placement assistance are examples of wrap-around recovery support services that maximize a person's chances of living in long-term recovery.

GREG WALDEN, OREGON
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April 20, 2018

Mr. Ryan Hampton
Recovery Advocate
Facing Addiction
177 East Colorado Boulevard; Suite 200
Pasadena, CA 91105

Dear Mr. Hampton:

Thank you for appearing before the Subcommittee on Health on March 21, 2018, to testify at the hearing entitled "Combatting the Opioid Crisis: Prevention and Public Health Solutions."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on May 4, 2018. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.dareshori@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

Attachment — Additional Questions for the Record the Honorable Gus M. Bilirakis

RESPONSE FROM RYAN HAMPTON

1. Thank you for joining us today and sharing your experience. The opioid crisis is not bound by socio-economic status, state lines, ethnicity, sex, or age –even our seniors are not immune to this public health emergency as they are highly impacted by acute and chronic pain. It's critical we hear from all stakeholders affected – especially those in opioid recovery.

- Can you describe for us the importance of sober housing to someone in recovery – why is it necessary?

ANSWER FROM RYAN HAMPTON:

Sober living houses (SLHs), more commonly called sober homes and sober living homes and more rarely sober living environments, are facilities used by people recovering from substance use disorder that serve as an interim environment between rehab and mainstream society. SLHs grew out of a need to have safe and supportive places in which people could live while they were vulnerable in early recovery. They are primarily meant to provide housing for people who have just come out of rehab (or recovery centers) and need a place to live that is structured and supporting for those in recovery.

Residents are often required to participate in 12-step meetings, take drug tests and shaw demonstrably that they are taking important steps to lang lasting recovery. As a whole, experienced addiction treatment providers ogree that remaining in sober living/aftercare following treatment can result in substantially improved results. One of the key factors has to do with the level of structure, however. Residences utilizing a higher level of structure tend to see dramatically improved results in terms of long-term recovery.

Recovery-supportive houses provide both a substonce-free environment and mutual support from fellow recovering residents. Mony residents stay in recovery housing during and/or after outpotient treatment, with self-determined residency lasting for several months to years. Residents often informally share resources with eoch other, giving advice borne of experience about how to access health care, employment, manage legal problems, and interact with the social service system. Some recovery houses are connected with the Nationol Alliance of Recovery Residences, a non-profit organization that serves 25 regional affiliate organizations that collectively support more than 25,000 persons in recovery across over 2,500 certified recovery residences.

2. Patient brokering continues to be an issue in Florida. Upon learning that various mental health and substance abuse facilities were making payments to individuals for the referral of patients identified in Alcoholics Anonymous meetings, homeless shelters, and other similar environments, Florida's legislature passed The Patient Brokering Act to prevent it by making the

perverse practice a third-degree felony punishable by up to 5 years in prison. However, monitoring and enforcement continue to challenge my state.

- That said, what are patients currently doing to protect themselves from being taken advantage of by these bad actors?

  ANSWER FROM RYAN HAMPTON:

  When desperate families and patients enter the addictian treatment and saber living spectrum for the first time, their level of awareness araund the patient brokering practices and bad actors is minimal. Peaple are not thinking of ethics when their loved one is on the verge af dying. They trust the system they are provided with. For example, when my mather went searching for help for me when it was apparent that I had a problem with heroin, she was nat thinking that she needed to explore the business practices of providers – rather she was loaking for what she thought was the best possible care. And unfortunately, there is no trusted roadmap for families and lax aversight and regulation. Therefore, families are often led right inta the hands af predatory providers and bad actors – nat knawing what they are getting into.

  Under the current system, bad actors can look exactly the same as good operators. It is easy for them to disguise themselves because there is no national standard, no system for distinguishing the good fram the bad, no oversight, and very little enforcement to protect families and people struggling.

  The federal government has a responsibility to set a natianal standard and provide guidance ta the states on how to effectively end this practice and protect people with substance use disarder, their families, and loved ones.

