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COMBATTING THE OPIOID CRISIS: HELPING COMMUNITIES BALANCE ENFORCEMENT AND PATIENT SAFETY

WEDNESDAY, FEBRUARY 28, 2018

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 1:04 p.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, Long, Bucshon, Brooks, Mullin, Hudson, Carter, Walden (ex officio), Green, Matsui, Castor, Sarbanes, Lujan, Schrader, Degette, and Pallone (ex officio).

Also Present: Representative Walberg.

Staff Present: Jennifer Barblan, Chief Counsel, O&I; Mike

Bloomquist, Staff Director; Adam Buckalew, Professional Staff Member, Health; Daniel Butler, Staff Assistant; Kelly Collins, 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, O&I, DCCP; Jay Gulshen, Legislative Associate, Health; Zach Hunter, Director of Communications; Ed Kim, Policy Coordinator, Health; Mark Ratner, Policy Coordinator; Kristen Shatynski, Professional Staff Member, Health; Jennifer Sherman, Press Secretary; Austin Stonebraker, Press Assistant; Hamlin Wade, Special Advisor, External Affairs; Waverly Gordon, Minority Health Counsel; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Jourdan Lewis, Minority Staff Assistant; Samantha Satchell, Minority Policy Analyst; Andrew Souvall, Minority Director of Communications, Outreach, and Member Services; and Kimberlee Trzeciak, Minority Senior Health Policy Advisor.

Mr. Burgess. The Subcommittee on Health will now come to order. I will recognize myself for 5 minutes for the purpose of an opening statement.

On the average, 115 Americans die every single day from an overdose of an opiate. Our Nation remains in the grip of a frightening epidemic. The latest report from the Centers for Disease Control and Prevention list West Virginia, Ohio, New Hampshire, Pennsylvania, and Kentucky, as the five States hardest hit, but we all know the crisis has ravaged every one of our States. The statistics are heartbreaking. Five people every hour on the hour die from an opioid overdose.

It has been said before; it bears repeating: Now more than ever we must come together and strengthen our commitment to fight this. It requires an all-hands-on-deck approach. Today's hearing is the first of three legislative hearings on combatting this crisis.

This hearing is the product of the Member Day the Health Subcommittee held last October where over 50 Members of Congress, bipartisan Members of Congress, both on and off the Energy and Commerce Committee, came to us and shared with us their personal stories of how the epidemic has devastated their communities, and they also offered potential legislative solutions. Since then, our teams have been hard at work examining these policies and engaging the relevant stakeholders.

There are two panels of witnesses before our subcommittee today. First, I do want to welcome Susan Gibson, the Deputy Assistant Attorney in the Diversion Control Division at the Drug Enforcement

Administration.

Ms. Gibson, we look forward to hearing your thoughts and the progress the DEA has made to stem the flow of opiates through our neighborhood, and how these legislative proposals would strengthen the agency's efforts in what is now a public health emergency in our country.

On the next panel, we will hear from a cross section of stakeholders representing local law enforcement, physicians, pharmacists, hospice, on one hand, and to the anti-opioid researchers, manufacturers, and policy groups on the other. We will look forward to learning their insights on one or more of the bills being considered today and anticipate a robust debate on the merits of these policies, as the title of our hearing indicates. We are seeking help from the communities to balance enforcement and patient safety.

Today, we will focus our attention specifically on the Controlled Substances Act. Over the last several months, the committee has come to realize that some areas of this law require an update or clarification. For example, synthetic opioids, like fentanyl, have flooded the United States cities and towns and pushed drug overdose deaths to levels never previously seen.

H.R. 2851, the Stop the Importation and Trafficking of Synthetic Analogues Act, offered by Representative John Katko, will better equip law enforcement to get illicit synthetic drugs off of our streets while modernizing scheduling guidelines for these drugs.

Another issue of critical importance is the growing risk and

misuse -- of the misuse and diversion of controlled substances. Representatives Tim Walberg and Debbie Dingell introduced legislation, H.R. 5041, the Safe Disposal of Unused Medication Act, that would reduce the number of unused controlled substances at risk of diversion or misuse by allowing hospice workers to safety dispose of these drugs in patients' homes.

Another bill currently in discussion form, authored by Representatives Ryan Costello and Rick Nolan, will improve dispensing of implantable and injectable therapies that were developed to make misuse and diversion more difficult.

We will examine two telemedicine bills that will improve access for patients.

The Special Registration for Telemedicine Clarification Act, written by Representatives Buddy Carter and Cheri Bustos, would clarify telemedicine waivers, and direct the Attorney General to issue regulations for healthcare providers to prescribe controlled substances through telemedicine in legitimate emergency situations.

The Improving Access to Remote Behavioral Health Treatment Act, written by Representative Gregg Harper and Doris Matsui, would expand access for patients in rural and underserved areas to their closest community mental health or addiction treatment centers by allowing these facilities to be obtain a DEA registration and qualify for the telemedicine exception under the Ryan Haight Act.

Lastly, the subcommittee will consider two provider education bills, the first bill, H.R. 4275, the Empowering Pharmacists in the

Fight Against Opioid Abuse, authored by Representatives Mark DeSaulnier and Buddy Carter, would help pharmacists detect fraudulent prescriptions through new education materials.

Another bill aims to improve doctors' understanding of pain management and treatment guidelines and best practices, among other things, by mandating 12 hours of continuous medical education on the subject every 3 years. This policy contained in H.R. 2063, the Opioid Preventing Abuse through Continuing Education Act, authorized by Representative Brad Schneider, does concern me because it seems to suggest that doctors are primarily at fault for this epidemic, but as we consider solutions critical to blunting this crisis, we must strike a careful balance prior to casting blame.

As I said earlier, an important aspect of today's hearing is to think through the debate that all of these policies have before us. I believe what we accomplish here today will set the tone for the next two hearings in this subcommittee.

With that, again, I want to welcome our witnesses, and thank you for being here. And I will recognize Mr. Green of Texas 5 minutes for an opening statement, please.

[The prepared statement of Mr. Burgess follows:]

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

Mr. Green. Thank you, Mr. Chairman.

I want to thank you for the work on addressing the opioid epidemic that has impacted countless families and communities in our country. And as you said, according to the National Institute of Health, 115 Americans die every day after overdosing on opioids.

The misuse and addiction that opioids, including prescription pain relievers, heroin, synthetic opioids, such as fentanyl, is a serious national crisis that affects public health as well as our social and economic welfare. The patterns of lives ruined and lost due to the opioid epidemic must be reversed. The opioid epidemic is complex and multifaceted, as you said. However, there are no simple or quick solutions.

Ending the crisis will require better coordination of care, community involvement, and finding solutions, and more consistent use of improved pain control options. A comprehensive response to this crisis must address the limited resources currently available, the societal ills that fuel addiction, and the stigma attached to drug use.

In recent years, Congress has expanded in this space. The Affordable Care Act expanded healthcare coverage to 20 million non-elderly Americans, giving access to the medical and behavioral attention opioid victims need to overcome their addiction. Any honest efforts to address the opioid epidemic must include measures to stabilize and strengthen the exchanges, make coverage accessible for Americans who currently do not have health coverage, including the 3 million Americans who lost their health insurance in 2017.

Last Congress, I was proud to support the passage of the 21st Century Cures Act and Comprehensive Addiction and Recovery Act, CARA. CARA authorized several grant programs to help prevent overdose, expand access to treatment, and help individuals recover. Unfortunately, some of the grants created under CARA have yet to receive funding through the appropriations process. I hope our committee will work with our colleagues on the Appropriations Committee to secure these necessary funds.

Speaking with local stakeholders at home about the opioid crisis, I can share that more Federal assistance is needed to properly combat this epidemic. The committee needs to seriously consider authorizing the necessary resources, and our State and local partners need to help Americans struggling with opioid addiction and recovery.

I look forward to hearing from our witnesses today, and continuing our committee's examination at this nationwide problem in the weeks and months to come.

Now, I would like to yield a minute and a half to my friend and colleague, Congresswoman Matsui, from California.

[The prepared statement of Mr. Green follows:]

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Ms. Matsui. Thank you very much.

Thank you for yielding.

Mr. Chairman, I appreciate very much this hearing. As we continue this discussion, I look forward to working together in a bipartisan manner to effectively confront issues of access and affordability for addiction treatment.

I am encouraged by the steps taken today, but want to emphasize that this is just the beginning of what must be an iterative and comprehensive approach to combating the opioid crisis.

We can all acknowledge that, while controlled substances should be carefully regulated, they also play a vital role in the effective addiction treatment. Accessing treatment continues to be a major hurdle in many communities. Today, we are examining a discussion draft that I am working on with my colleagues on the committee, Representative Gregg Harper, that looks at ways that we can use telehealth to increase access to substance use treatment.

We are also examining a bill authored by my colleague Representative Brad Schneider that requires providers to prescribe opioids for pain to undergo training on pain management. These are targeted strategies, among many that we must consider. It will also be imperative that we support Medicaid funding, which has already played a crucial role in reducing the treatment gap.

I look forward to continuing discussions here. This conversation must be paired with the significant resources to help patients and families who are suffering.

Thank you, and I yield back to the ranking member.

[The prepared statement of Ms. Matsui follows:]

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Mr. Green. Thank you.

Mr. Chairman, I have a number of statements that I would like to ask unanimous consent to place into the record. Documents: H.R. 2851, a letter from Dr. Halberstadt, of UC San Diego; a letter from College on Problems of Drug Dependence; H.R. 2063, a statement on support of the bill from Representative Brad Schneider; for Ensuring Patient Access to Substance Use Disorder Treatment Act, a Public Health Group letter regarding support for the Senate companion; a letter from ASAM and CLAAD, C-L-A-A-D, expressing the support for the Senate companion for Tableting and Encapsulating Machine Regulation Act; a letter from Catalent and PBOA. Anyway. Plus I have a Center for Budget and Policy Priorities that was just released today on the Medicaid expansion drastically increased coverage for people with opioid use disorders. The latest data from the Federal Agency on Healthcare Research and Quality highlight the importance of the Affordable Care Act, the Medicaid expansion, and increasing insurance among people with opioid use disorders. Our analysis of these data will offer a comprehensive picture of opioid-related hospitalization around the country, finds that the share of hospitalization in which patients were uninsured failed dramatically in States that expanded Medicaid from 13.4 percent in 2013, the year before the expansion, to 2.9 percent 2 years later. This steep decline indicates that many uninsured people are coping with OUDs have gained covered through the Medicaid expansion.

And I ask unanimous consent to place this in the record?

Mr. Burgess. Okay. Without objection, so ordered.

[The information follows:]

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Mr. Green. Thank you. I yield back my time.

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

The chair recognizes the gentleman from Oregon, the chairman of the full committee, Mr. Walden, for 5 minutes for an opening statement.

The Chairman. I thank the chairman for his leadership on this and many other healthcare-related issues, and I want to welcome our witnesses, and we look forward to your testimony.

No community is immune from the opioid epidemic. It is ripping apart the very fabric of our neighborhoods, from Oregon to Ohio, from one coast to the other, from Connecticut to California. Our friends and our neighbors are experiencing this epic tragedy neighborhood after neighborhood, one that is claiming the lives of more than 100 Americans each and every single day.

Working together, we can and we must continue to help. Congress must learn from the past. You know, the Comprehensive Addiction and Recovery Act, or CARA, was an important milestone in helping States. The breakthrough 21st Century Cures Act struck a fair balance of speeding up the availability of innovative new drugs while maintaining patient safety, and it is already delivering. Those two, in fact, put more money into the opioid epidemic effort than Congress has ever put forward, and then we doubled down with a budget agreement that was just passed and signed into law by President Trump.

Lawmakers must acknowledge the present. In 2016, opioid overdose deaths from both prescription and illicit drugs were five

times higher than 1999. And as public officials representing our communities, we must plan for the future, and that is why we are here today, to work towards our shared goal of combating the opioid crisis.

Each statistic is disturbing in and of itself. Even more tragic, every number has a name, a name like Mike. At a roundtable that I held in southern Oregon a year or two ago, a man named Mike simple showed up, sat in the chair next the wall. Didn't know who he was. And when we were done going around the room, he wanted to talk about his situation.

You see, Mike's son was injured in a high school sporting accident, and he became addicted to the prescription painkillers provided by his doctor to aid in his recovery. Eventually, Mike's son made the all-too-familiar transition to the cheaper opioid source: heroin. And to this day, Mike's son still struggles with his addiction that all began with opioid prescriptions.

Mike then went on to talk about his sister, who also suffered from addiction. She was a nurse. He commented that she found herself with easier access to pills as a nurse, and when coworkers and others caught on, she moved and continued to procure pills elsewhere. Sadly, Mike's sister died as a result of her addiction. So Mike came to the meeting, a roundtable of law enforcement and medical professionals, to share his story about what he had faced, what he had lost, and what he was coping with.

His, tragically, is not a unique story; it is the story that is ripping apart families all across our country. So we have to act.

And, as people know, this committee has had a very aggressive, ongoing, diligent, deep investigation through the Oversight and Investigations Committee on how we got to this place in this country, and we will hold people responsible from one end to the other.

The second track, however, is about the legislative initiatives we can all wrap ourselves around in a bipartisan way and move forward to get illicit synthetic drugs off the streets. To safely dispose of unused controlled substances, to improve patient access to substance use disorder treatments and remote services, to help providers and pharmacists to better prevent addiction: these are among just a few of the bills today. And this is but one of three upcoming hearings on this subject, with legislation we hope to be able to move to the floor routinely and regularly between now and Memorial Day.

So it is important to acknowledge that this legislative hearing is the appropriate venue to ask tough questions and to make constructive suggestions on how we can improve these bills. That is what the hearing is all about. Many of these are discussion drafts because they are admittedly in need of discussion.

So I look forward to the feedback from our witnesses and our members. In the coming weeks, we will continue this hard work, and we will continue the legislature hearings, and we will get our job done. People like Mike and Mike's son and his sister's family are depending on us, and we have a big job to do here.

So I thank the members who have been so active in participating. Together, we are going to get this job done, and we need your help.

So I would like to thank our two panels of witnesses for being here today, and I look forward to your feedback on these important issues.

I would also like to thank my colleagues for staying in town to have this vital discussion. When others went home to their districts, these Members said, "This matters," and they stayed. So combating the opioid crisis requires an all-hands-on-deck approach, and I appreciate everyone's shared commitment to that effort today and in the weeks and months ahead.

With that, Mr. Chairman, I appear to have run out of time, and I will stop.

[The prepared statement of The Chairman follows:]

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Mr. Burgess. Do you yield to the gentlelady from Tennessee?

The Chairman. I would be happy to yield to the gentlelady from Tennessee.

Mrs. Blackburn. Thank you, Mr. Chairman.

And I appreciate so much the hearing and our panels for being here today to work with us on this issue. Tennessee has seen a 10-percent increase in opioid deaths in 2015 and 2016. And while we have worked for years on this issue, first correspondence going back to 2012, on how we deal with this epidemic, we are pleased to have this -- Representative Katko's bill, SITSA.

We are interested in your perspective on that. Dealing with the synthetics is going to be important. Looking at the scheduling of this, we know it needs to be a focus, because much of the increase in the deaths deals with the synthetics and the analogues. And thank you for being here. Thanks for the perspective that you bring. And, as the chairman said, we have got three hearings that are going to be on bills going forward. We want to do our part at the Federal level to work with our State and local responsibilities so that they have the ability to address this crisis.

I yield back.

[The prepared statement of Mrs. Blackburn follows:]

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Mr. Burgess. The chair thanks the gentlelady.

The gentlelady yields back.

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

Mr. Pallone. Thank you, Mr. Chairman.

Today is the first in a series of hearings meant to address the opioid and substance abuse crisis that is ravaging communities across the country. In my home State of New Jersey, more than 2,200 people died from opioids in 2016 alone, but obviously, this is a national crisis that is devastating families every day, and, simply put, a lot more needs to be done.

Now I must say that I am utterly confused as to why the Republican leadership has chosen to hold this hearing on a day when Congress is not in session, because these are serious issues that deserve serious consideration. I know Chairman Walden was thanking those who didn't go home and stayed, but, frankly, no Member, in my opinion, should have to choose between staying in Washington when we are not voting or going home. And I think it is unfair to all the witnesses who have flown here today and will likely end up with less engagement by the time the panel ends.

I get the feeling that the Republican leadership is just checking the box instead of, you know, giving members, staff, and stakeholders the time to carefully consider the important issues like the opioid crisis.

But last Congress, we took bipartisan action to pass CARA and 21st Century Cures, both of which provided initial investments and steps to address this crisis. These laws are expanding access to treatments and providing recovery support services, financial resources to help States take action to prevent the misuse and abuse of opioids, and support the reduction of controlled substances in circulation. And I look forward to working to build on those efforts from both CARA and 21st Century Cures.

The legislative proposals we are examining today strive to address a number of discreet policy problems under the Controlled Substances Act that healthcare practitioners and law enforcement officials face in combating the opioid and substance abuse crisis. For example, we are considering legislation from Congressman Walberg and Dingell that would empower hospice employees to dispose of unneeded controlled substances after a patient has passed away.

Another proposal from Congressmen Costello and Nolan would allow pharmacies to dispense implantable and injectable controlled substances directly to a practitioner, reducing the ability for misuse or diversion. And we are also considering legislation from Congressman Schneider, who I note is here, that would require mandatory prescriber education as a condition of DEA licensure. This would provide -- ensure that all providers who treat patients for pain with opiates have training on the best practices for prescribing opioids, early detection of opioid addiction, and treatment and management of opioid dependent patients.

I know that Chairman Burgess -- I don't know if he was being very critical -- but seemed to suggest that he didn't like the fact that, you know, many of us consider doctors a part of the problem. I think doctors are part of the problem. Now, that doesn't mean to say that they are intentionally, you know, trying to overprescribe or do anything bad.

But my experience, Chairman Burgess, is that oftentimes doctors feel that they have to prescribe things and address pain problems. That comes from their education, you know, that that is sort of their obligation. And so I think a lot of times we do get doctors overprescribing, not because they are intentionally trying to do anything abusive or criminal, but just because they have learned in medical school that, you know, they need to do this, they need to, you know, take care of pain if people are in pain.

So I do think that we need more education. I think that many of the older doctors are not necessarily aware of the dangers of overprescribing.

So I am not trying to be difficult with you, but I do think that is something that needs to be addressed and that Congressman Schneider's bill does address effectively.

We also will discuss how we can employ telemedicine in treating those suffering from substance abuse and mental health disorders, including individual practitioners and community mental health centers and addiction treatment facilities. While this policy holds the potential to expand treatment options for those suffering, we must

carefully consider how we can safeguard against further abuse or misuse of controlled substances.

And, finally, we will consider two proposals that I continue to have strong concerns about. One is H.R. 2851, which attempts to address the problem of illicit synthetic analogues. And the second is the discussion draft that would propose scheduling tableting and encapsulating machine-like controlled substances.

I recognize the importance of addressing illicit synthetics drugs and illegal importation, but both of these proposals would give the Attorney General broad and unprecedented new authority, including criminal penalties, as a way to deter traffickers that fuel our opioid crisis.

I just want to say, Mr. Chairman, I do look forward to hearing more from DEA and our witnesses today on these issues, and I hope to work with all of us on a bipartisan basis to address these concerns. Thank you.

[The prepared statement of Mr. Pallone follows:]

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Mr. Burgess. The chair reluctantly thanks the gentleman. The gentlemen yields back.

The chair now is pleased to -- well, that will conclude members' opening statements.

I would remind members, pursuant to committee rules, all members' opening statements will be part of the record.

And we, again, want to thank our witnesses for being here today and taking the time to testify before the subcommittee.

We do have two panels, and each witness will have the opportunity to give an opening statement followed by rounds of questions from members. Our first panel today, we are hearing from Ms. Susan Gibson, the Deputy Assistant Attorney, Diversion Control Division of the Drug Enforcement Administration.

We do appreciate you being here with us today, Ms. Gibson.

