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RPTR ALLDRIDGE

EDTR ZAMORA

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, D.C.

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, Lujan, Kennedy, Degette, and Pallone (ex officio).

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

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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.

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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.

The Chairman. 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

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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 relevant 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

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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 support 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.

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[The prepared statement of Chairman Walden follows:]

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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.

[The prepared statement of Mr. Guthrie follows:]

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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.

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.

115 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.

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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, Lujan, 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

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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 noncontroversial 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:]

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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.

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.

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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

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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:]

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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.

[The prepared statement of Mrs. Blackburn follows:]

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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.

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

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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

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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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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.

[The prepared statement of Ms. Matsui follows:]

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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.

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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.

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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

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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

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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

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forward to working close with you to help safe lives.

[The prepared statement of Dr. Gottlieb follows:]

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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

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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

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data from emergency rooms, emergency medical services, 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.

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[The prepared statement of Dr. Schuchat follows:]

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Mr. Burgess. Thank you, Doctor.

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

STATEMENT OF CHRISTOPHER M. JONES, PHARM D

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

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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

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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

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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:]

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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. I mean, 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? I mean, 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

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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, you know, 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.

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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 are you able -- 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 commiserate 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. I mean, 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

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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, you know, 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. I mean, 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

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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 the 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.

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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. I mean, 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 Substances 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, you know, crossed the Rubicon, if you will, with respect

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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. Okay. 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, Lujan, and Bucshon, the Comprehensive Recovery Centers Act. That seems like something that we -- it 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

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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.

The Chairman. 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,

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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. Yeah. 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 sort of 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 -- you

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know, 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.

The Chairman. 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

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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. I mean, those are the large areas where we are working.

The Chairman. 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, I think it was -- 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

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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.

The Chairman. 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

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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, you know, 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,

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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:]

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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, you know, 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.

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[11:00 a.m.]

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.

You know 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, you know. 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

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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 you 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 .05 percent up to a more representative sample.

Mr. Pallone. Thank you. Thank you, Mr. Chairman.

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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, Lujan, 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 what -- 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

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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 released, 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 everybody -- 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 things for that patient access that they would be able to access that, same with buprenorphine 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. I mean 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 kind of 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

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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 who 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. There is one -- 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 kind of addressed it, but I just want to kind 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

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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 among the array of services an individual would need to be successful.

Mr. Guthrie. Thank you. I am about out of time. That kind of 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 increased 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 representative 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?

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Dr. Schuchat. You know 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 hepatitis 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.

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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 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, you know, 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. Okay. 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

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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 addicted, 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

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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. Okay. 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 well 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

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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 that I know -- 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 that -- 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 abused 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

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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 conveying 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,

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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 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 these bad actor who dresses up an opioid as an ordinary pharmaceutical

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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 treatment 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 is -- 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

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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 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

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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

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needed like almost at 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 sort of a siloed fragmented system where it may be, you know, 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 sort of of treatment on demand.

So when somebody comes in, that is again sort of 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 certainly a State that has been hard hit 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

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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 a 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

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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. So I think that it is -- we don't have, you know, 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 affects 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 their lives would be significantly changed if they can't have access or a long set through a

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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 kind of 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 been -- 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 --

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Mr. Shimkus. And let me finish on this one. I am sorry to be so short. Fred Upton kind of went down this rabbit hole on the long-term aspects of different drugs that aren't addictive. But how about the -- 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. Yeah. One of 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

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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 more 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 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 they are conflicting messages coming out of this

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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 around 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. You know, neonatal abstinence syndrome is an issue that obviously affects as it impacts on newborns because of addictions with 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

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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

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speed and can't comment on it.

Mr. Kennedy. Appreciate that.

\$800 billion less than Medicaid though you were there a little while ago. \$800 billion cut to Medicaid, will it strengthen or hinder the program?

Dr. Gottlieb. You know, 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

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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 labelling. And what we are seeing more and more are minimally labeled drugs.

Sometimes we are seeing whole boxes of just pills with no labelling 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 labelling 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 labelling is online. So what we have is our investigators in these facilities going online and doing a lot of research around these

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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 small number of packages per investigator. So this could make us for more efficient in those facilities.