- Knowing full-well that patient brokering is occurring, why hasn't the recovery industry created a national standard or distributed best practices?

  ANSWER FROM RYAN HAMPTON:

  I do not believe we can leave the recovery industry to palice itself when it comes to protecting people from patient brokering and unethical, criminal practices. There have been many attempts from within the recovery industry to set standards, however these organizations do not have regulatory oversight nor the power to enforce.

  The time has come for the federal government, as well as state and local governments, to step in.

  During the financial crisis of 2008, the federal government did not ask the questian as to "why" the financial/banking industry just doesn't regulate and police itself. They stepped in and took immediate action.

People's lives are at risk. We da not have the luxury of relying on a broken system to police itself.

# # #

GREG WALDEN, OREGON
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April 20, 2018

Ms. Stacy Bohlen
CEO
National Indian Health Board
910 Pennsylvania Avenue, S.E.
Washington, DC 20003

Dear Ms. Bohlen:

Thank you for appearing before the Subcommittee on Health on March 21, 2018, to testify at the hearing entitled "Combatting the Opioid Crisis: Prevention and Public Health Solutions."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on May 4, 2018. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.dareshori@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

National Indian Health Board

May 4, 2018

The Honorable Michael C. Burgess
Chairman, Energy and Commerce Subcommittee on Health

c/o Zack Dareshori
Legislative Clerk, Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Burgess,

Thank you for submitting additional questions for the record related to my testimony on March 21, 2018 at the Health Subcommittee hearing entitled, "Combating the Opioid Crisis: Prevention and Public Health Solutions."

Please see attached my responses to the questions submitted for the record. Thank you for your continued leadership regarding America's opioid crisis and your particular attention to the needs of American Indians and Alaska Natives on this issue.

Please do not hesitate to contact me with any questions.

Yours in Health,

Stacy A. Bohlen
Chief Executive Officer
National Indian Health Board

Attachment — Additional Questions for the Record

The Honorable Michael C. Burgess, M.D.

Ms. Bohlen, as you have read from Chief Cook of the St. Regis Mohawk Tribe written testimony, there are concerns regarding the bill to enhance and improve state-run prescription drug monitoring programs.

- While I understand that integration with state-level PDMPs has been difficult, to what extent are the Indian Health Service and tribal physicians and pharmacies using PDMPs today?

Chairman Burgess,

Thank you for your question. Currently, the Indian Health Service (IHS) uses the Resource and Patient Management System (RPMS) as its single, combined electronic information system for both clinical and public health data. All Tribes must upload certain reports into RPMS, although some Tribes run their own health programs, and may use a different electronic health record (EHR) platform.

RPMS faces challenges to data interoperability with state Prescription Drug Monitoring Program (PDMPs) and other coordinated efforts, such as Electronic Clinical Quality measures (eCQMs). This is one reason why the Veterans Administration (VA) is moving away from its VistA program, which is very similar to RPMS, toward a more integrated platform where electronic health records can communicate with PDMPs. Congress has provided resourced for the VA to make this transition, but IHS will be unable to follow due to lack of funding.

In July, 2016, the IHS released a new rule mandating all IHS providers and dispensers of opioid medications to utilize their state PDMP database prior to issuing or dispensing a prescription for opioids. This policy mandate did not extend to providers and dispensers employed by a Tribe – meaning that those providers can elect to check their state PDMP system at their own discretion. Training staff on how to utilize new information technology (IT) systems such as PDMPs can require a significant amount of agency resources including funding and personnel time, and thus the National Indian Health Board would encourage Congress to continue its support for Health IT training within the Indian health system.

In FY 2017, Congress appropriated $1 million to the IHS to create a specific PDMP that would serve all IHS, Tribal, and Urban Indian facilities. To my knowledge, IHS has not created this yet, nor has the agency proposed a timeline for doing so. I would encourage you to use your oversight authority to ensure administrators at IHS prioritize this I/T/U PDMP given its potential to improve surveillance of prescription drug access and diversion.