You are recognized for 5 minutes for an opening statement, please.

STATEMENT OF SUSAN A. GIBSON, DEPUTY ASSISTANT ATTORNEY, DIVERSION CONTROL DIVISION, DRUG ENFORCEMENT ADMINISTRATION

Ms. Gibson. Chairman Walden, Subcommittee Chairman Burgess, Ranking Members Pallone and Green, and distinguished members of the Health Subcommittee, thank you for holding this legislative hearing today on several bills impacting the Controlled Substances Act aimed at combating the opioid epidemic.

Let me say from the outset, the opioid crisis has been -- and will unfortunately continue to be -- the top threat facing our Nation. This epidemic includes not only prescription opioid medications but also the proliferation of heroin, illicit fentanyl, and fentanyl analogues.

Despite record numbers of overdose deaths, 64,000 in 2016 alone, we are making progress on the prescription drug front. However, I fear that we are witnessing a fundamental shift toward cheaper, easier to obtain illicit fentanyl produced in foreign countries. This is where the opioid epidemic converges with the synthetic drug threat.

Data has shown that the increase in opioid-related deaths is largely attributed to illicit fentanyl. Synthetic opioids, cannabinoids, stimulants are produced by rogue chemists who create new drugs with unknown pharmacological effects in humans. Because synthetic drugs are made in the lab, the profit potential is enormous, and the ability to stay ahead of the law only requires a small tweak in a molecular structure.

One kilogram of fentanyl purchased in China for roughly $5,000 can generate up to $1.5 million in drug proceeds. All the while, unsuspecting users of synthetics drugs are playing Russian roulette every time they use these deadly substances. The questionable legal status of these synthetics and their ever-changing chemical composition makes it difficult for our Federal, State, and local law enforcement counterparts to intercept these deadly substances before they hit our streets.

This is not a U.S. problem. It is an international problem that is growing in scope. According to the United Nations, more than 100 countries have reported the presence of synthetic drugs, and as of March 2017, approximately 750 substances have been reported to the U.N.'s early warning advisory.

So what is DEA doing about it? We are moving aggressively to place temporary schedule I controls on new and emerging synthetic drugs. Since March 2011, DEA has utilized this authority on 19 occasions to place 56 synthetic drugs in schedule I on an emergency basis, including 17 fentanyl analogues. This process is unfortunately reactive and means that we first observe the deadly consequences of synthetic drug abuse before initiating control.

On February 6, 2018, DEA temporarily placed emergency controls on the entire class of fentanyl-related substances in an unprecedented effort to curb the disturbing trend in fentanyl-related overdose death. Of course, we are continuing to conduct criminal investigations. For example, last year, DEA played a major role in helping take down

AlphaBay, the largest criminal marketplace on the internet and a key source of illicit synthetics, including fentanyl, being shipped into the United States.

Additionally, we have worked productively with China to try and stem the flow of synthetics to our shores, resulting in the scheduling of nearly 130 new psychoactive substances since October 2015. Last month, domestic controls became effective in China for two essential fentanyl precursors: NPP and ANPP.

Beyond the deadly synthetics threat, DEA is committed to combating the epidemic through several different avenues, including expansion, disposal, and treatment options, new pill press regulations, and outreach to practitioners regarding the prescription of opioids. The implementation of telemedicine regulations pursuant to the Ryan Haight Act of 2008 to the recent publishing of a final rule that help increase access to opioid addiction treatment, DEA believes that this is important to ensure access to opioid treatment options while mitigating the risk of diversion.

In July 2017, DEA implemented a final rule pertaining to domestic and international transactions involving tableting and encapsulating machines. Overall, this rule will give DEA greater visibility of transactions involving tableting and encapsulating machines.

Finally, DEA recognizes the importance of opioid prescription training for prescribers and has begun to ask whether they have received training regarding prescribing or dispensing of opioids. While this information is voluntary, it will provide better data to show how many

prescribers are taking training.

Thank you for the committee's focus on the opioid crisis, and I look forward to answering any questions you may have.

[The prepared statement of Ms. Gibson follows:]

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Mr. Burgess. We thank you for your testimony.

We will now move on to the portion of the hearing where members will be recognized to ask questions, and I am going to begin the questioning by recognizing myself for 5 minutes for questions.

On the proposed legislation offered by Mr. Katko on the creating a new level of scheduling on the fentanyl analogues, I guess, primarily, but I guess it could include other compounds as well. Now, we are going to hear some testimony from our witnesses -- our stakeholders on the second panel about how that will perhaps increase the bureaucratic load on people who are involved in the research on these compounds.

Do you see the potential for any difficulty there or any conflict there?

Ms. Gibson. Sir, I understand your concern for research, and it is our concern, too. DEA supports research. We have never denied a valid FDA research application, especially on synthetic drugs. We welcome research on synthetics drugs. Right now, we have 600 schedule I researchers that are approved. We have 420 that are approved regarding THC extract. And then we have another 120 that are approved on an additional CBD extract. So DEA is fully behind research.

Mr. Burgess. So, again, one of the observations that will likely be made by a witness in the second panel is concerning compounds that are put on a scheduling list, that once they get on, it is almost impossible to get off. And I believe the point is going to be made that the difference, the molecular difference, between agonist and an antagonist can be quite small. And if we restrict the access to

molecules of a certain class, that we may in fact be limiting the ability to research drugs or compounds that would be helpful as antagonists.

Is that something that your agency is looking at or concerned about?

Ms. Gibson. Sir, I understand your concern about the analogues and the quick-changing nature of it, and I believe with the bill that we are trying to pass here, it could be more proactive in that arena. I think the biggest problem is exactly what you said. We have a substance that we get; we identify it as a problem. They change one atom on it, and then it is a whole new substance. It is labeled differently, and it is another problem to attack.

We do believe that fentanyl analogues belong in schedule I. We will look at every substance differently. And we work with our counterparts at HHS and make sure all the scientific data is there, and we make sure that we do it right as much as we can. But we look forward to working with the committee about any kind of concerns regarding that.

Mr. Burgess. And that is, of course, the whole purpose in having the hearing, to explore some of these issues that are brought up. You all will work closely with the Food and Drug Administration as far as scheduling things in that class. Is that correct?

Ms. Gibson. Sir, we work very closely with our counterparts at HHS, FDA, and we rely on them and their expertise, yes.

Mr. Burgess. Let me just ask you a question. And you mentioned it. Mr. Pallone mentioned it, as far as the educational aspect. I

am a physician, and I did receive training on the use and potential misuse of opiates. It was called medical school. I would just ask you, as far as the agency is concerned, how -- you see legislation being proposed where you are going to be responsible for the oversight of an educational activity that will be administered to the Nation's physicians. I would just ask the question: Is the agency set up to do that? Is the agency set up to handle that?

Ms. Gibson. Sir, I understand your concern for continuing medical education, and we think it is paramount. We think it is critical.

Mr. Burgess. Let me just -- I do, too. And, historically, that is an activity that has been regulated by the State. My State requires me to receive a certain number of hours of continuing education. Although I am not active and in practice, I do keep my license active. So, yes, I am required to do those things every year before that license can be renewed. So they are set up, and that is part of the process.

Do you feel like your agency is -- I mean, is it ready to administer to the continuing educational needs on this front the same as, say, a State licensing agency is already doing?

Ms. Gibson. Sir, we definitely work closely with the States regarding that, and that is a procedure that we would have to look extremely close at, and we would have to work with the committee to make sure that we would get that right. Again, we do believe in continuing medical education. I don't think we can dictate exactly what they take. It is --

Mr. Burgess. And therein is the problem. I will just pledge to you that, yes, it is an issue that is important to me, and we will work closely on that.

Ms. Gibson. I look forward to working with you.

Mr. Burgess. I will yield back my time.

I am pleased to recognize the ranking member of the subcommittee, Mr. Green, 5 minutes for questions, please.

Mr. Green. Thank you, Mr. Chairman.

And welcome, Deputy Assistant Administrator Gibson. Thank you for joining us today.

I want to focus my questions on the impact of scheduling substances in schedule I, which you mentioned in your testimony, or under the proposed schedule A that H.R. 2851 would have on research.

We hear from Dr. Beardsley in our second panel about the difficulty associated with conducting research with schedule I substances. He noted in his written testimony that it can take over a year to obtain a schedule I registration. I heard from others that requirements associated with schedule I substances, such as the storage and security requirements, can be very costly. The time and resource burdens have, in some instances, been a disincentive for young and promising researchers who examine these substances for their therapeutic value.

My first question is, can you describe current requirements DEA imposes on researchers who wish to study schedule I drugs? And I am particularly interested in whether you offer any accommodations today

for researchers.

Ms. Gibson. Sir, I appreciate your concerns for research, and it is critical. We do have a strict process regarding research as far as the application process. And the reason it is strict and it has to be FDA approved is because we have to prevent diversion. That is the bottom line. And we have to make sure that everything that a researcher receives as product has to be retained and secured.

But as far as research, if somebody brings a valid FDA application to us, we will be approving it. In fact, if it is a synthetic analogue research application, I will expedite it because we need it done. We need it done.

Mr. Green. One concern I have heard from the registration process today is confusing nature and how Federal and State registrations interact. Some States require Federal registration prior to application, yet the DEA advises a State registration is needed prior to Federal application.

What guidance does DEA offer to researchers at States regarding their registration process?

Ms. Gibson. Sir, I understand interaction with the States and your concern how that could be different between State and Federal. It is kind of shocking sometimes the difference between the State and Federal Government on various issues. However, when it comes to working in this arena, it is critical for the Federal Government and the State government to work together. And in order for the Federal Government to operate in a State, we need their compliance, we need

their understanding.

So we are more than happy to work with each State individually and make sure that we come up with a proper procedure, and we get it done right. Yes.

Mr. Green. Yeah, it is confusing if the State requires Federal and Federal also requires State, so I don't know if we could do it simultaneously. That might be much easier for the researchers. One of the bills before us today, H.R. 2851, attempts to streamline the research registration process. We heard from HHS, however, that this process could still constitute a burden or barrier to research and could have a negative impact on drug development.

Can you share what discussions, if any, DEA is having with Health and Human Services regarding the registration process for researchers, and how such process could be streamlined?

Ms. Gibson. Again, definitely research is a big concern for us, too. We work closely with HHS regarding applications for research. And, again, we do have 600 schedule I researchers already that are ready to go. Again, we believe the new regulations could help streamline that process. So we look forward to any kind of tool that the Congress could provide to us to streamline that process, absolutely.

Mr. Green. Well, Congress doesn't always provide the funding for a lot of agencies. We wish we were the Appropriations Committee sometimes.

While I want to ensure that we are properly protecting against abuse, misuse, and diversion of synthetic substances, I also want to

ensure that we are not unintentionally restricting the ability of researchers and drug developers to discover new and promising therapies.

Would you work with us on legislation to ensure that we do not impede or inhibit or otherwise disincentivize research?

Ms. Gibson. Sir, I would absolutely love to work with you.

Mr. Green. Thank you.

And I yield back my time, Mr. Chairman.

Mr. Burgess. The gentleman yields back.

The chair thanks the gentleman. The chair recognizes the gentleman from Oregon, the chairman of the full committee, Mr. Walden, for 5 minutes for your questions, please.

The Chairman. Thank you, again, Dr. Burgess.

And to our witness, thank you for being here today. So, in your testimony and in other people's comments this morning, we have heard a lot of statistics, so I want to repeat a line from your written comments that says: "The sharpest increase in drug overdose deaths in 2015 to 2016 was fueled by a surge in overdoses involving fentanyl, fentanyl analogues, and synthetic opioids," closed quote. This was reported by the National Institute of Drug Abuse or NIDA.

You go on to build a compelling case to give DEA additional authority to get synthetics off of our streets. Under current law, the DEA Administrator acting on behalf of the Attorney General can temporarily schedule substances for a 2-year period, with a possible 1-year extension to avoid imminent hazard to public health.

And on February 6, 2018, this administrative tool was utilized to place classwide schedule I controls on fentanyl-related substances.

My question is this: What additional tools would SITSA give special agents to investigate and prosecute these substances that they do not have today?

Ms. Gibson. Thank you, sir. I understand and I appreciate your efforts to give us any kind of tools that we can to get this job done because it is unprecedented, and it calls for unprecedented measures to get this done.

The Chairman. Right.

Ms. Gibson. I do believe that the SITSA law outlines sentencing, which makes it a lot easier to prosecute, even though the prosecution sentencing guidelines are that of schedule III. But I think it streamlines the process, which it helps us tremendously. I think also, too, the false labeling I truly support because they take a substance, they change the atoms, and then they relabel it something, and it is a whole new product. So --

The Chairman. What happens in your world, the enforcement world, when that occurs?

Ms. Gibson. Well, right now, that we did the class of the fentanyl, that helped us out tremendous. It was the first time we ever did anything like that, and we are proud of that. But it does make it very difficult. We have gone out to convenience stores, banks. We have reached out to many people regarding the purchasing of these synthetic fentanyls online, the selling of them at the local

shops -- they got to know what they are selling, and it is a difficult arena. And especially my biggest concern is working with our counterparts because they are on the front lines; they have to be armed with the information they need to do their job.

And the dissemination of information, education to our counterparts, that is critical. And I think DEA is doing a pretty good job of that, as far as communicating with our task forces out there. We have expanded our tactical division squads, which I think can also provide a lot of expertise out there. And I think that is the wave of the future as far as tackling this subject.

The Chairman. Congressman John Katko, who brought this issue to our attention, is a prosecutor and won a national award from the former U.S. attorney for his work going after narcotics and organized crime in the narcotics world, and brought us this measure. And we want to make sure that -- because he has been on the front lines there. He has prosecuted these cases, and he says, you know, they change one thing, and then there you are out there. It just bollocks-es up the whole process to go shut down.

And he brought a woman to the State of the Union Address whose 19-year-old son, if I recall the story correctly, smoked something that he got at a head shop that I think had been sprayed with a synthetic fentanyl, and I remember his mother said -- or her son said, "What could be wrong with this? It is natural," even though it was labeled "not for human consumption" potpourri or something like that.

It is the wink and nod behind the curtain. They think they are

getting off on their liability when in fact they are poisoning a generation. Her son died. So that is -- in this bill -- one of the things we are trying to get at. Does this bill get to that?

Ms. Gibson. It is a massive problem. And I think this bill can help us get there. And, again, it is such a serious topic right now because we have people out there, we have kids out there, going purchasing this stuff thinking it is a legal alternative to the actual substance.

The Chairman. Exactly. And "because it is natural," that was the argument --

Ms. Gibson. Absolutely. I mean --

The Chairman. -- her son made.

Ms. Gibson. -- I mean, we are facing cannibalism in certain States when they take some of these substances. There has been a couple incidents in Florida where the person took a cannabinoid or a cathinone and actually started eating somebody. That is how serious of a situation we have here.

Taking these synthetic drugs is similar to taking meth and PCP at the same time. And the scientific term is excitable delirium. So imagine that: meth and PCP at the same time. These products are killing our kids out there. We have 750 substances right now that we have identified. We took 56; aggressively, we put them on the schedule. And out of that, what, I think my math is 696 that are still out there that can kill our kids -- 696 different substances --

The Chairman. Will this help get to that, or do we need more?

Ms. Gibson. It is going to streamline it. But we have to look at the sentencing. We have to make sure that we are -- these people are peddling death. It is not a victimless crime when you are dealing drugs.

The Chairman. That is right.

Ms. Gibson. And that is my biggest concern. I love to put handcuffs on people that violate the CSA. And this law can help us. And any other tool Congress can give us to tackle this problem, I will take.

The Chairman. We want to be your partner in this effort. And just to make clear, this is the first of three legislative hearings we have announced. This one is focused more on the enforcement effort. We fully understand we need to do more on helping people who are addicted and treating -- the treatment piece, the mental health piece. This is going to be across the whole spectrum. This begins the process to try and turn off the access to these illicit drugs.

So thank you for your good work, and we look forward to an ever-improving partnership between the administration and this committee on this matter. And we are going to get this done.

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

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

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

Mr. Pallone. Thank you, Mr. Chairman.

Ms. Gibson, in your testimony, you note that some traffickers of fentanyl and fentanyl analogues have had industrial pill presses shipped into the United States directly from China and have been operating fentanyl pill press mills domestically.

Now, DEA has also acknowledged that industrial pill press machines are widely available on the open internet and that some vendors mislabel the equipment or ship it disassembled so as to evade regulatory oversight. And this is clearly one way traffickers have been able to further increase the production and availability of illicit fentanyl and other synthetic opioids.

So my question is -- I have several. Under current law, importers and exporters are required to notify DEA of the shipment of tableting and encapsulating machines. So how does DEA ensure compliance with those requirements?

Ms. Gibson. Sir, I appreciate your concerns about those machines, and I am happy that DEA did take that measure and get up that regulation and get it in place. That requires any importation of a tabulating and encapsulating machine 15 days prior to it coming to the country.

Obviously, you are going to have the legal people out there that abide by the laws, and they are going to be telling us they are bringing it in. But we, as DEA, I have to worry about the ones that aren't playing fair.

Mr. Pallone. The bad actors.

Ms. Gibson. Exactly. As an agent in New York City, I know the

criminals are very industrious. They are very creative; that is their job. So they make their own kilo presses; I am sure they can figure out a way to make their own pill presses. And that is something else we can, you know, address in the sentencing guidelines with SITSA. However, some organizations also piecemeal it into the country, too. And then from different sources, different shippers, they get one part of the machine, and another part of the machine coming in separately. So that is the problem.

But we are excited at least to see how the regulation works and to see how many actually are coming into the country and go from there. So it is really fairly new; it is July 2017 that we started that.

Mr. Pallone. Do you think that DEA needs additional authority over tableting and encapsulating machines?

Ms. Gibson. Sir, any kind of control regarding those machines getting into the wrong hands, we would love a tool, any kind of mechanism to prevent that from happening, yes. We also have to understand that there are some people out there that bring them in for legitimate business purposes, like vitamins and different things like that.

So it is, again, a balance. And that is what I feel like, since I took this position, you got to have that balance. And making sure that people can do their job in the personal arena and the business arena, that is important.

Mr. Pallone. Yeah.

Ms. Gibson. But also to keep these machines out of the hands of the people that don't need them is a problem.

Mr. Pallone. Well, let me go to the bill that we have, this Tableting and Encapsulating Machine Regulation Act that we are considering, that would define in statute tableting machine and encapsulating machine. In addition, it would also propose a schedule of such machines in a to-be-determined schedule.

Is there a precedent under the Controlled Substance Act for scheduling machines or other devices?

Ms. Gibson. Sir, again, this is an unprecedented time. So I can understand thinking outside the box. We never at DEA have ever scheduled a machine. So that would be a new arena for us, and that would be something that we would have to work closely with you regarding.

Mr. Pallone. Let me just ask this because I know we are going to run out of time. Can you describe for us the types of requirements that tableting and encapsulating machine owners would be subject to if they were placed into schedule I? And then I will ask also, what would be the penalties an owner could potentially be subject to if they were not in compliance with those requirements?

Ms. Gibson. Well, again, if you put a machine under a schedule, they would have to obtain a DEA registration to obtain that machine. So they would have to go through the DEA registration process. Again, that is something we would have to discuss with you further. We can definitely talk to our counterparts at DOJ to see if they have any kind of understanding of how we could go forward with a process like that, but we would definitely have to talk to you more about it.

Mr. Pallone. What about penalties? You don't want to comment on what penalties an owner could potentially be subject to if they are not in compliance?

Ms. Gibson. I think penalties could be part of -- addressed in SITSA as far as sentencing, if you have a tableting machine or encapsulating machine in your possession and you are not using for it a legitimate purpose, I think that could be a sentencing guideline that we could use, and that could be an option.

Mr. Pallone. Thank you, Mr. Chairman.

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

The chair recognizes the gentleman from Michigan, Mr. Upton, 5 minutes for questions, please.

Mr. Upton. Thank you, Mr. Chairman.