Mrs. Blackburn. Okay. 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

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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

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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. Yeah 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. Yeah. 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. Okay. 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 expand treatment programs. We have already had \$15.7 million in Colorado. It has already helped 22,000 people in

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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 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. Okay. 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

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funding for that.

Ms. DeGette. Okay. Great.

Dr. Gottlieb, 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. We don't -- 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

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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

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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 find -- 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. You know, 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

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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 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 the outcomes, multiple outcomes for patients.

Mr. Latta. Dr. Jones you also mentioned that 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.

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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 kind of 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. Okay. 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. Lujan. 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

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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. Lujan. 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. Lujan. 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. Lujan. 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

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these drugs has contributed to the opioid epidemic.

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

Mr. Lujan. 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 from 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 CDC -- 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 of 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 six-fold 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

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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 three-fold the prescribing of opioids that they have in Europe but we do not have threefold the pain that they have there.

Mr. Lujan. 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. Lujan. 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. Lujan. 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

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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.

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RPTR ALLDRIDGE

EDTR ZAMORA

[12:00 p.m.]

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 follows:]

***** COMMITTEE INSERT *****

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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. Yeah. 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.

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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 Lujan 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.

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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. 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. 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.

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Mr. Lance. I will not.

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

Next slide. 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. This, again, shows you an individual package, again, with a

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potpourri of different drugs in it, including opioids. The drugs on the far right with the green labeling are actually narcotics.

Next slide. 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. But they do, you know -- 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. This is a teddy bear. We didn't set out to seize the teddy bear, but -- next slide. 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. 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

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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. You know, 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, you know, 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. I mean, these are typically, you know, 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

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pills isn't going to an individual.

Ms. Schakowsky. Is there followup to the receiver of these pills?

Dr. Gottlieb. Depending on what we find, sometimes we -- we refer hundreds of cases for investigation, and sometimes criminal investigation, depending on what we find. And sometimes we will -- 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.

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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, you know, 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, you know -- 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 of 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

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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. -- 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

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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

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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. We focus on -- 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

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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, yeah.

Mr. Griffith. -- 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. Yeah. 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. Yeah. Not labeled, destroy it.

Dr. Gottlieb. I haven't contemplated it. You know, 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.

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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 -- how would that discussion draft help CDC?

Dr. Schuchat. Yeah. We think that having -- 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 be controversial, but you said something earlier that triggered, you know, my brain to working on something.

Dr. Schuchat. Okay.

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

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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 quicker 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. You know, 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 the -- what the prescription drug monitoring programs are doing is they are looking at prescribing to the patient, not, you know, 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. Okay. 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

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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 context in

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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, you know, some of the specifics of our budget are still working through and, you know, we have a budget and brief that is out, but the other

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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 follows:]

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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 dependency 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

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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 now address, in closing -- oh, my time is up.

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 -- 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, you know -- 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, direct it to be done, particularly for the IR drugs. But we will continue to work within the scope of our authorities to see, you know, whether this

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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. And that would presumably -- I think it would, you know, very clearly take more pills out of circulation that didn't go on to be diverted. Because we have data -- 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 follows:]

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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. Yeah. 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 towards 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 worst. 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

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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. You know, 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, you know, 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

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statement about patients who have medical need. I mean, 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, you know, 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.

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You know, 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

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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

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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 kind of 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

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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

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funding announcements so that we are actually helping to drive evidence into practice through our funding streams and not continuing to support nonevidence-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

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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. Yeah. 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, I think, again, sort of 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

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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 supported 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 know, you thought you had a problem in city X, but it is actually, you know, 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 when they -- 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, he said, I knew when I got out of rehab that I couldn't do the same amount, you know, of heroin

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that I used to do. But, you know, I just did a -- I can hardly get it to melt on a spoon, and, you know, it about killed him. So they got him on whatever drug it is, the high-price injection thing. I mean, I say high price, \$1,000 a month. You know, and 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, I mean, if we -- if you just sit there and write checks all day, is there anything we can do that -- I mean, 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. Okay. I am way past my time.

I yield back. Thank you.

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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. You know, 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. Okay. Yeah. Because, I mean, 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 very -- across an entire spectrum. So that

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is difficult.