And I really appreciate your remarks and the full committee chairman's as well. This is something that we need to deal with, and I am glad to say that it is, for the most part, it has been bipartisan from the get-go. We want to provide you all the tools that you need. I dare say that every one of us knows someone that it has impacted, and with the budget agreement that we passed and the President signed -- you know, when we did sequestration a number of years ago, no one ever heard of opioids for the most the part in terms of where things are today. No one would have thought that we would lose 65,000 people a year 8 to 10 years ago on this thing.

So I am glad to say that the budget agreement did increase money

versus what otherwise would have been a cut, and specifically earmarked opioid abuse as one of the increases that I know that the appropriators are going to come back with us for before that March 23 deadline. And, of course, all of us here on this committee supported 21st Century Cures, 51 to nothing. And in that bill, we included a billion dollars for opioids, and we know that that was only a 2-year bill, so it expires. So that is one of the reasons this budget agreement is so important where we focus on opioid abuse.

Last year, I met with a number of my law enforcement officers undercover, and we talked -- I met with a good number of folks in southwest Michigan, but I wanted to spend some time with my law enforcement folks to find out how easy is it to get fentanyl and some of these other products like heroin and others into west Michigan. They said it is real easy, because it comes in oftentimes through the postal center. And Grand Rapids is sort of the postal distribution center. They have one postal inspector for that -- all of west Michigan.

And it comes in in counterfeit labeling, and it changes. They felt that they had good cooperation with FedEx and UPS, but in fact, they know that it comes in there, too. And particularly for the drug dealers, the folks that are getting it, you know, they can track it. They can find if it is delayed even, you know, 1 day, they are not going to be there to pick it up, you know, go someplace else. It is a huge enormous problem.

So I cosponsored a bill that would require the Postal Service to

provide package level detail, information for packages imported from overseas to Customs and Border Patrol as private carriers like UPS and FedEx are already required to do. Because of that -- and I applaud the President, he had a number of us, on a bipartisan basis, down to the White House last summer -- I raised this issue with him and how we needed more resources. And, frankly, you know, when you think about trying to identify some of these drugs coming in and we have seen cases where just, you know, because of its potency, just any contact at all can actually kill, whether it is dogs or people, so there is an enormous problem.

Can you tell us how you -- how are you interacting with where -- you know, as we know, when the President went to China a few months ago, I signed a letter with a number of my colleagues to raise the fentanyl issue to see what China can actually do to stop some of this junk coming here.

But how is your frustration level with the law enforcement -- or with the shippers, and what can we do to help you there as well?

Ms. Gibson. I understand your concern about tackling this problem, and it is daunting. And that is one of the reasons why I am proud of DEA, because we never give up. And drug work is the most labor-intensive, frustrating entity that you can encounter in law enforcement.

I know, when I was an agent in New York City, we routinely worked with the postal inspectors. We have worked with different shipping companies in various capacities, and we have had a lot of success with

them. Sometimes you strike out, but you just got to keep on getting up to the plate and taking another swing.

It is too important of a problem to just give up on. But we definitely will take any kind of resources, any extra resources that can be given to us. Specifically, if you have one major concern, please let me know.

Mr. Upton. Let me ask you one quick question. Disposal of pharmaceutical waste in the hospital requires strict adherence to necessary protocols to avoid diversion of opioid waste, primarily administrated doses that are medically necessary for most surgical procedures from being improperly disposed of.

So to make the -- to render those opioid nonretrievable and unusable products for DEA regs at a much lower compliance burden than what many providers currently experience, what are you doing to help being able to dispose some of these that people may voluntarily bring in that they can then rest assured they are not going to be abused by someone later on?

Ms. Gibson. Sir, I understand your concern because I think we have all been there where we had a loved one that passed and we had all this medication that we didn't know what to do with it. DEA prides itself on the National Take Back Initiative, where we actually have one coming up April 28. Through the beginning and the inception of that program, we have taken 9 million pounds of prescription drugs off the street -- 9 million pounds. And, unfortunately, four out of five heroin users right now start with taking the pills out of the medicine

cabinet and going ahead, using them, and developing a horrible habit.

So it is incumbent for us to get those pills. And we do a lot with operation prevention. We get information out to parents, students, teachers. Operation 360 right now. We are working with communities to get the information out there. DEA wears many hats, and I think a lot of times people think we are just kicking in doors and arresting bad guys, but our Diversion Control Unit, we tackle those problems as far as making sure we get the information out there.

Mr. Upton. 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 questioning, please.

Ms. Matsui. Thank you, Mr. Chairman, and I want to thank all the witnesses who are yet to testify yet for being here today and also you, too. I -- my priority here is to improve access to care. And, as mentioned before, I am working on improving access to remote behavioral health treatment. It is a discussion draft, which is what it means: It is a discussion draft. And we are still working on it, but I think it is important to lay it out there so we can have a conversation as to how we might improve it.

This is with Representative Harper. And both of us believe that telemedicine has the potential to improve access, especially in the midst of this opioid epidemic. However, I am looking forward to hearing from stakeholders -- all the stakeholders -- about how best

to improve access via telemedicine without creating new problems.

The last thing we want to do is to make it easier for unscrupulous actors to prescribe controlled substances. And I think you mentioned before that the bad actors are always the ones who, I don't know, that is their job to figure out how to mess up things, right?

Ms. Gibson. Yes.

Ms. Matsui. So we are going to have to try to figure out what to do to prevent that. But, you know, I do though believe that many people in our communities are receiving high-quality comprehensive care in their local community behavioral health clinics. And access to medication can be a part to treating patients suffering from opioid use disorder and other mental illnesses.

Ms. Gibson, according to DEA's interpretation of the Ryan Haight Act, a hospital or clinic must first be licensed by the State before registering with the DEA. Can you provide us with some insight into the reasoning for DEA's narrow interpretation?

RPTR KEAN

EDTR HUMKE

[3:04 p.m.]

Ms. Gibson. Ma'am, DEA agrees with any kind of efforts that we can do to get somebody on the right path forward, and to get them help. So I understand your concern, and I would love to work with you.

It is incumbent that DEA works with the State government regarding registrations. A lot of times, active investigations, whether criminal or administrative in nature, we work hand-in-hand with our State. So if there is a problem going forward with having registrations, and if State is the problem, we can figure that out and get you information that you need.

Ms. Matsui. So are there circumstances, then, under which DEA could modify or loosen -- maybe loosen is not a good -- modify, work with this requirement to be more inclusive at clinics that may be authorized by the State or county but not licensed by the State?

Ms. Gibson. Again, this is where I have to put my DEA hat on as though we were enforcement and regulation, because it is so important to make sure that these clinics are abiding by Federal and State laws.

Ms. Matsui. Right.

Ms. Gibson. So if a clinic wants to move forward with obtaining registration for a narcotic treatment program and to dispense MAT, medical assistance treatment, we would be more than happy to work with them, because we want to make sure that people have access to those

types of treatment centers.

Ms. Matsui. Right. So you are saying that -- I am looking at it from a drug enforcement perspective, and you are looking at certain guardrails that must be put in place to assure appropriate prescribing of control substances for a medication assisted treatment via telemedicine. That is the aspect of it here that we are trying to address.

And it is a little bit different, but on the other hand, is there a situation, I am trying to get to where we can narrow this in a way, not so widely but not so narrowly as it is today so that we might be able to have this remote telemedicine ways of treatment in this crisis.

Ms. Gibson. Well, ma'am, as it stands right now, telemedicine is authorized.

If we can get the patient to either a registered hospital or clinic, with DEA, or a registered physician, physician assistant, nurse practitioner, they use appropriate audio-visual equipment, to their prescription and data-waived physician, it can happen.

Ms. Matsui. The only problem, though, is that in a situation, you would want the person to be in place and, you know, we are looking at community clinics where that is not necessarily a hospital or something that is licensed by the State. And that would take away the efficiency of the telemedicine then. And we are trying to get to that place where we can get the community health clinics to be able to be participant in this with the patient without having to move them somewhere, if you know what I mean.

So anyway, it is something that we are trying to figure out, Congressman Harper and I, to figure out how to get the guardrails in place but have it flexible enough so we can do this.

So thank you very much. We are going to be working with you, I believe.

Ms. Gibson. Absolutely. I want to work with you and see how we can figure that problem out.

Ms. Matsui. Thank you. I yield back.

Mr. Burgess. The chair thanks the gentlelady. The gentlelady yields back. The chair recognizes the gentleman from Illinois, Mr. Shimkus, 5 minutes for questions.

Mr. Shimkus. Thank you, Mr. Chairman. Thanks for being here. I want to applaud my colleagues on both sides who -- it is easy for us to try to run home when we are not voting and they are here working. And so hats off to both sides, because it is such a national issue and a national concern. And we have got a long way to go. This is a plethora of options and bills. There is a lot of ideas out there, and a lot of them sponsored by my colleagues on this committee and some outside the committee.

So I want to focus on this issue of FDA and DEA and this pseudo, not a conflict, but the scheduling and the FDAs approval for scientific safety and efficacy, and then the listing. Where on this what we need to do is try to keep people from taking the first dose and getting hooked, and that is a whole set of problems, but then the other side is the treatment. And some of this treatment has opioid-type events.

And so it is a total ban when you got to use that on the treatment end, there is also a concern.

So I want to make sure the FDAs role in the scheduling process is strong and solid. I think both sides talked highly about the strength of FDA and its record, but it seems like there is certain factors within the current eight-step process to bring new drugs under the Controlled Substances Act such as the state of the current scientific knowledge about the substance or its risk to public health, are better suited for the FDA and agency focused on scientific safety and efficacies of drugs than the DEA, which enforces the criminal and civil justice on control substances.

Does the DEA believe that in order to strike the balance between addressing the risk posed by illicit use and allowing the scientific research needed to develop new therapies that the FDA should continue to have some role in the temporary and permanent scheduling of control substances?

Ms. Gibson. Sir, I appreciate your concern about scheduling substances and getting them out of the hands of our kids as quickly as possible, too. It is critical to work with our counterparts at FDA and HHS. I have the utmost respect for them and I look forward to working with them in the future.

The only way we can tackle this problem is together. I came from a task force in New York City comprised of DEA, NYPD, and New York State Police, and the only way that we were as successful as we were is because we worked together. So I promise you that any kind of scientific data,

anything that FDA, HHS can bring to the table, I will be more than happy to work with.

Mr. Shimkus. Yeah, because the concern is to make sure that you all make reasonable technical accommodations for research, which is critical, and that FDA should continue to have some role in the scheduling process. I appreciate your comments. What we had hope was that you all, the DEA, would help provide some technical comments to, in essence, the Katko bill, which is the H.R. 2851, which I scribbled -- I don't like to use acronyms, so I try to scribble down, but then I can't read my writing, so Stop the Importation and Trafficking --

Ms. Gibson. Synthetic Analogues --

Mr. Shimkus. Yes, you got it. So if you could provide us some feedback on how we can address this concern about making sure that the FDA can be, you know, involved in this process and what your concerns will be as this bill -- my guess would be this bill would get a fair hearing and will move through the process. And we would like to have your input on that.

Ms. Gibson. Again, sir, I understand all your concerns. And especially being that I just came to this position, I have been here a month-and-a-half.

Mr. Shimkus. Welcome. What a time.

Ms. Gibson. Thank you. But you know what, I think it is a great time to be a part of it because it is such a massive problems that it takes all hands on deck, and it takes everybody to get on the same page

and figure this out.

So I promise you, that is my motto. I need to work with people. We need to bring people into this conversation. Because I can talk about regulation all day long and making sure the stuff stays out of the bad guys hands, but I need to rely on my scientific counterparts to understand everything going on.

Mr. Shimkus. We just don't want the two agencies to trip over -- we have the same objective. We just don't want the two agencies to trip over each other. And so we need help clarifying the language, that suits both sides, that would be helpful.

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

Mr. Burgess. The gentleman yields back. The chair thanks the gentleman. The chair recognizes the gentlelady from Florida, Ms. Castor. 5 minutes for your questions, please.

Ms. Castor. Thank you, Mr. Chairman. Welcome, Ms. Gibson.

A U.S. District Court judge in Ohio, who is overseeing hundreds of lawsuits that have now been consolidated into one, these are lawsuits filed against opioid manufacturers and distributors. The judge has directed DEA to release data about the national distribution of opioids. The judge ordered the DEA to inform him very soon that it will consent to releasing data from the automation of reports and consolidated order systems, ARCOS. ARCOS data, which drug companies must provide to the government under the Controlled Substances Act shows transactions made by opioid manufacturers and distributors.

The database shows how many pills were sold, where in the U.S.

they were sent, and what pharmacies bought them. The database, as you know, is often used by agents conducting criminal investigations into trafficking of prescription opioids.

The judge proposed that the DEA give a list of drug companies that manufacture and distribute 95 percent of the opioids in each State broken down by each State for each year between 2006 and 2014. The judge also would like the data to include the total number of pills sold in every State each year and how much market share each company enjoys.

Will the DEA comply with the judge's request?

Ms. Gibson. Ma'am, I understand what you are discussing right now, because it has been a big part of my time since I have been here in this position. I know personally, and I have been part of the meetings, that we are working as much as we can with the coalitions. We understand their goals. We have, though, a right -- well, not a right, but we have to protect business proprietary information. We are working with them right now to come up with the mechanism.

Ms. Castor. That is the business information of drug manufacturers and distributors?

Ms. Gibson. Proprietary information, yes. And that is statute. That is not something that I can chose to do. It is statute.

Ms. Castor. But the DEA said you would provide a couple of years of information. What is the difference?

Ms. Gibson. Ma'am, I actually -- there are multiple lawsuits going on right now, so I have to clarify actually which one, if you

are specifically talking about Ohio.

Ms. Castor. Yes.

Ms. Gibson. I know we have moved forward with several States as far as giving them information. Some States we have already. Some States we are still trying to work that out. So I would have to get back with you regarding exactly Ohio.

Ms. Castor. I know the DEA will have to get back to the Federal District Court judge.

Ms. Gibson. We have. We absolutely have.

Ms. Castor. -- shortly.

Ms. Gibson. We absolutely have.

Ms. Castor. I would just encourage the DEA to be as responsive as possible.

If there is a law that is preventing you from sharing certain data, the Congress needs to understand that. And I know there has been a lot of press reports about what has happened with drug laws and things, but we need some honest brokers in this business to help us combat it.

And you said you are committed to combatting the epidemic. And I would think DEAs full compliance with the District Court judge's request for information would go a long way to doing that.

Now, the Controlled Substances Act requires drug companies to report the unusually large or suspicious orders, and if they fail to do so, they are fined or they are suspended, or they lose their registration. Then DEA has the ability, if they are not complying, to issue orders to show cause or immediately suspend them.

I am wondering, in this physical year, how many enforcement actions have been taken by DEA, and can you characterize that? Do you have those statistics in front of you?

Ms. Gibson. As far as enforcement action, DEA --

Ms. Castor. I think your microphone.

Ms. Gibson. -- we have taken approximately 900 registrations per year in the past 7 years. In the past 7 years, I believe we opened, what 10,000 cases, about a couple thousand cases a year. So we are aggressively going after people and we are opening up cases, and we are using every tool that we have --

Ms. Castor. Could you provide those specific statistics to the committee, up-to-date? Because looking on the website, the data only goes through 2016, and it would be very helpful.

Also, there has been a lot of criticism about the DEA and the revolving door between the DEA and drug companies and manufacturers. What regulations are in place right now that -- just like Congress, we are prevented from lobbying for a couple of years -- what is in place right now, in ethics and government that prevents an employee from the DEA leaving and going to work for a drug manufacturer or a law firm that represents them or a drug distributor right now currently in law or in agency regulation?

Ms. Gibson. Ma'am, I wish I was close enough to retirement to have to worry about something like that, but unfortunately you are stuck with me for several years. I would have to get back to you with specific information regarding that. We do have an ethics committee and counsel

back at DEA, and he can provide exactly what you need regarding that.

Ms. Castor. Do you know of any restriction that is currently operative at the agency?

Ms. Gibson. Again, I wish I had the opportunity to know. That meant I was closer to retirement. But I --

Ms. Castor. Please get us that information.

Ms. Gibson. Absolutely.

[The information follows:]

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

Ms. Castor. Thank you very much. I yield back.

Mr. Burgess. The gentlelady yields back. The chair thanks the gentlelady. The chair recognizes the gentleman from Ohio, Mr. Latta for 5 minutes for your questions, please.

Mr. Latta. Thank you, Mr. Chairman, and thank you very much for being with us today on this panel. You know, being from Ohio, we are kind of, unfortunately, right in the middle of this. We have seen some, you know, sobering statistics that we had from overdose deaths. We go back to 2015, we had 3,050 people lose their lives. In 2016, that number went up by 1,000 to 4,050 people. And just in the period ending from the physical year from the end of June of 2016 to 2017, that number went to 5,232. So we are seeing this horrible increase in the State of Ohio. And also, a lot of this is being caused because of fentanyl.

And when you look at in 2016, we saw about 58.2 percent of all the overdose deaths because of something involving fentanyl. So, you know, our topic today is on the opioid crisis, but for us in Ohio, we are going through an epidemic because of how bad it is out there.

And if I could, because it is important for you, and I know there is a little bit of discussion that you have had already talking about drug take-back days and things like that. We have participated in two within Lucas County with the sheriff. I was absolutely astounded at how much came in that day. And then I was with the Findlay Police Department, just south of there in my district on another drug take-back day, and the amount of drugs that were taken back that day.

So, you know, there is things happening out there, and it is

important, but I am also working with legislation on getting the information out for my communities. And it is the Info Act. Because one of the things I have heard from my communities, because I represent a lot of small areas. And the problem is that they don't have the grant writers, they don't have the information. They need to have some place they can go to get the information, what is happening on the Federal side. And also, just as importantly, where the money is to help. So, you know, we have been working on that because it is very, very important.

But let me ask you, because in your testimony, again, just this data information back and forth, but in your testimony you talk about the heroin-fentanyl task force which is the intergovernmental working group, and you have a lot of, you know, law enforcement, Homeland Security, investigative Postal, even Defense and Intelligence Agency. Is it an oversight or is HHS not part of that working group?

Ms. Gibson. Sir, which working group?

Mr. Latta. Okay. This is the heroin-fentanyl task force that you mentioned in your testimony. I did not -- see that HHS is not in that group.

Ms. Gibson. Sir, I would have to get back with you exactly what the role would be. But I know for a fact anything that comes across my desk, I reach out for HHS immediately because they provide the scientific expertise that I need to get this job done. I have a lot of experts at DEA also, but we work hand-in-hand with them. So even if it is not listed, we would be more than happy to partner with

anybody --

Mr. Latta. Okay. Well, if you could just tell me if they are in that working group, that would be important. Let me go on. Because, again, when you are talking about fentanyl, and when you are talking about the importation, especially from China, and, again, I have had meetings with my 14 county sheriffs in conference calls and meeting with them personally, and also with my police chiefs across the districts.

One of the concerns out there, what is happening is, we are seeing that fentanyl is now being laced with marijuana. And not specifically in this case, but a young individual died in my district recently from fentanyl about the size of three grains of salt that took that person's life.

And what is DEA trying to do right now, trying to stop the importation? I know a lot of it is coming across from there. You brought up the fact it is $3,000-$4,000 and how much you can get on the street level, out there on the street with it over $1 million. But what is the active role DEA right now is taking on stopping the fentanyl from coming into the country, especially from China or if it is being sent to, you know, Mexico or into Canada and somehow getting brought back in the United States. But what exactly are we doing at DEA?

Ms. Gibson. Sir, I appreciate your question, because I am really proud to be sitting here saying that our DEA Beijing country office works closely with the Chinese Government.

China has been a very good friend to us. And the fact that they

have put 130 -- I think 138 new psychoactive substances. They regulated them over in China for us, and they are not even a problem over there. And statistics have shown if they regulate a substance over there, it has a direct impact on law enforcement encounters. It dramatically declines.

So DEA, we are very present in a lot of foreign countries that I am very proud of, and I think our job starts thousands and thousands of miles away from the United States borders, and I think that is just one example of it. And we are really appreciative for anything that the Chinese Government can do regarding regulating those substances.

Mr. Latta. Mr. Chairman, my time has expired.

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

The chair recognizes the gentleman from Maryland, Mr. Sarbanes. 5 minutes for your questions, please.

Mr. Sarbanes. Thank you, Mr. Chairman. Thank you, Ms. Gibson, for being here. I appreciate it.

I was looking at the website of the Diversion Control Division and some frequently asked questions on there. And I was focusing on a part of it that talks about how while DEA doesn't directly regulate the marketing of control substances, it is in keeping with your mandate to ensure appropriate safeguards against diversion, and you do have concerns when marketing and advertising tactics appear to create increased possibility for diversion or misuse.

And if you see such tactics leading to oversupply or minimizing

risk of abuse, you make every effort to work with pharmaceutical companies and the FDA to find appropriate solutions to these problems.

And I am really curious about sort of the history of OxyContin and the extent to which the Diversion Control Division had its wits about it when it came to the marketing practices of Purdue Pharmaceuticals and anybody else who was using unscrupulous marketing techniques and what kind of lens that the vision that you head up brought to that and continues to bring to that since it is something that appears to fall within the mission of the agency.

Ms. Gibson. Sir, I appreciate your concern.

The bottom line is the prescriber. One of our goals for 2018 is to have conferences regarding prescribers. Our goal is to get as much information out there to prevent a physician falling for those ads, and to make sure that opioid prescription is done correctly.

Just recently over our website we added the link to the CDC opioid prescription guidelines. So right now when it comes --

Mr. Sarbanes. So let me just interrupt. So your focus is on the prescriber but let's say you see a pattern of prescribers being bombarded with marketing tactics, false and misleading information, broad campaigns to stretch the facts on what a particular drug can and cannot do, the harm it may present, and so forth. Presumably, if you see a pattern of that among the prescribers that you are focused on, you would say you are, in effect, trying to protect from some of those marketing tactics, you then turn your attention, at least in part or in concert with other agencies that have jurisdiction, to the source

of the marketing and bring some attention to that.

So that is what I am interested in right now. What is that kind of focus? What are the questions you bring to those doing the marketing? What is the inquiry, and investigation, and pressure you bring to bear so that these marketing practices aren't bombarding these physicians, or pulling them in to a large disinformation enterprise?

Ms. Gibson. Sir, I appreciate your question because I have to say, that is something that I have not encountered and or really addressed since I have been here. So that would be a learning curve for me, too. I would definitely want to sit down with you and get you information regarding that because that is information, too, the marketing tactics I think would have to go a few years back for what your scenario is that you are giving to me. And I would love to find out myself exactly what we do.

Mr. Sarbanes. Well, I hope you get interested and it does seem to fall squarely within the mission to pay attention to these marketing practices. And there is a lot of history to look at with how OxyContin was marketed, how Purdue managed to overcome well-founded concerns and anxieties in the medical community about the addictive nature of that particular medication.

And the reason to study the history of it is because from what I can tell, those kinds of marketing practices continue in force. They may have, you know, altered them slightly to respond to pressure in the public and from some agencies, but I think the practices continue and we need you all to cooperate with any agency that has relevant

jurisdiction on this to make sure we shut those kind of practices, marketing practices down to protect people out there in the country. So I hope you will bring attention to it.

Thank you. And I yield back.

Mr. Burgess. The gentleman yields back. The Chair thanks the gentleman. The chair recognizes the gentleman from Indiana, Dr. Bucshon. 5 minutes for your question, please.

Mr. Bucshon. Thank you, Mr. Chairman.

I was a practicing cardiothoracic surgeon for 15 years prior to coming to Congress. You know, I have kind of known about this opioid situation for probably 25, 20-25 years. This is not a new problem, but it kind of reached the tipping point, and it has gotten dramatically worse, but the tipping point where it is become a public health issue, specifically.

And a little background from a physician perspective. Back in the 1990s there was a big push to control pain, both chronic and acute pain. And that came really from everywhere. It came from accrediting agencies for hospitals, it came from inpatient advocacy groups, it came from nursing groups, doctor groups. You know, those little smiley face, frowny face on the patient's chart. You know, your pain from 1-to-10, type of thing.

And so what happened is -- and I am going to be quick here because I have a question -- what happened is that we somewhat as a society started to create a culture of, in my view, of prescribing opioid-type pain medicine, probably in many cases, inappropriately when there were

non-opioid alternatives that could have been used for both chronic and acute pain.

And then, you know, and then it started to get linked to payment, where patient satisfaction scores, hospitals and others were worried about getting their payment cut because of patient satisfaction scores. And that included the quote-unquote, "fifth vital sign," which was pain.

That is not a defense of practitioners, but it also is the truth. And I think, you know, our society has created a culture that it is going to take a while to turn the Titanic, right? We are not turning the speedboat here. We are going to have to change our medical culture to fix some of that.

So a couple questions: What percentage, approximately, do you think of heroin being abused in the United States comes across the southern border of the United States?

Ms. Gibson. I don't know if I can give you a specific number, but I would think a fair majority of it would be coming --

Mr. Bucshon. The majority comes across there. So, you know, we have some, not only in areas where we have the international shipping, that is a huge issue, but my parents stayed down in Brownsville area for 20 years over the summer. And almost weekly they would catch a semi-load full of either cocaine or heroin, or something, right? And that is the ones they caught. So, you know, I think we do have an issue down there.

So in Indiana served the 8th district. It is very rural. And

this is going to change, we are going to change to a different direction here a little bit. And we have a problem with access to medication assisted treatment and the support for the use -- and I support the use of telemedicine.

In your testimony, you mentioned that there is confusion over whether a doctor is authorized to treat opioid-use disorder using MAT, medication assisted treatment, can perform the services via telemedicine, and the DEA is in drafting process to implement regulations regarding special registration for telemedicine.

Do you have a timeline of when you expect to promulgate these types of regulations?

Ms. Gibson. Sir, I understand your concern about the special registration. Upon my arrival here, I met with my drafting unit, and I realize that that has been pending a while, and it has been put on our unified agenda. And we are going to make it a priority right now. But I really think it is important for me to get out to 1.7 million registrants that it can be done.

Mr. Bucshon. Yeah.

Ms. Gibson. In certain circumstances it can be done. So the special registration has nothing to do with telemedicine being done now.

Mr. Bucshon. Right. Yeah, I mean, just do your best to tell everybody what the rules are. I mean, I think that is the bottom line, right?

With that, Mr. Chairman, I yield back.

Mr. Burgess. The gentleman yields back. The chair thanks the gentleman. The chair recognizes the gentlelady from Colorado for 5 minutes for your questions, please.

Ms. DeGette. Thank you so much, Mr. Chairman. Before I ask my questions, I just want to take a moment of personal privilege and thank my wonderful healthcare staffer, Polly Webster, whose last day is today, as a matter of fact.

Polly was instrumental in helping -- Fred Upton is sitting here, and he will tell you, she was instrumental in getting 21st Century Cures over the finish line. And we are going to really miss her. So thanks for all your good work, Polly. I appreciate it.

I also want to just make an observation, Mr. Chairman, which is I am hoping, I know there was some disappointment that a lot of the members left, but we had a very good showing on both sides of the aisle today for this hearing. And when the hearing was originally scheduled, it was a scheduled for a day when we thought we would be having votes. But having said that, I think -- and listening to Ms. Gibson's testimony here, unfortunately, I am going to have to miss the second panel because I am going to have to go home -- but I think there are so many issues around this opioid issue, and certainly the scheduling of fentanyl and other compounds is one issue.

Some of the other members have raised other issues. I believe that you are intending to have a whole series of these hearings. And I think that it really will be worth it.

Some of you know, everybody on the committee knows, I am the

ranking Democrat on the Oversight Subcommittee. And over the last few years, we have had a number of hearings on the Oversight Subcommittee around the opioid issue, so if there is anything we can do to assist this committee, you know, we could have some joint hearings, or whatever.

Someone said it has reached a tipping point, and it really has in every community in this country. And we need to take aggressive action. You know, Ms. Gibson when I hear you talking about the struggles with telemedicine and how do we, and how are we listing these substances and so on, it is just really clear there is a lot of facets to this and a lot of things that can be tightened up. So consider us to be your partners in this.

I did want to ask you about something that hasn't really been discussed today. As tempting as it is to go very deep into the issue of synthetic opioids, I want to ask you about drug take-back programs. As you know there is a lot of unused prescription drugs lying around in homes. And so Congress passed the Secure and Responsible Drug Disposal Act in 2010. What that says is it allows DEA registered entities like pharmacies and hospitals to collect prescription drugs for disposal.

Now in Colorado, my home State, the Consortium For Prescription Drug Abuse Prevention Has piloted a number of successful drug take-back programs that have helped remove these unused opioids. But unfortunately, as I understand it, the Colorado Consortium is the exception not the rule.

Last October, the GAO released a report that said nationally just 3 percent of DEA-registered facilities are operating take-back programs. So I am wondering Ms. Gibson, if you know what the primary challenges that DEA registered facilities face when they are trying to operate this program? Is there something we can do to -- or that you can do or we can help you do to make this program more robust?

Ms. Gibson. Ma'am, I appreciate your endeavors to expand upon this process because it is so critical getting this stuff off the streets for our kids. I know what keeps me going during the day is thinking about diversion and making sure that anything that is taken from our citizens out there, get it out of the hands of the kids to take is paramount to me. But I have to make sure that it goes to the right person and that it is not being diverted from that person and it goes to an entity where it is secured and it is not going to be stolen. So there is a lot of --

Ms. DeGette. Well, you are totally right, but those are called, those are called DEA-registered facilities, and they are supposed to be implementing this program. But only 3 percent of them are. I am not talking about getting people who aren't registered to do it. I am talking about people who are okay to do it, to do it. Do you know if DEA has programs to bolster up these facilities doing the take-back programs?

Ms. Gibson. I am going to have to look at that. I know we have one coming up in April. And if I can address that and take that back to my counterparts --

[The information follows:]

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Ms. DeGette. That would be great, because if --

Ms. Gibson. Right.

Ms. DeGette. We are all committed to it.

Ms. Gibson. Yes.

Ms. DeGette. We just need to make it happen.

Ms. Gibson. Thank you.

Ms. DeGette. We have to make that happen.

Ms. Gibson. All right.

Mr. Burgess. The gentlelady yields back. The chair thanks the gentlelady. The chair recognizes the gentleman from Missouri, Mr. Long. 5 minutes for your questions, please.

Mr. Long. Thank you, Mr. Chairman. And Ms. Gibson, you mentioned in your testimony that the drug control process under the Controlled Substances Act is reactive, and that it requires an extensive interagency collection and evaluation of data and an arduous and time-consuming process. Is this current process satisfactory?

Ms. Gibson. Sir, I appreciate your question. And I have to say, and I am just not saying this, since my time at Diversion Control Division, I am so impressed with the people that work there, primarily because we were able to do the class of fentanyls within 2 months. It may not sound quick to some people, but to get that done and get those substances scheduled in 2 months, a whole class, I think that was pretty darn good. So you know, SITSA can help streamline that process a little bit, but I think we are also doing our job just because of the diligent efforts of the people in Diversion.

Mr. Long. So even though it is an arduous and time-consuming process, according to your testimony, they are doing it quick?

Ms. Gibson. We got it done in 2 months, and that is because people, they went above and beyond.

Mr. Long. You also mentioned the difficulty of preventing the distribution and abuse of controlled substances analogue, designer drug, and you state the Analogue Act is cumbersome and resource-intensive. Can you discuss what is and is not working with the current structure?

Ms. Gibson. There is a process. And a lot of times the process takes a little bit longer than what we want. Look, I have 696 substances that I wish tomorrow I could put on a schedule and get them dealt with and get them regulated. But there is a process. And I have to adhere to that process. And, again, it is up to the valiant people that work for me that do their job above and beyond and get the process done.

Mr. Long. Well, speaking of the process, what can we do to make it less cumbersome, or can we, so the DEA can use its resources more effectively? If you had your druthers, what would you rather them do?

Ms. Gibson. If I had my what?

Mr. Long. If you had your druthers. If you would rather do something, what would you rather them do?

Ms. Gibson. If I had a choice, what I could do to make this --

Mr. Long. That is English, yeah. Choice, yeah.

Ms. Gibson. Okay. Sorry, I am a simple girl from Pennsylvania.

You know, again, I think that is one of the neat things, that I come from an enforcement background. I was an agent in New York City for 20 years, and now I have this hat to put on under Diversion. And it is exciting because now I get to ask those questions, and in a perfect world, what can I do, what can I make better. And I ask that question a lot.

And so I am still formulating exactly what I can do to think outside the box, but I know one thing I am definitely believing in is getting information out there. I just recently visited a methadone clinic. It was Dr. Hoffman's methadone clinic here in D.C., PDARC, and I learned a lot of invaluable tools from that and dissemination of information to get people help, to get local law enforcement, you know, help to tackle dealing with this issue.

So, yes, sir, I can get back with you. Give me a month and maybe I can have a lot more ideas. I have ideas brewing. I just got to make sure that I take them into the right arena and move forward with them. But I promise you, I am thinking outside the box as much as I can.

Mr. Long. Okay. Thank you. And thanks for being here. And Diana had my other question there, so we got that answered when she was asking her questions. So now that I have introduced your druthers to the committee, I yield back.

Ms. Gibson. Thank you.

Mr. Burgess. The chair thanks the gentleman. The gentleman yields back. The chair recognizes the gentleman from New Mexico, Mr. Lujan for 5 minutes for questions, please.

Mr. Lujan. Thank you, Mr. Chairman. Ms. Gibson, thank you so much for joining us today. According to the CDC, in 2013 providers wrote almost 250 million opioid prescriptions in the U.S. Enough for every American adult to have their own bottle of pills.

Can you briefly explain how the high volume of opioids prescribed in the U.S. contributes to the misuse of prescription drugs?

Ms. Gibson. Sir, I appreciate your question. And from what I am experiencing and what I am learning here, regarding prescription of pills, we have a lot of doctors out there that do God's work. They do the right thing. But we have some people out there that have overprescribed. And it is incumbent upon DEA to make sure that we get the education out there and maybe provide guidance and correct some behavior, and go after the people that are stockpiling currency at their house because they are writing too many prescriptions, and they are doing nefarious things. And that is actually happening. So that is my concern, are those doctors. And I want to make sure I get the education out there to streamline prescriptions.

Mr. Lujan. And so I think what you are referring to, Ms. Gibson, is that the DEA recently started asking if new or renewal of registrants for a DEA license have received training on safety prescribing, prescription drugs.

Can you explain why the DEA took the action, and how the DEA will utilize data on prescriber opioid training?

Ms. Gibson. We did it on a voluntary basis right now, so any registrant that renews the registration or its initial application for

registration, they voluntarily check a box to let us know that they received CME, continuing medical education. Again, we have a great website. I have got 1.7 million registrants. And the best way of me communicating with them is through that website so, and that is what I am intending to do.

Mr. Lujan. So in the future, will the DEA increase supplement prescriber training on the dangers of opioid and safe prescribing practices for opioid medications?

Ms. Gibson. Absolutely, sir.

Mr. Lujan. I appreciate your testimony in that space, Ms. Gibson. One thing I wanted to, I think, just bring up to the caucus -- or to the committee: Ms. Gibson, how long has this opioid crisis been affecting America?

Ms. Gibson. Sir, way too long.

Mr. Lujan. Do you know when it started?

Ms. Gibson. I mean, according to another physician that was here, he has been a physician for 25 years, and he saw it. So I think prescribing of opioids have happened well before we actually recognized it as an epidemic.

Mr. Lujan. Would it surprise you if I said that the opioid epidemic has been affecting America since before we were a country?

Ms. Gibson. It wouldn't surprise me because I believe that methadone was actually a World War II development, if I remember correctly.

Mr. Lujan. Well, let's go back to the 1800s, at the very least.

So as we talk about the 19th century. The reason I bring this up -- and I am going to ask an article be submitted into the record --

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Mr. Lujan. Is just so that we don't lose sight that this problem is at least a couple hundred years old, if not over 300 years old, from where we are today, and what I hope that we realize is that while we are talking now about pills, that some of these drugs and strains that have hit the streets, these were developed by companies to deal with opioid addiction. They say, you are addicted to an opioid, so we are going to come up with another opioid to treat that opioid addiction, and we are going to warn about this one to treat that one.

And so the reason I ask that question, and I see some giggling in the audience, which alarms me, this is a serious epidemic, I think earlier someone said this was maybe 8 to 10 years old. People have been getting killed in all parts of America for too long. And I know that in my district, we have had problems in this space that whether they are prescription drugs or heroin, as we have seen grow across the America.

I am real interested in going after all parts of the problem that we see. I think earlier you said that you never give up, "we never give up at the DEA." Are there current investigations pending with companies that were recently fined to see if they have corrected their behavior about distributing large amounts of pills in our communities?

Ms. Gibson. Yes, sir.

Mr. Lujan. I believe that Mr. McKinley joined our chairman and our ranking member of this committee to inquire about some of these questions to these manufacturers and distributors, and it is something that we need to get to the bottom of, and that we look forward to working

with you.

And with that, Mr. Chairman, I would like to submit two articles into the record, one titled, The Opioid Epidemic, a Crisis Years in the Making, from the New York Times, October 26th, 2017, and from Smithsonian.com, inside the story of America's 19th Century opioid addiction.

Mr. Burgess. Without objection, so ordered.

[The information follows:]

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Mr. Lujan. Thank you, Mr. Chairman.

Mr. Burgess. The gentleman's time is expired. The gentleman yields back. The chair recognize the lady from Indiana, Mrs. Brooks. 5 minutes for questions, please.

Mrs. Brooks. Thank you, Mr. Chairman, and thank you so much, Ms. Gibson, for being here.

I have worked with the DEA. I was U.S. attorney in southern district of Indiana from 2001 to 2007, worked very, very closely with the DEA during that time. Not only prosecuting large drug trafficking organizations and know the incredible dedication that agents have, but also worked with Diversion at that time, because we did a very significant case involving significant diversion of OxyContin by a physician.

And so I know that DEA has been involved in the prescription, then-heroin problem for a long time, to my colleagues on both sides of the aisle. But what I think has changed over time is that we now know, because of the incredible epidemic, I think in large part fueled by far too many people being on opioids as a prescription initially, and I think the research has shown that, that about 80 percent or so, started with prescription drugs, moved to heroin, moved to fentanyl, and that is where our overdose deaths are.

But I think we do have a lot of prescribers, not just physicians but nurse practitioners, dentist, podiatrists, lots of others that maybe have not had sufficient medical education or continuing medical education.

And so in the spirit, in some ways, of Representative Schneider's bill, I have been working on a bill as well, but in a bit different format, because you mentioned there has to be that interaction, DEA -- and I was looking at your Diversion website -- between the States and the Federal Government on regulation and on licensing.

Can you please talk with us about how DEA, DEA for anyone to be a prescriber, they have to get what is called the magical DEA number. Is that correct?

Ms. Gibson. Yes, ma'am.

Mrs. Brooks. And that is what it is called, isn't it?

Ms. Gibson. Yes, the DEA registration number.

Mrs. Brooks. The DEA registration number. And am I missing categories of prescribers, besides physicians? We all know physicians. But who is eligible to get a DEA number?

Ms. Gibson. As far as prescribers?

Mrs. Brooks. Yes.

Ms. Gibson. Well, right now anyone that dispenses, that can write a prescription, needs a DEA number. Since I have been there at Diversion, I have definitely been made aware of data-waived prescribers, and that is for drug treatment.

Mrs. Brooks. And how long have you been there, in Diversion? I know you have been an agent in the field for a long time.

Ms. Gibson. A month and a half, ma'am.

Mrs. Brooks. Okay. Well, welcome.

Ms. Gibson. Thank you.

Mrs. Brooks. -- to leading the effort, because I really do believe you are and need to be the person leading the effort for DEA because we have to do a lot of things differently than what we have been doing.