So information on people that truly have, I think, chronic pain syndromes that may require long-term opioid treatment would make -- 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. Yeah. I think it could be helpful, but also knowing what are the best approaches for that. You know, 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. Yeah. So I think we have been taught that, you know, 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. I mean, 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.

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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 nonpharmacological 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, amongst 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

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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 that don't -- 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 sort of 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. Okay. I appreciate that. Yeah. 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.

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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 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. Yeah. 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

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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, you know, 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. Yeah. 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

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to be looking for, monitoring for, and raising the level of awareness with our State and local health officials?

Dr. Schuchat. Yeah. 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. You know, 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 hepatitis -- 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.

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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.

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RPTR ZAMORA

EDTR SECKMAN

[12:59 p.m.]

Dr. Gottlieb. Yeah. I mean, 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 avenues 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. Okay. 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 towards blister packs, you, in fact, are going to cut down on the rate of

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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. Okay. 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, 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

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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. And, you know, 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 starting July 1st.

Dr. Schuchat. Yeah. 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. Okay. 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, okay.

But, you know, 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?

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I mean, 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. I mean, 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. Yeah. I mean, 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. I mean, 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. Okay. Dr. Jones.

Mr. Guthrie. [Presiding.] We have got to run over time on this. We need to

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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

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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.

[The information follows:]

***** COMMITTEE INSERT *****

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Mr. Mullin. 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 sort of marginalization. So, you know, 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 couldn't -- I literally couldn't agree more with that. You know, 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

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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 -- you know, 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, you know, 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? Yeah. 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? Okay. They can receive them in the mail. The prescription would be controlling the size in that circumstance.

Mr. Carter. Right. Right. Okay. 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

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the VA, and many other 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.

There are people -- 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

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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 public, 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,

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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 of -- 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 the -- 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. I mean, yeah, we need to attack the supplier, but we need to attack the users as well. I mean, are we doing that?

Dr. Gottlieb. Yes, we are.

Mr. Carter. Okay. 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

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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 expert 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.

So it is not -- 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. Yeah. 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.

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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 we do -- 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.

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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.

Mr. Jones -- or 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

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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, you know, 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?

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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 my -- 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, you know, 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," you know, "I made my decision, this is how I want to proceed," while getting pressure from the anesthesiologist that, you know, "Well, you need this."

I mean, 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.

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Mr. Walberg. I appreciate that. Thank you.

Mr. Guthrie. Thank you for yield 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 think 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 -- as you know, 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

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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, you know, 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 what we -- that is 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 a useful tool 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 decisionmaking, 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.

You know, I stick to my knitting, and I stay within the scope of where I can affect

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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. You know, 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 work -- worse.

In terms of, you know, 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.

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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. You know, my highest priority is rapid quality data so that we don't make mistakes. And if we have unintended consequences like we, you know, 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, you know, 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 through -- 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.

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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 am -- 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 needs to have -- says he needs to have serious pain medicine, I see both sides of this.

And I am getting more and more -- I am very active on this issue, as you know. I am doing many -- 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 are -- that are legitimately

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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, I think that -- 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

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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 is -- 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

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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 to -- and so each of you will be given the opportunity to do an opening statement, and it will be followed by -- member 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?

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Ms. Thau. It is Thau.

Mr. Guthrie. Thau, okay. 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.

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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

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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

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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:]

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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

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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,

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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

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treatment of these diseases.

BIO strongly believes that innovation is a key component of efforts to address opioids -- 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:]

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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.

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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 physicians and other prescribers; and the proper prescribing of prescription drugs, particularly opioids; mandatory ongoing training for

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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.

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[The statement of Mr. Francer follows:]

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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

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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

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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.

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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:]

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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 stigma. 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 response -- 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

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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 of up 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 a great -- 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

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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 want -- us here today to -- 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.

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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.

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RPTR DEAN

EDTR ZAMORA

[2:00 p.m.]

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 this piece of -- 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

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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. Okay. 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

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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, is the -- 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 prescriber passes. And I am very -- 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 just 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 or is there -- 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. Yeah. 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

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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. Yeah, 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. Yeah. I mean, look at the hospice patient who may be on painkillers and other, you know, 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.