What we have been doing isn't working. We haven't turned the corner yet. We are not just at the tipping point. We are beyond the tipping point. We are losing far too many people. I attended a funeral of a family friend in December, far too many funerals last year. And we have not changed it.

And yet, I know that our prescribers do not want to be a part of the problem, but I think we need more education. And I think in Indiana, our State medical association, as well as a number of the groups we have talked to are willing and want to be a part of the problem and get more education. And in fact, have done it in Indiana. Some States do. Some States don't.

And what I am asking is whether or not what we are working on is 3 hours of continuing medical education over the period which is every 3 years, is that correct? Do you know?

Ms. Gibson. According to your bill, I think it was 3 hours every 3 years.

Mrs. Brooks. Correct. And that the States would then have jurisdiction over determining what is the appropriate training.

And how do you feel about that? That the State medical associations and the State medical licensing boards would be the ones that would be in charge of working, of course, and looking for the best

practices of training from HHS?

Ms. Gibson. Ma'am, we rely on our State counterparts. We need them. Hands down, we need them.

Mrs. Brooks. Well, in fact a prescriber can't get a DEA license unless they show they have a valid medical --

Ms. Gibson. Yes.

Mrs. Brooks. -- or a valid license --

Ms. Gibson. Yes.

Mrs. Brooks. -- in the State, is that correct.

Ms. Gibson. Yes. And oftentimes we work with the States regarding, if a State can easily take away a registration, then if they don't have that State registration, we are able to revoke their Federal registration.

Mrs. Brooks. Is there enough coordination between all 50 States and DEA, or are there some problem States? I won't ask you to name them.

Ms. Gibson. I have to say, again, I am proud of Diversion investigators because their imbedded in these communities, and they all work closely with their States regarding those issues. So I haven't heard of any issues, but obviously, if there are, I will make sure that they are addressed.

Mrs. Brooks. I have a number of other questions but will submit in writing. Thank you so much for your efforts.

Ms. Gibson. Thank you.

Mr. Burgess. The chair thanks the gentlelady.

Mrs. Brooks. I yield back.

Mr. Burgess. The gentlelady yields back. The chair recognizes the gentleman from North Carolina, Mr. Hudson. 5 minutes for questions, please.

Mr. Hudson. Thank you, Mr. Chairman. Ms. Gibson, thank you for being here today.

As you know, the opioid epidemic is arguably one of the worst public health crises we have ever faced in this country. In North Carolina, we have 4 of the top 25 worst cities for abuse in the country, including Fayetteville, North Carolina, in my district. I don't believe there is one silver-bullet solution, but I have honed in one area that I do believe we can make a big difference, and that is the proper disposal of opioids.

As I examined disposal, I have found that almost every one I talked to back home, a light bulb goes off when we start talking about it, and they say, you know, I have a bottle of pills in my medicine cabinet. I talked to one woman who for 5 years moved her bottle of opioids with her as she moved from apartment to apartment.

And just a few statistics to provide: There are as many as 200 million opioids prescriptions written each year. As many as 92 percent of patients don't complete that. In other words, have pills left over. Less than 10 percent of those folks properly dispose of them. So we are talking about a huge amount. And according to the National Institutes of Drug Abuse, 70 percent of heroin addictions start by a product found in a home medicine cabinet.

I went on the DEA website last night, and the recommendations for disposal of unused medications, including DEA take-back programs -- which I participated in -- flush them down the toilet, mix them up with something undesirable, such as kitty litter or coffee grounds or dirt in a resealable bag and throw them in the trash. These are recommendations updated as of October 25 of 2017.

Given all the statistics I have just listed and the scope of the opioid epidemic, we are facing, do you think these recommendations are effective? Just yes or no.

Ms. Gibson. Yes.

Mr. Hudson. Okay. And then would you agree that we might, though, need to explore some new ways to help patients dispose of unused prescription drugs, in particular opioids?

Ms. Gibson. Absolutely.

Mr. Hudson. Great. Would you be willing to work with me on some solutions we have been working on and taking a look at to try to bring more options for consumers?

Ms. Gibson. Absolutely.

Mr. Hudson. Great. Well, I appreciate your testimony and your time here today, and look forward to working with you on this.

Ms. Gibson. Thank you.

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

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

The chair recognize the gentleman from Virginia, Mr. Griffith, for 5 minutes for questions, please.

Mr. Griffith. Thank you, Mr. Chairman. I appreciate it very much. I appreciate you being here with us today.

So I have heard a lot of comments from my colleagues on both sides of the aisle about concerns about doing research with different -- and I don't know what the right word is -- but when you change the formula a little bit on fentanyl, and they are concerned about, you know, we don't want this stuff on the street, but what about research because it may be helpful, the drug might, if you change it a little bit, it might actually have some positive impacts. And you responded that you have 600 folks working on THC and cannabidiol.

My concern is, and I think probably where this concern has come from other folks is, is that this has been a long standing complaint with the DEA on substances that are either unscheduled or schedule I, such as marijuana. You mentioned THS and cannabidiol. You know, Virginia had the first medical marijuana law in the United States passed in 1979 by former Congressman Rick Boucher when he was in the State Senate, and member of the House of Delegates, the late Chip Woodrum.

And from 1979 to 1998, there wasn't a whole lot going on, because in 1998, somebody tried to take that law off the books. That is when I got involved in this issue. And what we heard at that time in Virginia was, yeah, they say they are doing research at the DEA, but we have a hard time getting approval.

And I note that with some interest that in our next panel, we have

a witness, Dr. Beardsley, who in his testimony, his written testimony, tells us that in one instance, it took over 4 months to get cannabidiol added to my schedule I registration. And this drug has no abuse potential and no street value, so I think it is pretty much accurate.

So I want to work with you to get the language right. I don't want this stuff on the street. But I also want to make sure that we don't have a repeat of the past, and then once it gets, you know, put into a schedule I or schedule A, as the Katko bill would have it do, that we not just immediately taken all those substances off the table for research. Because if we don't continue to look at all the possibilities for all kinds of treatments, we may not know what we are missing, and we may have some value in that.

Will you agree to work with me on that and others to get this language right so that we can do the research while trying to give you the power to get the nasty stuff off of the streets that we don't want our kids using, but knowing that sometimes a little poison can be a medicine?

Ms. Gibson. Sir, I appreciate your concern about research, and it is my concern, too. And I will be more than happy to work with you regarding research. If we can streamline the process, if we can get the right people to do --

Mr. Griffith. What I want is not just the research. I want your folks and your legal team to help our legal team come up with language that allows us to do both. To make it, you know, improper to have it on the streets, but still to allow our research universities and our

folks and our doctors and our medical community who are doing research, to look for those miracle cures, even if one of those may have some component that is a fentanyl derivative.

Ms. Gibson. Sir, I will be more than happy to work with you.

Mr. Griffith. On getting that language down?

Ms. Gibson. Yes, sir.

Mr. Griffith. Excellent. Thank you.

Also, Mr. Beardsley's written testimony mentions a policy change made a few years ago that now requires a researcher to have a separate control substance registrations for each building that they conduct research in.

So he goes through a system, and he says, you know, I used to have one person who could be in charge of it, now I have to have 20 people. And some of those people have to have four different registrations because they work in four different buildings. And he is at MCV, Medical College in Virginia, VCUs medical school. And it is in downtown Richmond, and they do stuff in lots of different buildings, four for research, apparently.

I am just wondering why that policy change was made and if we couldn't change it back?

Ms. Gibson. Sir, again --

Mr. Griffith. You have been here a month and half and you don't know the answer to that one. Can you research that and get it for me?

Ms. Gibson. But I want to find the answer for you.

Mr. Griffith. Yes, ma'am.

Ms. Gibson. I am sitting here and I want to find the answer for you. And I definitely want to work with you regarding this, because I believe research is very important.

Mr. Griffith. Yes. And I understand that. That is a reasonable answer in light of the fact you have been there 6 weeks.

Have you all released any updated regulations or guidance to pharmacists or other healthcare professionals and/or patients regarding the implementation of Section 702 of CARA, which allows prescribers and patients to request a partial fill of schedule II control substances. And if yes, where can that information be found. And if not, why?

Ms. Gibson. Sir, I believe that is still in my regulations department, still being drafted. And we are trying to get that language right, but is it definitely part of the CARA bill, and we are definitely working on it.

Mr. Griffith. Well, and I would hope that, and I appreciate that you all worked hard to get the fentanyls rescheduled or scheduled in 2 months, but this would cut down on supply out there on the street and would really appreciate if your department that handles that could get that done expeditiously.

With that, I have to yield back because my time is up and I thank you much.

Mr. Burgess. The chair thanks the gentleman. The gentleman yields back. The chair recognizes the gentleman from Georgia, Mr. Carter, 5 minutes for questions, please.

Mr. Carter. Thank you, Mr. Chairman. Thank you, Ms. Gibson, for being here. I appreciate it very much. We talked earlier today, you had a question from another member about a bill that I am cosponsoring along with one of my Democratic colleagues, the Special Registration For Telemedicine Clarification Act of 2018.

And you mentioned that it is available now that you can, through telemedicine that you can get a waiver in order to write a prescription for an opioid for pain medication without seeing the patient but seeing them through telehealth. Is that right?

Ms. Gibson. It is not a special waiver, from what I understand. Telemedicine under the Ryan Haight Act --

Mr. Carter. Right.

Ms. Gibson. -- has been outlined as far as there are certain situations that you can follow and you can engage in telemedicine.

Mr. Carter. But the Ryan Haight Act limits that. But nevertheless, the intent of this bill that we are cosponsoring, Representative Bustos and myself, is to allow or to direct the agency to come up with and to promulgate the rules so that we can do this, so that it can happen. Because this is extremely important, particularly in rural areas where telemedicine is vital, and particularly for patients who need that pain medication who may not have access to a professional at that time.

Ms. Gibson. I agree that telemedicine is definitely needed. But, again, when I put my regulatory hat on and my main concern is diversion.

Mr. Carter. I understand. Do you feel like this is something that you can do? Because what we say in this legislation is to direct the agency to come up to DEA to promulgate the rules within 30 days of the passage of the law.

Ms. Gibson. I understand.

Mr. Carter. Okay. Well, I just want to make sure. And certainly, we are concerned about the fraudulent use of it as well. So another bill that I am cosponsoring, again, along with one of my Democrat colleagues Representative Mark DeSaulnier, is Empowering Pharmacists in the Fight Against Opioid Abuse Act. And that, of course, is for the DEA to help pharmacists to identify fraudulent prescriptions. And that is something that is very important. For your information, currently I am the only pharmacist serving in Congress. I practiced for over 30 years. And I have to tell you that this is something we do need help with, and we welcome this help. We want to have the ability to identify fraudulent prescriptions.

However, you have to keep in mind that we are not law enforcement officers. The only thing worse, I think, for myself as a practicing pharmacist, the only thing worse than dispensing medication that would be opioids, in particular, that would be for abuse and for diversion, would have been to deny a prescription to a person who truly needed it. That is very difficult.

I don't want to have to profile. It is unfair for you to expect me to have a patient come in and for me to make a decision by looking at that patient and saying that, you know, they don't look like they

need this, that I am supposed to keep them from having it. That is simply not right. And something that I am not trained in. So I hope you will keep that in mind during the time that you are looking at it.

Another thing I wanted to touch on was what we did in CARA, the Comprehensive Addiction Recovery Act, is to allow 3 prescriptions for a 30-day supply to be written. One of the things that has been suggested, and it was just mentioned, was the fact that possibly allowing physicians to have a refill on a prescription, in a smaller amount.

All of us in pharmacy have experienced getting a prescription for, you know, for a simply dental procedure for 30 oxycodone. And that is something we hate to see.

So I hope that the Department will look at possibly allowing for a smaller quantity with perhaps just one refill that has to be filled within a certain time period. That is something that I had hope you will look at as well.

RPTR FORADORI

EDTR SECKMAN

[3:04 p.m.]

Mr. Carter. One of the things that concerns me is -- look, there are rogue practitioners in every profession, every profession, including the medical profession, and practitioners. And one of the things that concerns me is that I have never had a doctor who said: I didn't know opioids were addictive.

Physicians are smart people. They are intelligent people. They have gone through intensive training. They understand it. They do need to have continuing education with it.

But it does concern me, and it concerns me on how long it takes for the DEA to respond to some of these rogue doctors. Sometime I hope you will look at that.

The last think I wanted to touch on is, when I was a member of the Georgia State legislature, every year, we have a dangerous drug act, and we include drugs into the schedule I classifications in our State. I did that on numerous occasions. It is very difficult. It is going to be very difficult with you with the synthetic drugs. I know how they get around it.

I just want to ask you. After it becomes a schedule I drug, a State can't overrule you and say that that could be legal, can they? You know where I am going.

Ms. Gibson. I know where you are going.

Mr. Carter. Okay. Yes or know.

Ms. Gibson. And if Federal law identifies a substance to be schedule I, it is schedule I.

Mr. Carter. Can I ask you one question?

Ms. Gibson. Yes, sir.

Mr. Carter. What is marijuana?

Ms. Gibson. Schedule I.

Mr. Carter. Thank you very much.

Mr. Chairman, I yield.

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

The chair recognizes the gentleman from Kentucky, Mr. Guthrie, the vice chairman of the subcommittee. You are recognized for 5 minutes for questions.

Mr. Guthrie. Thank you, I will be -- thank you for being here today. And I have -- there we are -- in your testimony, you mentioned AlphaBay, a criminal marketplace website operated for over 2 years. I understand it took a lot of national and even international resources to take them down.

Can you please tell me if there is now a timely process in place should another AlphaBay surface again?

Ms. Gibson. Sir, I appreciate your questioning because these cases are difficult. These cases are labor intensive to include diversion cases. Going after physicians, it is incumbent that we use every tool in our toolbox to go after them, to include working with

our State. So, yes, they are labor intensive, but we get it done, and that is why I am proud of the DEA, because no matter what the task is in front of us, we figure it out, how to do it, and we get it done.

Mr. Guthrie. I understand that, and I agree. But if there is something unique like website -- this new website that came on board, you went through a 2-year process, and you did, there had to be lessons learned, to say, well, this is something that we could have done differently, done better that would have sped up the process again or sped up the process, and hopefully that is more of a -- adopted into plans?

Ms. Gibson. Sir, I am a fairly aggressive human being, and I believe that we learn from anything that we do, and we make it better. And that being said, anything that we can improve upon to get these bad actors out there in handcuffs, I am all for. Anybody who violates the CSA intentionally, they will be in handcuffs, if it is up to me.

If it is a distributor and if I have a criminal case that I can make against them, they will be in handcuffs, I promise you.

Mr. Guthrie. Thank you, I appreciate that. And also, yesterday, Attorney General Sessions announced the formation of the new Prescription Interdiction & Litigation Task Force at DOJ. I was very pleased to hear about this. And can you please speak to the DEA's role in this task force and how the DOJ task force will work with the DEA Special Operations Division on heroin/fentanyl task force.

Ms. Gibson. Sir, I appreciate your question, and that is a new endeavor. And we are working with our counterparts at the Department

of Justice right now to understand our role. So I would have to get back with you regarding your answer.

Mr. Guthrie. Okay. Thank you.

Also, I know several people, Ms. DeGette and Mr. Hudson and others, have mentioned the National Drug Take Back Initiative. I think several of us have asked about that. It has been effective, but we can do more. I know that Mr. Walberg, who is probably going to go in a couple of minutes, has a bill addressing unused opioid disposal for hospice. I won't get into his area, but I know he is going to talk about that.

But would you just kind of speak to safe disposal and what options do we have, and what you would like to see Congress do in that respect?

Ms. Gibson. Sir, I appreciate that concern because it is a concern of mine, because once we can get these drugs off the street in the prescription pill form, we have to make sure that they are not diverted again. So that requires guidelines. That requires policy. And we would be more than happy to work with any entity out there to come up with a game plan so that when we get those pills off the street and we can get them into a safe location and they remain in custody to be disposed of, that is our ultimate goal.

Mr. Guthrie. Okay. Thank you. And that finishes my questions. I yield back a minute 26.

Mr. Burgess. The gentleman yields back. The chair thanks the gentleman. I think we have accommodated all the members of the subcommittee, and I am now pleased to recognize Mr. Walberg, who is

a member of the full committee, 5 minutes for your questions.

Mr. Walberg. I thank the chairman for your hospitality and allowing me to sit with this panel today.

And, Ms. Gibson, thank you for the work that you do, and thank you for being here.

In Mr. Mulder's testimony to come, it expresses support for H.R. 5041, a bill that I have sponsored along with a couple of other members of our committee. He expressed the support of it being expanded to authorize hospice personnel to dispose of unused medication when a living patient undergoes a medication change. Would the DEA have concerns with that proposal?

Ms. Gibson. Sir, we definitely want to work with you and the committee to make sure that we get the language right and we get the process right, because we want to make sure that we get those drugs into the hands of an entity that can secure them and prevent them from being diverted.

Mr. Walberg. Well, I think that would be the concern of the hospice personnel as well at this point, plus making sure that there isn't a temptation by leaving those in the medicine cabinets or -- we look forward to working on that.

Would the DEA be supportive of language being included in the bill to add additional reporting requirements? For example, a notation on the patient's record that state the date the medication was destroyed, the dosage, and who destroyed the medication, could that alleviate concerns?

Ms. Gibson. That is definitely language that we can talk about and add. Absolutely, it would be a mechanism that would we could use.

Mr. Walberg. Thank you. I won't wear out my welcome. Those were two questions I had. I yield back.

Mr. Burgess. The chair thanks the gentleman. The gentleman yields back. I believe that has accommodated everyone who had questions.

Mr. Green, do you have a followup?

Mr. Green. No.

Mr. Burgess. Neither do I. We are going to take the briefest of recesses while we transition the panel.

Ms. Gibson, I want to thank you for your participation today. I expect we will have an opportunity to talk about all of these things in more detail as your tenure in the agency increases. So thank you for being here today.

Ms. Gibson. I look forward to it. Thank you.

[Recess.]

Mr. Burgess. I think we have successfully transitioned -- almost successfully transitioned. We still have a couple of vacant chairs. There we go. Well, I think we have transitioned to our second panel today, and we want to thank our witnesses for being here and taking the time to testify before the subcommittee.

Once again, each witness will have the opportunity to give an opening statement, and that will be followed by rounds of questions from members. So, today, this afternoon, in the second panel, we are

going to hear from Mr. Frank Fowler, chief of police, Syracuse Police Department; Dr. Patrick Beardsley, professor, Department of Pharmacology and Toxicology, Virginia Commonwealth University; Dr. John Mulder -- I have got you out of order -- Dr. Mulder, John Mulder, director, Trillium Institute; Dr. Ponni Subbiah, chief medical officer, Indivior; Dr. David Kan, president, California Society of Addiction Medicine; Richard Nance, director, Utah County Department of Drug and Alcohol Prevention and Treatment; Thomas Cosgrove, partner, Covington and Burling, LLP; Dr. Andrew Kolodny, codirector, Opioid Policy Research, Brandeis University; and Richard Logan, owner of L&S Pharmacy.

We appreciate each of you being here today and, again, are grateful for your forbearance in what has been a long afternoon. Chief Fowler, you are recognized for 5 minutes to give a summary of your opening statement.

And, chief, make sure your microphone is --

STATEMENTS OF FRANK L. FOWLER, CHIEF OF POLICE, SYRACUSE POLICE DEPARTMENT; PATRICK M. BEARDSLEY, PH.D., PROFESSOR, DEPARTMENT OF PHARMACOLOGY AND TOXICOLOGY, VIRGINIA COMMONWEALTH UNIVERSITY; JOHN MULDER, M.D., FAAHPM, HMDC, DIRECTOR, TRILLIUM INSTITUTE; PONNI SUBBIAH, M.D., CHIEF MEDICAL OFFICER, INDIVIOR PLC; DAVID Y. KAN, M.D., PRESIDENT, CALIFORNIA SOCIETY OF ADDICTION MEDICINE; RICHARD J. NANCE, LCSW, DIRECTOR, UTAH COUNTY DEPARTMENT OF DRUG AND ALCOHOL PREVENTION AND TREATMENT; THOMAS J. COSGROVE, PARTNER, COVINGTON AND BURLING LLP; ANDREW KOLODNY, M.D., CODIRECTOR, OPIOID POLICY RESEARCH, BRANDEIS UNIVERSITY; AND RICHARD N. LOGAN, JR., PHARM.D., OWNER, L&S PHARMACY.