Let me just turn -- so I appreciate that. I think that is something we have to

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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 would -- 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 mean, 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.

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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 for 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,

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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

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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. Okay. 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

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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.

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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 sort of 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

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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, you know, speaking for myself, I remember growing up with kind of 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 Detera 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 eliminated 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.

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Mr. Guthrie. I thank gentlelady for yielding back.

The chair now recognizes Mr. Lujan for 5 minutes for questions.

Mr. Lujan. 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, quote: "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, quote: "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 use -- combating drug issues, including the current opioid epidemic. Most of the emphasis 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?

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Ms. Thau. Yes. I would say absolutely in general it does. We need to -- 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, especially -- 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. Lujan. 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'

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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. Lujan. 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 addictive 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. Lujan. 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. Yeah. There is a lot of data saying that selective interventions, as well as indicated interventions, are very effective.

Mr. Lujan. 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.

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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 there has actually been -- 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 able to -- 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

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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. Okay. 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

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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, you know, 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

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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, are you -- 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.

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Mr. Pallone. Well, you know, we have -- 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.

Would your organization support -- 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. Yeah. 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, you know, looked to see what -- you know, these -- 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. Yeah. 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

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this, any of the other panelists? I still have 1-1/2 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. Yeah. 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, you know, raising the price of cigarettes and, you know, 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 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 mean, 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

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extra \$6 billion. But there is no easy answer. And I always take -- 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, you know, 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.

The Chairman. 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.

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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, you know, 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.

The Chairman. There you go.

Ms. Thau. These are places a decade ago where people were dying of fentanyl!

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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 less 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 less people who start using, the less 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.

The Chairman. 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, you know, 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 sort of stop, and you wonder, do we need all of this? Are there alternatives that are better in terms of pain management?

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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. I apologize 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.

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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. -- that you would put into your prescription vial with some water, shake it up, and throw it away.

You know, 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.

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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

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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, okay, 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

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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, is 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, you know, 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

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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, you know, 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. I think -- but really truly, you know, 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

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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.

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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, you know. 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. Okay, very good.

Okay. 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

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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, because that -- 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

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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

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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 -- excuse me -- 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

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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 take -- 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 things that -- changed behaviors, recycling.

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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 acceptable -- or 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

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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 receive -- 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 you can't count on -- 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.

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RPTR ZAMORA

EDTR SECKMAN

[2:59 p.m.]

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.

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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," you know, 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 them -- 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 can -- 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, you know, 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 and do encourage people, because it is safe; it is convenient. We have always encouraged them to, you know, 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, you know, 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.

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I mean, once you get passed ibuprofen and tramadol, you go to the opioids, and there is really nothing in between. Now, you know, 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 what they -- the innovation they have come up with through research and development. But there is a big gap there.

One of the things that -- one of the -- 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. You know, 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.

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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 reexamined. 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. Okay. Well, I was really -- I really do think that that was something that we needed to do. And, you know, right now, it is just between -- 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, you know. It is going to take all of us and many solutions to help with this. So thank you.

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And I yield back, Mr. Chairman.

Mr. Burgess. The chair thanks the gentleman.

The gentleman yields back.

And, Mr. Francer, let me just ask -- 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 followthrough 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 that -- in addition to the coverage barriers that -- and the NIH data analysis proposals we have put forward.

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Again, going back to my earlier statements about the importance of signaling to investors that the development of improved -- of treatments that are better, that provide improved quality of care, and are safer are our top priority. There are lots of ways that -- to create an environment that will stimulate investment.

And at the FDA, there are development issues as we look over sort of 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, you know, 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.

There is also some -- 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 you are sort of diverting -- 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. You know, 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

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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, you know, again, we find there is a lot of value, again, in just holding public -- you know, where you have a topic, you hold a public meeting, you bring the best and brightest together to discuss critical issues. And then the important part -- 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

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before.

And I would like to, you know, just if I have -- 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. Okay. And I am just asking for a friend. I was not going to chew the emulsified pills.

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Seeing -- Mr. Green, did you have a redirect?

Mr. Green. No.

Mr. Burgess. You have been sitting here so patiently.

Seeing that there are no other -- 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.]