STATEMENT OF FRANK L. FOWLER

Chief Fowler. Thank you. Thank you, Chairman Burgess, Ranking Member Green, and the distinguished members of the Committee on the Energy and Commerce. I am here today to make an effort to paint a picture of a community that has been ravaged by synthetic drug abuse. Beginning in 2013, the Syracuse Police Department responded to an increase in the use and subsequent overdose of synthetic marijuana known as Spike. The Syracuse Police Department implemented various means of tracking the problem in addition to our law enforcement efforts.

In 2015, the Syracuse Police Department saw its largest number of overdoses from the use of synthetic marijuana, the largest number

of overall cause for services, cause for services related to overall overdoses and persons down, and also made the largest number of arrests related to this substance. While the department took steps to get these drugs off the streets, new chemical formations of Spike were beginning to put -- were beginning to be put into circulation.

In addition to all of the Syracuse Police Department's efforts, the only thing that we could charge a person with was a local law violation, issuing them an appearance ticket and releasing them. This is just one example of the dangerous synthetic compounds that are flooding our streets. Toxic synthetic drugs are designed to mimic drugs like marijuana, LSD, cocaine, ecstasy, and other hard drugs. They could be more potent than the real thing, and oftentimes are more deadly.

In addition, these drugs are not simply affecting the users, my officers and other first responders are put in harm's way simply by coming in contact with these often lethal substances.

As a local law enforcement official, we need H.R. 2851, the SITSA Act, which was introduced by Congressman Katko. This bill takes a big step towards eradicating these harmful substances and protecting our community. SITSA will give my officers the tools they need to target synthetic substance and the criminals who distribute and traffic them.

Under this bill, a drug such as Spike could be temporarily or permanently be added to the new schedule under the Controlled Substances Act in as little as 30 days after the chemical compound has been identified. The abusers of these synthetic drugs are not simply

confined to my jurisdiction. Colleagues of mine from across the country are dealing with the same issues and have expressed a need for a solution. H.R. 2851 is that solution.

I urge this committee to pass this bill and to give us the tools we need to combat this deadly epidemic. Thank you again for this opportunity and I welcome your questions.

[The prepared statement of Chief Fowler follows:]

******** INSERT 3-1 ********

Mr. Burgess. Thank you, Chief Fowler.

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

STATEMENT OF PATRICK M. BEARDSLEY, PH.D.

Mr. Beardsley. I am Dr. Patrick Beardsley, a professor of pharmacology and toxicology at the Virginia Commonwealth University. In addition to my faculty appointment, I am a member of the Expert Committee on Drug Dependence for the World Health Organization, a committee that is the first step for processing drugs for their international control.

Thank you for the opportunity to be here today to discuss SITSA, H.R. 2851. We are all dedicated to finding paths to take us away from our present opioid crisis. I believe one path will be through research. There is a perpetual need to strike a balance between regulatory control of drugs to ensure public safely and the necessity for researchers to have access to controlled drugs to further science.

The Controlled Substances Act, the CSA, explicitly recognizes both those needs, and I am personally sympathetic to both needs. As a researcher of the drugs of abuse, however, I have concerns that SITSA upsets that balance. I would like to take the next few minutes of your time to identify my concerns.

It is my opinion that the Attorney General has already been able to effectively regulate all synthetic opioids that are known to be a current problem via the present CSA. Effective February 6 of this

month, the DEA issued a scheduling order that included all fentanyl-related substances that are not currently scheduled to be included in schedule I.

Fentanyls constitute the greatest portion of all synthetic opioids abused. A few non-fentanyl synthetic opioids that have been identified as abused have previously been scheduled. Because most, if not all, currently abused synthetic opioids are currently scheduled under the CSA, it is unclear of the introduction of schedule A by SITSA to help address the current problems with abused synthetic opioids.

Considering 13 fentanyls are exclusively identified in SITSA to be included in schedule A, it is likely all will eventually be transferred. How public health would be enhanced transferring these compounds from schedule I to schedule A conditions is also unclear. The addition of another category of drugs by SITSA to the CSA is problematic. In so doing, it adds another level of costly bureaucracy to researchers who work with drugs of abuse.

Registrants with only a schedule II to V registration will have to obtain a schedule A registration. All registrants, whether they hold a schedule I or a schedule A registration, will have to submit protocols to the Attorney General for his approval to justify the use of each drug in schedule A. Functionally, this arrangement is very similar to how research with schedule I drugs are now handled. It can take a year or longer to obtain a schedule I registration, and it can require many months to have a new drug added to one's existing schedule I registration. With similar delays that are now impeding research

with schedule I drugs transferred to schedule A drugs, SITSA will provide nothing to the research that will has hasten our understanding of synthetic opioids through science and will likely only impede that progress. This problem is compounded by an absence of a mechanism in SITSA for removing a drug from schedule A once it is scheduled.

Under SITSA, the Attorney General has the power to place a compound in schedule A based upon a drug structure. And in the absence of additional scientific information, commonly provided by HHS and NIDA, the National Institute of Drug Abuse, this can result in misclassifications of drugs and missed opportunities for discovering medications we need to confront the opioid crisis with.

Determining scheduling driven by chemical structure can be misleading. For example, the chemical structures of morphine and naloxone are very similar, yet one is highly abused and the other is an antagonist that is an antidote to the effects of the other. Adding a compound just based upon structural similarity to an abused compound may inadvertently ban an antidote to the abused compound.

In addition to my concerns regarding SITSA, I do have suggestions that would make conducting research with synthetic opioids and controlled substances in general more efficient, far less costly, and bring much relief from the bureaucratic burden of conducting research with them. My statement time doesn't permit me to enumerate them, but my suggestions can be found in my written statement, and I would be happy to discuss them later, if asked.

I have tried to identify a few concerns I have with SITSA as a

researcher, and I welcome any questions you may have. Thank you.

[The prepared statement of Mr. Beardsley follows:]

******** INSERT 3-2 ********

Mr. Burgess. Thank you, Dr. Beardsley.

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

STATEMENT OF JOHN MULDER, M.D., FAAHPM, HMDC

Dr. Mulder. Thank you, Chairman Burgess and members of the committee. We appreciate the opportunity to just share a few moments with you this afternoon. I am John Mulder. I am a physician who has been practicing in the field of hospice and palliative medicine for over 30 years and have cared for a lot of folks, thousands over that period of time.

I am here in support of House bill 5041 and appreciate Representative Walberg, as well as Representative Dingell and Representative Hudson, for crafting and advancing this bill. It is pretty straightforward. This bill would allow hospice -- licensed hospice personnel to destroy medication in the home that is left over after a patient dies, or in cases where someone is still living, but the medication has been changed, leaving excess medication in the house. It would allow for them to properly dispose of that.

Every year in America, we care for between 1-1/2 and 2 million hospice patients, which means that those are the numbers of patients that are dying. And I would submit that virtually everyone has medication left over. We can't predict when someone is going to die. Therefore, we prescribe medications, typically in small amounts, but they die, and medications are left over.

So the mathematical extrapolation is pretty straightforward. We end up with tens of millions of doses of controlled substances that are left in the homes of our hospice patients every year. And at this point in time, our hospice personnel are not legally allowed to handle that. They can make recommendations, but as we have already heard in earlier testimony, the availability of take-back programs, the process of using the mail-in envelopes and other processes that are in place legally are sometimes onerous, and families typically don't take advantage of that. That just leaves too many medications left on the shelf and ultimately potentially to be sometimes innocently, but sometimes nefariously, abused by family members or diverted.

So, when we are talking about a quick and easy way to get rid of millions of doses of controlled substances off the streets -- potentially off the streets -- this is a very simple, and I would note, bipartisan effort that has -- that to me makes an awful lot of sense. And that is it. That is it.

The only thing I would add is -- just the one thing I have noticed in a lot of legislation, both Federal as well as State, is that in the effort to push forward legislation, a lot of times the role of hospice in the care of the patients and the unique and special plight of hospice patients is sometimes overlooked, and sometimes the legislative burdens and barriers could have the potential of introducing preventable suffering for our hospice patients.

So I would just ask that the committee and members be mindful of the unique nature of hospice concerns and to take advantage of the

resources of the National Association of Home Care and Hospice as a resource for additional input. I as well am available for -- to answer any questions or concerns that someone might have about this issue.

[The prepared statement of Dr. Mulder follows:]

******** INSERT 3-3 ********

Mr. Burgess. Thank you, Dr. Mulder. We appreciate your testimony.

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

STATEMENT OF PONNI SUBBIAH, M.D.

Dr. Subbiah. Good afternoon. I am Dr. Ponni Subbiah. I am a neurologist and chief medical officer at Indivior, global specialty pharmaceutical company with a core focus on addiction medicine. We have a 20-year commitment to the vision that all patients have access to evidence-based treatments. We developed the first buprenorphine-based medication for treatment of opioid dependence in the U.S.

Today, we have a portfolio of treatments for opioid addiction, as well as a pipeline of product candidates to address unmet patient needs for this and other disorders, including alcohol use disorder and schizophrenia. To address the opioid epidemic, it is important to understand the patient journey. It is complex and often misunderstood.

Addiction is a brain disease and not a moral failure. However, social stigma, prejudice, and misconceptions about addiction coupled with feelings of guilt and shame often prevent people from seeking help. Even when people want help, cravings and withdrawal symptoms can be so intense that there is generally only a small window of time when a person can emotionally and physically pursue treatment.

The healthcare system, however, does not always encourage treatment during that window due to structural barriers to care. This is one reason that many of those who need help go untreated. Any patient in need of treatment for opioid use disorder should have access to the medication-assisted treatment prescribed by their healthcare professional.

Indivior's focus on patient needs to drive decisions inspired the R&D team to develop Sublocade, which received FDA approval on November 30 of last year. Sublocade is the first once-monthly schedule III buprenorphine extended release injection for subcutaneous use. In the face of this growing addiction crisis, FDA granted the product fast-track approval and priority review designation.

Now, it is indicated for the treatment of moderate to severe opioid use disorder in patients as part of a complete treatment plan that includes counseling and psychosocial support. Sublocade uses the Atrigel delivery system, which allows for once-monthly dosing and is intended to be administered only by healthcare providers. Sublocade will be distributed through a restricted distribution system, which is part of a risk evaluation and mitigation strategy program. The goal of this program is to mitigate serious harm or death that could be result from intravenous administration, self-administration, by the patient.

All healthcare settings and pharmacies that order and dispense Sublocade must be certified and establish procedures to verify that the medication is dispensed directly to a healthcare provider for administration by a healthcare provider only. As every patient's

journey toward recovery is different, access to all evidence-based treatment options is critical. Sublocade represents one such option.

Government policies impacting these treatments must adapt to ensure patients to have access to new innovative medical technologies. Historically, buprenorphine treatments have been daily oral medication, and the Controlled Substances Act allows for dispensing this medication directly to patients. However, Sublocade, as required by our FDA approved REMS can only be administered directly by the healthcare provider and cannot be dispensed directly to the patient.

In recent years, the distribution of injectable products have evolved from a transitional buy and bill system where physician practices purchase drugs directly from a distributor to one that allows specialty pharmacies to ship a patient's prescription directly to administering provider. For example, current long-acting injectable treatments used for schizophrenia utilized both these distribution methods to ensure optimal patient access to these medications.

Current law, however, is ambiguous and could impede patient access to new treatment innovations. We agree with Representatives Costello and Nolan that the law needs to be clarified so that these next-generation buprenorphine products can be accessed directly by healthcare providers through a specialty pharmacy restricted delivery system, as well as a traditional buy-and-bill system.

We support the proposed legislation to remove ambiguity in the current law to ensure that patients of opioid use disorder and their

providers have the same level of access to these innovative treatments as they do to other injectable products. This technical clarification will ensure the safest distribution channels for these new medical technologies.

Thank you again for the opportunity to address the committee. Together, we can transform addiction from a human crisis to a recognized treatable disease. Thank you.

[The prepared statement of Dr. Subbiah follows:]

******** INSERT 3-4 ********

Mr. Burgess. Thank you for your testimony.

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

STATEMENT OF DAVID Y. KAN, M.D.

Dr. Kan. Chairman Burgess and Ranking Member Green, thank you for inviting me to participate in this hearing. Thank you to the subcommittee for your leadership in addressing our country's opioid epidemic.

My name is Dr. David Kan, and I am the president of the California Society of Addiction Medicine, a chapter of the American Society of Addiction Medicine, also known as ASAM. This testimony is offered on behalf of ASAM. Established in 1954, ASAM is a national medical specialty society of more than 5,000 physicians and allied health professionals whose mission is to increase access to high-quality addiction treatment. I am board certified in addiction medicine and psychiatry. I served 10 years in Federal service at a VA methadone program within the San Francisco VA Medical Center as medical director. I am the current medical director at Bright Heart Health, which provides telemedicine services in 21 States across the United States.

My testimony today will focus on three facts. Number one, addiction involving opioid use is effectively treated with a combination of medications and psychosocial interventions. And ASAM has published guidelines that detail best practices for the use of these medications.

Number two, there are significant barriers to accessing medications for addiction involving opioid use and a nationwide treatment gap.

Number three, changes to the Controlled Substances Act to facilitate the use of telemedicine and new medication formulations can expand access to medications for addiction involving opioid use to close the gap. There are currently three medications, methadone, naltrexone, and buprenorphine that are FDA approved and have substantial evidence for their effectiveness treating addiction involving opioid use.

Given the bills being considered today, I will focus my remarks on the safely and effectiveness of buprenorphine. Compared to full opioid agonists like methadone, buprenorphine is much safer with significant lowered overdose deaths and adverse events. The direct healthcare savings per treated opioid dependent patient per year exceed $20,000. ASAM has published clear standards of care for clinicians treating patients with addiction, as well as prescribing guidelines.

Despite the strong evidence used for the use of buprenorphine, very few eligible patients are offered medications to help treat their disease. Studies have shown that 80 percent of patients with opioid addiction don't receive any treatment, and the majority of States don't have enough treatment providers to provide the capacity to meet the need.

Other access barriers include transportation difficulties, limited hours of operation, and few prescribers who accept Medicaid

or Medicare, often making access to treatment next to impossible. Making smart and targeted changes to the Controlled Substances Act to facilitate treatment of buprenorphine and for addiction involving opioid use via telemedicine and the use of new buprenorphine formulations are steps this Congress should take to expand addiction treatment access.

Telemedicine provides significant opportunities to reach more patients. The Ryan Haight Act limits the expansion of treatment with buprenorphine for addiction involving opioid use via telemedicine by generally requiring an in-person medical evaluation or the presence of the patient in a DEA-registered hospital or clinic.

Consistent with ASAM's standards of care and national practice guidelines, ASAM recommends that the requirement for an in-person physical exam by the prescribing clinician be revised to allow for a physical exam to be conducted by another appropriately licensed healthcare professional and documented in the patient's medical record.

Additionally, ASAM recommends limiting this exception to the in-person physical exam requirement only to those physicians who hold additional certification or who practice in a qualified practice setting per the definitions in the 2016 SAMHSA rule that raised the dated 2016 prescribing limit. These changes would increase access while ensuring high-quality care from competent healthcare providers and safety for the patients to reduce diversion.

Secondly, ASAM encourages Congress to amend the Controlled

Substances Act to allow for specialty pharmacies to deliver new injectable and implantable buprenorphine formulations directly to the administering clinician's practice rather than relying on the buy-and-bill method for obtaining and being reimbursed for the medications. Such a change is not a new pathway for medication delivery; it would allow for these controlled substances to be delivered as many noncontrolled substances are already. It is a technical, commonsense fix that will expand treatment access while potentially reducing buprenorphine diversion. And ASAM urges this subcommittee to advance the bill to approve it.

Thank you again for the opportunity to present here today. I look toward to your questions.

[The prepared statement of Dr. Kan follows:]

******** INSERT 3-5 ********

Mr. Burgess. Thank you, Dr. Kan.

Mr. Nance, you are recognized for 5 minutes, please, for an opening statement.

STATEMENT OF RICHARD J. NANCE, LCSW

Mr. Nance. Thank you, Chairman Burgess, Ranking Member Green, and members of the committee, I appreciate the opportunity to testify on an issue that is impacting community-based addiction and mental health centers across the country.

Thanks to Representatives Carter, Bustos, Harper, and Matsui for their leadership on the two discussion draft bills focused on the Ryan Haight Act. We appreciate your work.

I am honored to be here today on behalf of the National Council for Behavioral Health, a national group that represents 2,900 member centers who serve more than 8 million adults and children living with behavioral health disorders in the United States. Since 1998, I have served as the director of Utah County's Department of Drug and Alcohol Prevention and Treatment. I am a member of the National Council. I am also a licensed clinical social worker in the State of Utah. My department provides a comprehensive range of drug and alcohol prevention and treatment services, including medication-assisted treatment for opioid addiction and abuse.

Over 40 percent of the people I have in treatment at my agency right now are there for an opiate issue, and over 30 percent of them

are receiving medication-assisted treatment. That is nearly 400 out of 850 clients I have in treatment today.

I am here to discuss an issue that limits community addiction and mental health centers' ability to provide patients access to treatment using telemedicine. Medically appropriate treatment for behavioral health conditions sometimes involves controlled substances. Unfortunately, today, thousands of centers across the country are unable to utilize telemedicine that results in a prescription for a controlled substance due to the DEA's narrow interpretation of the Ryan Haight Act.

In my remarks, I will explain why this is and why the Matsui-Harper bill provides the relief we need in order to be able to serve patients more effectively. Let me state upfront first, though, the National Council appreciates and affirms the importance of the Ryan Haight Act. As recent reports have shown, even with the act in place, it is still far too easy to go online and buy controlled substances without a valid prescription.

In November of 2016, two junior high students in Park City, Utah, ordered a drug called U47700, a synthetic opiate analogue, sometimes referred to as Pink, took the drug and overdosed and died. These studies underscore the importance of the DEA's vigilance over the online ecosystem and the rogue actors that claim to be doing telemedicine and operating an online pharmacy but, instead, are functionally pill mills.

Our goal is to allow licensed, DEA-regulated, community addiction

and mental health centers staffed by regulated and licensed professionals to be able to comply with the Ryan Haight Act in order to improve patients' access to care. So what we are asking is that you regulate us. I don't know too many people who would come in here and ask you to regulate us.

Here is how the situation plays out in Utah and illustrates the problem around the country. The act allows for a prescription of controlled substance without a prior in-person examination in limited circumstances, known as telemedicine exceptions. The most common way telemedicine is allowed is when the patient is located in a DEA-registered hospital or medical clinic and is being treated by a DEA-registered provider located offsite. The problem is DEA has interpreted the hospital and clinic exception so narrowly that it often does not apply to community-based addiction and mental health centers.

For an example, one patient at one of the Utah's community addiction and mental health centers is in crisis. I am giving you an example here. The patient may need addiction treatment involving medication-assisted treatment with a controlled substance like Suboxone. The center is staffed with the social workers, nurses, counselors, and other licensed mental health professionals, sometimes including physicians. Due to shortages of providers in parts of Utah, the center where our patient is located rarely has a DEA-registered doctor onsite. But the center does have the ability to connect the patient to a DEA-registered addictionologist using telemedicine technology. The problem is my center is licensed by the Utah

Department of Human Services as a drug and alcohol treatment agency, not licensed as a hospital or medical clinic by the Utah Department of Health, as the DEA requires.

As such, my licensed center is unable to register with the DEA and the hospital or clinic telemedicine exception in the Ryan Haight Act doesn't apply. Accordingly, we can't provide the needed care to patients using telemedicine. Instead, we must wait for a DEA-registered doctor to go on the road to do an in-person physical examination before the patient gets a prescription for Suboxone or another controlled substance to treat their opioid addiction. This is just one illustration of the problem.

As discussed in my written statement, there are many other examples of how the DEA's narrow interpretation of hospital or clinic is keeping legitimate centers from treating patients utilizing telemedicine when controlled substances are needed. The Harper-Matsui bill aims to remedy this.

Finally, although the opioid epidemic is the subject of today's hearing, it is critical that the DEA allow centers to use telemedicine to treat other mental health conditions, too. This is discussed also further in my written statements.

Thank you very much. I appreciate the opportunity to be here, and I am also willing to take questions.

[The prepared statement of Mr. Nance follows:]

******** INSERT 3-6 ********

Mr. Burgess. Thank you, Mr. Nance.

Mr. Cosgrove, you are recognized for 5 minutes, please.

STATEMENT OF THOMAS J. COSGROVE

Mr. Cosgrove. Thank you, Chairman Burgess, Ranking Member Green, and members of the subcommittee, for the opportunity to testify today. My name is Tom Cosgrove. And until last year, I was an official at the Food and Drug Administration responsible for current good manufacturing practice enforcement and compliance within the Center for Drug Evaluation and Research, or CDER.

In that role, I was responsible for ensuring manufacturing quality and compliance for the thousands of drug manufacturing facilities around the world that make medicines distributed in the United States. Since December of 2017, I have been a partner at the law firm of Covington & Burling here in Washington. Covington represents a number of clients in the food, drug, and cosmetics industries that use tableting and encapsulating machines. The subject of the draft bill under consideration, which is the Tableting and Encapsulating Machine Regulation Act of 2018, but the views expressed today here are my own.

I share Congress' and the public's concern about the opioid abuse epidemic and am encouraged to see so much action in Congress and society at large aimed at ending the crisis. In my role at FDA, I was aware of the acute problem of the importation of illicit opioids, opioid

analogues, and synthetics drugs from overseas from international mail facilities. This appears to be a different issue, however, than the use and regulation of tableting and encapsulating machines in the United States.

Virtually all manufacturers of solid oral drugs in the United States use tableting or encapsulating machines in some form, at least as those terms are defined under the draft bill. This includes prescription, nonprescription, and many animal drugs covering everything from innovative new drugs to OTC products that people use daily. In addition, dietary supplement manufacturers commonly use tableting and encapsulating machines as part of their manufacturing processes.

One need only walk down the health and wellness aisle of the local supermarket to get a sense of the ubiquity of products manufactured using tableting and encapsulating machines. Furthermore, tableting machines are often used in the manufacture of candy, cosmetics, and certain household products such as cleaning agents.

Were the draft bill to be enacted as now written, lawful domestic manufacturers using tableting and encapsulating machines to produce legally marketed, noncontrolled products, including nondrug products, they would be subject to the CSA's strict requirements for controlled substances.

A straightforward reading of the draft bill at hand would appear to require manufacturers to register with the DEA and with State authorities in each location that they hold or operate a machine.

Manufacturers apparently would need to store tableting and encapsulating machines in secured areas, such as the ones used to safeguard controlled substances themselves. This includes things like electronically-monitored safes, steel cages, or vaults that meet certain specifications.

Manufacturers hoping to dispose or replace malfunctioning machines could need to transfer machines to companies specifically registered by DEA to render those machines nonretrievable. In addition, manufacturers might need to comply with additional recordkeeping and paperwork requirements each time they move a machine. Such requirements, if enacted, could cause domestic manufacturers to incur direct costs of machine registration, recordkeeping, security, and disposal, and indirect costs from training, education, and audits to ensure compliance.

We live in a time also where there is enormous pressure on drug manufacturers to move their operations overseas for cost reasons. In fact, one of FDA's main challenges today is keeping up with the pace and explosion of drugs being manufactured overseas in places like India and China.

Ironically, the draft bill would burden most the companies that have nothing to do with opioids or other controlled substances because these companies would need to establish CSA compliance systems from scratch. Furthermore, Congress has already amended the CSA to give DEA special authority to regulate tableting and encapsulating machines.

In 1988, Congress passed the Chemical Diversion and Trafficking Act, or the CDTA. That act is described in the written testimony of Ms. Gibson, who testified earlier today, and I won't recap that here.

If Congress decides that enhanced regulation of tableting and encapsulating machines is needed. I would encourage a more tailored approach that builds on existing authorities. First, I would want to know -- I would want to better understand why DEA's existing CDTA authorities are not sufficient. One potential further approach would be to consider amending the CDTA, such that companies would also register equipment with DEA beyond only reporting transactions. This could be tethered with an appropriately crafted exemption for firms regulated by FDA. This way, DEA could develop a more robust database of tableting and encapsulating machines so that perhaps thousands of companies around the United States would not suddenly be regulated as if they were holding controlled substances.

If Congress decides to move forward on this or any similar proposal, I would be happy to serve as a resource in deliberations going forward. Thank you for the opportunity to testify today. I would be happy to take any questions.

[The prepared statement of Mr. Cosgrove follows:]

******** INSERT 3-7 ********

Mr. Burgess. Thank you, Mr. Cosgrove.

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

STATEMENT OF ANDREW KOLODNY, M.D.

Dr. Kolodny. Thank you, Chairman Burgess, Ranking Member Green, and members of the Health Subcommittee, for the opportunity to testify today. And my name is Dr. Andrew Kolodny, and I am the codirector of Opioid Policy Research at Brandeis University. I am also the director of Physicians for Responsible Opioid Prescribing. My testimony today is on behalf of PROP, Physicians for Responsible Opioid Prescribing.

As you all think about solutions to the opioid crisis, I think it is very important to frame the problem and to frame it the right way. I believe that the correct way to frame the opioid crisis is as an epidemic of opioid addiction. Not everyone who dies of an opioid overdose was suffering from opioid addiction, but the studies tell us that the vast majority of the people dying are opioid addicted.

If we frame the problem the right way, as an epidemic of opioid addiction, the strategies, the big picture strategies, for bringing it under control become much more clearer. We really have to accomplish two things. We have to prevent more people from becoming opioid addicted, and we have to see that the people who are addicted are accessing effective treatment.

When I say "epidemic," I am not exaggerating. From 1997 to 2011, there was a 900-percent increase in the number of people suffering from

opioid addiction, and it is that increase in the number of Americans with opioid addiction that explains why we are experiencing record high levels of overdose deaths, why we are seeing a soaring increase in infants born opioid dependent, outbreaks of injection-related infectious diseases, and a flood of heroin and fentanyl into our communities.

To bring the epidemic under control, we have to prevent new cases of the disease. That primarily is going to be through cautious prescribing. And I am going to focus the remainder of my statement on H.R. 2063, a bill to mandate prescriber education.

Although I do not support the bill in its current form, I am strongly in favor of mandatory education for DEA registrants who intend to prescribe more than a 3-day supply of opioid analgesics. And I commend Representative Schneider and his cosponsors for introducing this legislation. The need for this law becomes clear when we look at the cause of our opioid addiction epidemic. And the CDC has been perfectly clear about why we are experiencing this epidemic.

What the CDC has shown us -- and we have got a slide up here. If you look at the slide, the green line at the top represents opioid consumption or prescribing in the United States. The red line represents deaths involving prescription opioids, and the blue line represents addiction involving prescription opioids. The CDC has really been saying that, as that green line went up, addiction and overdose deaths went up right along with it. As the prescribing increased, it has led to the epidemic that we have got today.

The reason that that green line began to go up so rapidly, the reason the medical community began prescribing so aggressively is because we doctors were responding to a brilliant multifaceted marketing campaign that changed the culture of opioid prescribing in the United States. Starting in the nineties, we began hearing that patients were suffering because we were too stingy with opioids. We began hearing that we should stop worrying about addiction, that even with long-term use, the risk of addiction was much less than 1 percent.

We began hearing that opioids were safe and effective for conditions like low back pain, where the leading experts tell us they are neither safe nor effective. We would have been less gullible if we had just heard these messages directly from drug companies. But as we heard earlier, these messages came to the medical community from every different direction. In particular, we were hearing these messages from professional societies.

The America Academy of Pain Medicine and the American Pain Society in 1997 put out a consensus statement calling for much greater use of opioids and claiming that the risk of addiction had been overblown, even that the risk of overdose deaths had been overblown.

My greatest concern with H.R. 2063 is that it relies on these organizations and other professional groups with industry ties to provide the government-mandated prescriber education. One of the most important lessons from the crisis is the need for strict firewalls between pharmaceutical company marketing and medical education. Had marketing not been so cleverly disguised as education, we might not

have an opioid addiction epidemic today.

If we learn from our past mistakes, we will not rely on the same industry-funded professional societies that got us into this mess to provide the education we need to get out of it. It may be hard for you to believe that, in the midst of our opioid addiction epidemic, that doctors are still overprescribing, but we are. The United States continues to prescribe more opioids than any other country on Earth.

Millions of dollars were spent misinforming the American medical community about opioids, but very little has been done to correct the record. That is why prescriber education must be made mandatory, and that is why the content for the education must be developed and administered by individuals and organizations who do not accept payments from pharmaceutical companies. Thank you.

[The prepared statement of Dr. Kolodny follows:]

******** INSERT 3-8 ********

Mr. Burgess. Thank you.

Mr. Logan, you are recognized for 5 minutes, please.

STATEMENT OF RICHARD N. LOGAN, JR.

Mr. Logan. Chairman Burgess, Ranking Member Green, members of the subcommittee, thank you for holding this hearing on the opioid crisis. I am Dr. Richard Logan. I have been a community practice pharmacist since 1975 and currently own two pharmacies in southeastern Missouri. Oddly enough, in addition to my duties as a community practice pharmacist, I have spent the last 25 years as a Missouri certified police officer and am a recently retired prescription drug diversion investigator for the Mississippi County, Missouri, Sheriff's Department.

I am here today on behalf of the National Community Pharmacists Association to present some of my experiences and viewpoints focusing on viable solutions to prevent drug abuse and diversion while maintaining legitimate access of patients to needed medication.

NCPA represents America's community pharmacists, including owners of more than 22,000 independent community pharmacies just like mine. Our job as healthcare professionals is to help patients safely navigate medication-related treatment across multiple disease states. We are focused on positive outcomes and safe medication usage.

Yet, as pharmacists, we struggle to meet these goals in the midst of an opioid epidemic that kills hundreds of people daily and over

200,000 Americans since 1999. My flagship pharmacy is in Missouri. It is the first pharmacy across the Mississippi River on I-57 and Highway 60 from Illinois, Tennessee, and Kentucky. My State has no adequate functioning PDMP and, as such, is a magnet for those who would abuse prescription opioids.

It is not unusual for travelers to drive hundreds of miles from eastern Kentucky, Ohio, or other areas distant to me to visit a pill mill in Georgia or Florida and end up at my prescription counter with prescriptions for narcotics, lots of narcotics. Common sense tells me that somewhere between Kentucky, Florida, and Missouri, those folks have passed a pharmacy, but they end up at mine.

I once investigated a traveler who had driven U.S. Highway 60 across just southern Missouri, had seen eight physicians and visited 18 pharmacies in search of opioids. I served on many search warrant teams, made many arrests, some at my own prescription counter, had lots of convictions, dodged bullets in the line of duty, spent nearly 25 years fighting drug abuse, was responsible for putting together a bicounty prescription drug task force that led to many arrests, and still -- still -- I feel like I have done nothing to stem the tide. It is just that overwhelming.

All the while, as a practicing pharmacist, I go to bat for my legitimate patients who need opioid therapy so they can lead a productive life and not be denied therapy or declined therapy due to the stigma attached to opioid abuse. As the final checkpoint in the system of checks and balances, pharmacists play a vital role in ensuring

all medications, including controlled substances, are appropriate for their patients.

Pharmacists are often the last professional an opioid patient sees and the first professional to realize that a patient is slipping into an abusive pattern. Pharmacists must monitor their patients and work in collaboration with other healthcare providers, understand the risks and benefits of opioid therapy, and keep the best interest of the patient at the center of all decisions.

There are promising policies that Congress or the administration could move forward that would have a positive impact on mitigating or preventing abuse. One such policy is included in H.R. 4275, the Empowering Pharmacists in the Fight Against Opioid Abuse Act, to provide for the development and dissemination of programs and materials for training pharmacists, healthcare providers, and patients on indicators that a prescription is fraudulent, forged, or otherwise indicative of abuse or diversion. This is not only a commonsense policy; it is one that fits in well with the DEA 360 strategy to engage all of those involved with opioid treatment.

NCPA supports such efforts to bring greater diversity and education to other healthcare providers and patients regarding a pharmacist declining to fill a controlled substance. NCPA offers itself as a resource, if necessary. Thank you.

[The prepared statement of Mr. Logan follows:]

******** INSERT 3-9 ********

Mr. Burgess. Thank you, Mr. Logan.

And thanks to all of our witnesses for your testimony. It has certainly been insightful.

At this time, I would like to yield to the gentleman from Oregon, the chairman of the full committee, for your questions.

The Chairman. Thanks, again, Mr. Chairman, for your leadership on this issue and your subcommittee's good work.

And to all our witnesses, thank you for your testimony, it is very, very helpful in our work.

I want to ask Chief Fowler, you provided a crime analysis report as part of your written testimony. The primary focus of the report is overdoses related to Spike or synthetic marijuana. Have you seen other synthetic drugs on the streets in your community? What has been the impact of these substances? And is synthetic marijuana the worst analogue drug on the streets of Syracuse, or do you have data that fentanyl and other opioids are worst?

Chief Fowler. So, currently, Spike, the one that I spoke about, is the one that we are having the most problem with. But fentanyl is certainly a tremendous problem, and it ranks second.

The Chairman. Which is the most deadly?

Chief Fowler. Fentanyl is indeed the most deadly. We see the most deaths associated with overdoses with fentanyl.

The Chairman. What is the practical effect with Spike? What happens when you come on a scene?

Chief Fowler. It is marketed as a synthetic marijuana, but it

has a hallucinogenic effect. And what we see is people in what I could best term as psychosis. They are acting out in a very bizarre fashion, oftentimes violent, incoherent. And then they exhibit a number of medical issues in which they have to be addressed at the local hospital.

The Chairman. Such as?

Chief Fowler. Rapid breathing. Some even pass right out after they have exhausted themselves from running around and acting in a very bizarre way. Sweating profusely. And I am not a medical expert --

The Chairman. Right.

Chief Fowler. I would imagine that everything that a company -- a person's heart rate rising, their blood pressure rising, I would imagine that that has some type of medical effects on a person, but I am not a medical expert, so I can't tell you what those are. But the bizarre behavior and the violent behavior, that is something that I can really identify with.

The Chairman. What is the youngest age that you have seen either --

Chief Fowler. Quite young.

The Chairman. What is that?

Chief Fowler. When this first came on the scene, what we discovered was that it was sitting right on the shelf in the local convenience stores.

The Chairman. Now, wait a minute. It was what?

Chief Fowler. When it first came on the scene, it was sitting right on the shelf of local convenience stores in these very colorful

packages, and I personally overheard a couple of high school students talking about why it is that they would choose to use Spike over marijuana; it is because they happen to be on probation, and if they were to have to give a urinalysis test, that this substance would not appear. And so they were using this to get away with being -- a probation violation.

So our young people started to use this substance, and they were experiencing the same things that everyone else was, these episodes of psychosis there in the schools, on the streets. So we see all ages.

The Chairman. So the legislation Mr. Katko brought to our attention and worked hard on is drafted -- is very focused on the fentanyl analogues?

Mr. Nance. Sure.

The Chairman. In your police department's experience, what other synthetic drugs do you think we should be addressing comprehensively by class? What else should we be looking at here?

Chief Fowler. Well, I think that all of the synthetic drugs that we can identify, we need to take a look at them because what is happening is, is that they are all appearing on our streets. The minute that we bring one substance under control, a different or another substance will pop up. And we have a simultaneous problem with Spike and fentanyl right now.

The Chairman. And so, broadly speaking, do you feel like your department has the tools you need when your team comes across illicit synthetic drugs? What else do -- the goal here is we want to get this

right when we put this legislation together. So what are we missing here that would be helpful in your efforts?

Chief Fowler. Sure. Law enforcement is only as effective as the laws that we enforce.

The Chairman. Right.

Chief Fowler. And when you look at -- let's take Spike, for example, because that is what I have talked about the most. Right now, it is not scheduled. And the only thing that we can do is give people an appearance ticket for a local law violation for --

The Chairman. What does that mean, a local law enforcement violation?

Chief Fowler. Well, we went to our local legislators and had them enact a local ordinance to --

The Chairman. Against Spike?

Chief Fowler. Excuse me?

The Chairman. Against Spike.

Chief Fowler. Yes. To make the substance illegal. And that is the charge that we utilize.

The Chairman. What is the penalty?

Chief Fowler. It is a violation, so --

The Chairman. Oh, it is a traffic ticket, in effect.

Chief Fowler. Basically, sir.

The Chairman. So it is not a deterrent, to speak of?

Chief Fowler. Not at all. Not at all.

The Chairman. Thank you.

And thanks again to the whole panel. You all have been most helpful in our work, and we are going to continue down this path, and we are going to get it right, and we are going to pass new laws so you have the tools you need to stop this to the best of your ability. But we need your input, so thank you very much.

Chief Fowler. Thank you, sir.

RPTR KEAN

EDTR HUMKE

[4:12 p.m.]

Mr. Guthrie. [Presiding.] Thank you. The chairman yields back. And the chair will recognize Ms. Castor from Florida for 5 minutes.

Ms. Castor. Thank you very much, Mr. Chairman. And thank you to all the witnesses for being here this afternoon.

Dr. Kan, in your testimony, you talk about the significant barriers to access for folks who are suffering from opioid addiction. And you call it, you say we have a significant addiction treatment gap in America. You cite the journal of the American Medical Association, a report in 2015 that says 80 percent of Americans with opioid addiction do not receive treatment.

And you have recommended, and a lot of you here have recommended some ways to tackle the problem. It seems like it is so piecemeal, though. These recommendations are good, to do a little more in telemedicine and buprenorphine formulations and distribution, but I mean, this is a public health crisis. And what I am hearing at home from parents and others, there is just no capacity out there. There is just no, you know, even in the Affordable Care Act now, we have new requirements that insurance cover essential health benefits, including mental health.

Under Medicaid, yes, you have some treatment options, but it is

just not happening on the ground. So what else can you recommend to us to help improve the long-term treatment that so many Americans are going to need to tackle their addiction?

Dr. Kan. Thank you for that question. I think telemedicine is one piece of the entire puzzle. There is a very much broader puzzle when it comes to reducing stigma around the illness, that is part of the effect in this telemedicine, in that people don't have to walk into a clinic and be publicly identified as being treated.

In addition to that, we need to expand access to all forms of treatment, both different formulations and different avenues in which people can get that type of treatment. If I think about opioid use disorder as a physician, about 80 percent of the effect sides is predicted by medications alone. Meaning that with medications, you can effectively reduce the risk for accidental overdose, and counseling is significant. It is incredibly important in changing people's lives, but we need to create expanded access. We need to keep people alive.

This is a position that has been considered the American Society of Addiction Medicine, and it is certainly a position that ASAM has taken in that we need to reach out to patients that we do not see. I don't worry about the patient that is in my practice. I don't worry about the patient that I am treating because they are in front of me, and I can monitor them and give them appropriate treatment.

However, the person who leaves my practice or they disappear from care, I worry about because I know they are not receiving care.

Ms. Castor. So Mr. Nance, you are on the ground doing this. What is it going to take for us, really, to make sure that the folks who need long-term treatment, receive that long-term treatment.

Mr. Nance. Well, Dr. Kan is right. The biggest problem we face is capacity. You mentioned this yourself, that was the beginning of your question. We have got the capacity in Utah to treat less than 20 percent of the people that need drug and alcohol treatment. So workforce is a huge factor. If we don't have the staff to deliver the services, we can't provide the treatment.

Effective evidence-based treatments are important as well. And we strive very hard to identify those that we can afford, implement them, train our staff to implement them to fidelity --

Ms. Castor. So you are recommending to offset, we need to do more in workforce training for doctors, nurses, counselors? Is that part of it?

Mr. Nance. Yes, we need to provide more primary behavioral health staff, but other specialties that don't deal primarily with drug and alcohol prevention and treatment services need more training and education on how to identify and refer someone to treatment and provide some of those treatments themselves.

Ms. Castor. And Dr. Kolodny, you have cited some very stark statistics that we are now -- what are your recommendations to really tackle the barriers to access for -- JAMA says 80 percent of Americans with opioid addiction don't receive any treatment. How do we get to that?

Dr. Kolodny. I very much appreciate that question. I think the only way we are going to get there is with 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-licensed drug and alcohol treatment programs don't offer buprenorphine. Many of them don't even have enough physician time to be able to prescribe buprenorphine. Among people who are getting it right now, even people with good insurance often have to pay out of their own pocket for the doctor's visit, their Medicaid or their commercial insurance is only paying for the prescription.

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. If someone who is opioid-addicted when they wake up in the morning, they are going to need to use. Many people will have something by the bedside because they are going to be feeling very sick when they start to wake up. If they have got $20 in their pocket and they know where they can go get heroin, even if it has got fentanyl in it, that is what they are going to do. And if finding a doctor is more expensive and more difficult, we are not going to start to see overdose deaths start to come down.

So we really have to build out a system that doesn't exist, and I don't see any other way other than investing billions for that system.

Ms. Castor. Thank you very much. I yield back my time.

Mr. Burgess. [Presiding.] The chair thanks the gentlelady. The gentlelady yields back. The chair recognizes the gentleman from

Kentucky, Mr. Guthrie, 5 minutes for questions, please.

Mr. Guthrie. Thank you very much, Mr. Chairman. And thank you all for being here. This is very informative.

And, Dr. Kan, I have a question for you. Thank you for your insightful testimony. Knowing that you have firsthand experience treating patients with opioid addiction, as well as utilizing telemedicine builds your credibility both as a practitioner and a witness.

My questions will be two. When using medication-assisted treatment, how common is it for you to pair this medicine with cognitive behavioral therapy? And is it important that any changes to the Ryan Haight that increases access to medicated-assisted treatment not be so tailored that the result unintentionally cuts off behavioral therapy?

Dr. Kan. Thank you for those questions. So the answer to your first question, how often do I combine treatment with therapy, and you mention cognitive behavioral therapy, which is a very specific type of therapy, but we use multi-modal therapies that we pick because of the patient assessment, what is it that they need. And within my practices, within the VA, within my company, it is 100 percent. One hundred percent of patients receive psychotherapeutic intervention.

The second question -- I am sorry, I forgot the second question at this point.

Mr. Guthrie. The second question, is it important that any changes to Ryan Haight that increase access to medicated-assisted

treatment not be so tailored that the result unintentionally cuts off behavioral therapy?

Dr. Kan. I think that the room for psychotherapeutic intervention should always be available. And when we talk about the qualified practice setting within the data -- 2016 amendment, it does cover those things that the people have the capacity to provide the therapy, if it is indicated.

Mr. Guthrie. Thank you. And I have a question for Dr. Mulder. Thank you for your testimony and for the Michigan Home Care Hospice Association support for the Safe Disposal of Unused Medication Act.

In your testimony, you note that roughly 98 percent of hospice care days are provided in a patient's residence. You go on to explain that at a moderate-sized hospice care with 2,000 patients per year, approximately 1 million pills will be prescribed per year.

So kind of a series of questions: If 98 percent of these prescriptions, roughly 1 million pills are going into homes, isn't this statistic alone enough to validate the need for safe disposal? Is it your belief that safe disposal would reduce the likelihood of misuse or diversion? And are you able to give some examples of safe disposal that hospice workers have used in the past or currently use in States that allow this type of --

Dr. Mulder. Yes. Yes. And I will give you some examples.

Mr. Guthrie. Perfect.

Dr. Mulder. So going back a few years, as I mentioned, I have had the privilege of working in the hospice industry for over 30 years.

And so we have seen, it is very, very common in past years, a nurse would come out, she would declare the death, she would sit and work with the bereaved family. And then with a witness, she would either, you know, crush and flush the pills, or in case of liquid opioids, just put them down the sink and turn the facet on. That is what they did.

In later years, when they said, oh, maybe we shouldn't be doing, you know, the flush thing, that they would, most of the nurses would carry kitty litter in their trunk, and they would bring in some of that. They would crush the pills and the liquid and just mix them with kitty litter, take it back and dispose of it back at the office. I suppose it ended up in a landfill somewhere, but I don't really know.

But that is how they did it in the past. Since I had --

Mr. Burgess. Will the gentleman yield for 1 minute.

Mr. Guthrie. Yes, I will yield.

Mr. Burgess. We also have the EPA under our jurisdiction. Be careful. They might be watching.

Dr. Mulder. I understand.

Mr. Burgess. I yield back.

Dr. Mulder. You didn't hear that from me.

But, again, that is in the past. That is in the past. And I think some of the more recent strategies are simply because of that.

They just didn't want opioids winding up in our water supply and our landfills. And so, you know, more recently when the laws were amended and changed and introduced, that restricted the personnel, who could really take back medications, that really put the hands off. And

I want to say that goes back to about 2013 or 2014, 2013 or 2014. I don't remember the exact dates of the legislation, but so that is how they did it in the past.

I don't know how they are doing it in States that they currently allow that but now -- and there has also been another trend that we saw developing, where patients families would say, oh, you can't touch that, that is mine now. He died, but I inherit everything that was his. And so those are my pills, and you may not touch them.

Mr. Guthrie. Well, thank you for your testimony. And it is certainly an area, when you start looking at the volume, that we have to address. And so I appreciate my friends from Michigan for bringing this forward.

Dr. Mulder. Thank you.

Mr. Guthrie. And I yield back my time.

Mr. Burgess. The gentleman yields back. The chair thanks the gentleman. The chair recognizes the gentlelady from California, Ms. Matsui, 5 minutes for questions.

Ms. Matsui. Thank you, Mr. Chairman. As I mentioned in my question to DEA, the purpose of the discussion draft I am working on with Representative Harper is to expand access to treatment where it is not currently available. We are seeking to do this within the current Ryan Haight telemedicine prescribing framework.

Mr. Nance, you are familiar with the community behavior health clinic system in Utah and see a need for additional access to remote prescribing for the patients you serve. Can you expand upon the need

that you see for more access to medication-assisted treatment and the challenges that clinics and their patients face?

Mr. Nance. Sure. Here is a visual representation of one of the challenges. This is a pretty good shot of the road from Moab down to Blanding, Utah. From my office to Blanding is about a 300-mile drive. There are about 4,000 people that live in Blanding. If someone down there has an opioid addiction problem and rural and frontier areas have a higher rate than the rest of the country in general for opioid addiction problems, their access to treatment is very, very limited.

So I kind of hang out with some farmers from time to time.

Ms. Matsui. Okay.

Mr. Nance. And one of the funny things I have heard one of them say was, the darn beavers can irrigate better than I can, but the water has got to the end of the row. So we need to have access to telehealth treatment so that if a client shows up in the community behavioral health center in Blanding and needs opioid addiction treatment, that that can be provided for them through a physician that may be located in Provo or Salt Lake, or some other place along the Wasatch front where the majority of the population of the State lives.

If we can't do that, we are going to have a higher death rate than we already do. We had 600 last year in the State of Utah, 187 of those were heroin, and all the rest were preparation opioids. So we need to be able to have qualified, certified license addiction medicine professionals to be able to provide services in those small outlying towns across the country, not just in Utah.

Ms. Matsui. So you are dealing with putting doctors on the road to do in-person --

Mr. Nance. -- if --

Ms. Matsui. -- exams, is that right?

Mr. Nance. Yes, I am sorry to interrupt you. If my addictionologist was to drive to Blanding, it would take her 2 days away from the office to possibly see one patient, if that patient showed up. People with opioid disorders typically are sick and disorganized and cognitively impaired. They have a difficult time keeping appointments. That would take the ability away for her to see somewhere between 48 and 60 patients in my own office and would cost us close to $2,000 in her time and travel time and overnight stay to be the able to see that one patient.

Ms. Matsui. So you mentioned it is important for the committee to allow telemedicine to be used for mental health treatments as well, not just substance use disorder. Why is that?

Mr. Nance. Same thing. In rural Utah, there aren't that many psychiatrist to go around. Right now we have been doing telehealth through Project Echo with the University of Utah as kind of a platform to do that. The same thing happens in New Mexico. And it is pretty easy for a child psychiatrist, for instance, and there are even fewer of those than there are addictionologists in the State, to be able to use telehealth technology to evaluate a patient at that remote site.

But if they are going to write a prescription for a controlled substance, like a benzodiazapine for an anxiety disorder, or ADHD for

attention deficit and hyperactivity disorder, that face-to-face issue still exists under the Ryan Haight Act.

Ms. Matsui. Okay. Could I just address some concerns that have been expressed?

Now, you expressed strong support for preventing fraudulent remote prescribing. Obviously, they all do. There may be concerns that opening a new pathway to registration for non-DEA-registered clinics may lead to fraudulent prescribing. We need to ensure that there are sufficient requirements on both the clinic with a patient present and a doctor doing the prescribing remotely. For clinics you represent, how are the authorized, and what is the regulatory oversight they undergo?

Mr. Nance. That is a very good question, too. We are licensed by the Utah State Department of Human Services. We have a licensing inspection every year. We also get an inspection from the Utah Medicaid program. We also get a contract compliance audit from the Utah Department of Human Services, and a peer-review visit. We get at least 3 or 4 oversight visits every year.

So our centers are licensed, our staff are licensed. And what I am proposing we do is kind of an agency-to-agency practice model. It is very similar to the Vermont hub and spoke model. You may be familiar with that. If you are not, you ought to look that up.

Ms. Matsui. Okay.

Mr. Nance. It is on addictionpolicy.org, I believe, website. And Vermont is kind of small. I think the furthest distance between

one side and another might be 100 to 150 miles. It is a lot further than States on the left.

Ms. Matsui. Well, I have a lot of questions, but I also know we will be working on discussion drafts, so I will be hopefully conferring with you and others on the committee. So thank you very much for that.

Mr. Nance. And the National Council staff will be happy to be a resource for you as well.

Ms. Matsui. Thank you.

Mr. Nance. It is just up on K street.

Mr. Burgess. The gentlelady yields back. The chair would observe that Project Echo was a product of the Energy and Commerce Committee.

The chair now recognizes Dr. Bucshon from Indiana, 5 minutes for questions, please.

Mr. Bucshon. Thank you, Mr. Chairman. Dr. Kan, Section 303 of CARA, the Comprehensive Addiction Recovery Act was something that meant to expand available treatment and give patients information basically on what their treatment options are. It also included requirements for individual treatment plans and other things. How is SAMHSA doing with implementing, you know, the new, some of the changes that were made in CARA?

Dr. Kan. I probably couldn't comment on how SAMHSA is doing. I think Dr. McCants Kats could probably provide some of that testimony, but my understanding, is that they are making affirmative --

Mr. Bucshon. I have already asked her so.

Dr. Kan. Okay. I would defer to her on the answer.

Mr. Bucshon. All right. Okay. I didn't like her answer, but that is okay.

Mr. Nance.

Mr. Nance. You want me to answer the same question?

Mr. Bucshon. Yeah.

Mr. Nance. Well, this has been a great thing --

Mr. Bucshon. I mean, are you getting good guidance from SAMHSA after CARA was --

Mr. Nance. Yeah, what SAMHSA has done is, you know, transmitted the guidance to the Utah State Department of Substance Abuse and Mental Health.

We had several meetings back in the spring of 2017. The funding was made available to us. We had to write applications for that that complied with what the State guidance was.

Mr. Bucshon. Yeah.

Mr. Nance. So it has been really helpful. I had 10 hours a week of physician prescriber prior to the CARA Act and the 21st Century Cures Act. Now I have her full time.

The physician I had on contract with before would not prescribe buprenorphine for me. Now, I have a full-time physician that will prescribe buprenorphine and that we can make available to other parts of the State.

Mr. Bucshon. Okay. Now, HHS would increase the therapy -- the number of people. Has that been implemented? I mean from 100 to any

practice to, you know, HHS --

Dr. Kan. Yes, that has. Both on an ongoing basis for people who are qualified but also in emergent circumstances when people reach 100 patient cap.

Mr. Bucshon. Okay. That is good to hear. Doctor -- yeah go ahead.

Dr. Subbiah. I would just add something to that. I think the caps have been increased, but if you look at the physicians or healthcare providers who have been waivered, not many of them are prescribing up to capacity. Because it is not only stigma of disease, we have to overcome also stigma of treatment --

Mr. Bucshon. Understood.

Dr. Subbiah. -- and taking care of these patients.

Mr. Bucshon. Yeah, I agree. In fact, this next question is for you. For long-acting buprenorphine, is insurance companies and CMS paying for this?

Dr. Subbiah. This product, Sublocade, just got approved at the end of last year and it is going to be on the market in March.

Mr. Bucshon. It got approved by FDA, right?

Dr. Subbiah. FDA.

Mr. Bucshon. Yeah, that is different than CMS?

Dr. Subbiah. Yes. So it is not, right now, in the market yet. It will be in the market starting in March.

Mr. Bucshon. Yes, I am just asking, did CMS give a coverage decision on it?

Dr. Subbiah. Not yet.

Mr. Bucshon. Not yet. Because what we are finding in a lot of areas in healthcare right now as we get FDA-approved products, both drugs and devices, and then we get delayed payment decisions from CMS, which is preventing access to patients. So that is a big problem. If that is the case, I would appreciate knowing about that because we try to have some impact on that.

Dr. Kolodny, I was interested in your testimony about talking about continuing education for physicians. I mean, do you think -- is there anything the Federal Government can do to encourage, maybe, what I would call ground-level training, which is not after people are already out of medical school and practicing, but I have been talking with the Association of American Medical Colleges, for example, about implementing more training programs for assessing pain and properly treating pain in medical schools, and then certainly residency programs.

I mean, do you have any thoughts on that?

Dr. Kolodny. You know, I think the bigger problem are the older doctors, not the docs coming out of training. Doctors who are in their 20s and 30s, they have come of age during our opioid addiction epidemic. Many have lost friends to opioid overdoses. They are much less likely to fall for the nonsense that you can prescribe long-term and a patient won't get addicted.

The bigger problem are doctors my age and older --

Mr. Bucshon. Okay.

Dr. Kolodny. -- who had it drilled into them for 15 years that, you know, we need to prescribe more and more.

Mr. Bucshon. Right. And I commented on that during the testimony from the DEA. I am in that boat. I mean, I went into practice in 1995. We all understood that.

Dr. Kan, last question real quick, I got. The existing laws in-person medical evaluation as well as allowable exemptions, you explained in your testimony that the in-person evaluation committee accepted if a patient is being treated by and physically located in a DEA-registered hospital or clinic or a patient is being treated by and in the physical presence of another DEA-registered practitioner, does this narrow exception cause geographic access problems -- and you may have answered this in part -- particularly for patients in rural areas that cannot physically get to a DEA-registered hospital or clinic or a DEA-registered practitioner?

Dr. Kan. I am speaking on behalf of ASAM. So ASAM does not have a position on this specific issue. I will say in my practice, we lose 20 percent of our patients because we can't get a physician to them between the time that they call and our 72 hours that we set out the goal to meet with them. And we send the physicians to the patients. We don't require prior the patients to travel to us.

Mr. Bucshon. Understood. Thank you. I yield back, Mr. Chairman.

Mr. Burgess. The chair thanks the gentleman. The gentleman yields back. The chair recognizes the gentleman from Texas,

Mr. Green, 5 minutes for questions, please.

Mr. Green. Thank you, Mr. Chairman.

Mr. Cosgrove, your testimony was basically, not to make it harder to import these pieces of equipment that make pills is that correct?

Mr. Cosgove. Well, I don't think it is necessarily that. I think my testimony really is focused on making sure that legitimate users of tableting and encapsulating machines are not suddenly stuck with the requirements of the CSA, the Control Substances Act.

Mr. Green. Okay.

Mr. Cosgrove. I think there can be ways for importation to be monitored and blocked in appropriate circumstances, but what we don't want is thousands of facilities around the country to suddenly have controlled substances within their walls.

Mr. Green. Well, for example, I assume some company in the United States actually produces these machines also?

Mr. Cosgrove. I believe that is correct. I think some of them are also imported from Germany and other countries.

Mr. Green. Okay. Dr. Beardsley, I want to thank you for sharing your experience as a researcher because this is the Health Subcommittee, and we are proud of our efforts to try and plus up NIH funding.

You noted in your testimony, it will take over a year to obtain a schedule I registration. I heard from others that the requirements associated with schedule I substances such as storage and security requirements can be cost prohibitive, in some instances, be a

disincentive for researchers to examine these substances for their therapeutic value.

You note in your testimony the confusion in the application process and delay in obtaining an approved registration inhibits researchers, especially young researchers, from commencing research with drugs of abuse and from dedicating their careers to study.

To what extent does this confusion in the process and other hurdles you mentioned, protocols, registration, costs, obtaining institutional support, inhibit researchers and institutions from taking up projects with schedule I substances?

Mr. Beardsley. Well, thank you for that question. There is a huge hurdle in becoming a schedule I registrant, for instance. The application process entails submitting security requirements, detailing how much drug you will be using in your protocol. In my case, I work with laboratory animals. I have to identify how many doses I will be giving each animal and what routes of administration. I have to estimate the amount of drug I will be administering to be approved with the protocol.

And just that point is particularly difficult to estimate the amount of drug one needs to do research.

Mr. Green. Well, we have a piece -- I only have 5 minutes.

Mr. Beardsley. Oh, I am sorry.

Mr. Green. We heard from HHS, however, that H.R. 2851 attempts to streamline the researcher registration process. But we heard from HHS that there may still be, constitute a barrier to research that may

have negative impact on drug development.

Could you reiterate why you think this and what steps we can to remove those hurdles, and clearly getting bumped between Virginia and the DEA on which one registration you get first. That seems pretty silly. We ought to be able to deal with that.

Mr. Beardsley. Right. First off, with SITSA, a drug can be put into schedule A only based upon structure. That is problematic because there are many drugs that have similar structures, some of which are drugs of abuse, some of which are antidotes to those drugs of abuse.

So if a drug is scheduled, it is really a disincentive for a researcher to begin conducting research with that drug. If the drug is in the schedule for no other reasons than its structure, we will never know whether it is a drug of abuse or a breakthrough medication. So that is one instance in which scheduling a drug just based on structure can be a disincentive for conducting research with these drugs.

And for younger researchers to go through the hurdles of obtaining the schedule I registration, for instance, that is yet another hurdle.

Mr. Green. Well, we don't want to do anything that would eliminate the potential for research, because that is the other thing that we want to do. But be that as it may, we will see what we can do.

Dr. Kolodny, do you believe requiring 12 hours of continuing education every 3 years is a practical requirement for healthcare practitioners to prescribe opioids?

Dr. Kolodny. I do think that we should be mandating prescriber education. I think that we should allow doctors who don't intend to prescribe more than a 3-day supply of opioids to opt out. If we had an opt out, then you are not making people take training irrelevant to their practice. Many doctors would opt out, because 3 days is more than enough. You would reduce the number of doctors able to prescribe aggressively. And for doctors who do major surgery or treat cancer, they would take the training.

I think that is the way to go. I would like to point out that for buprenorphine, a medicine much safer than drugs like oxycodone, we have an 8-hour training requirement, and then we limit the number of patients the doctor can treat. Whereas, for the drugs that are causing addiction, causing overdose deaths, we have no training requirement and we have no caps on the number of patients that they can prescribe to.

Mr. Green. Okay. Thank you. I yield back, Mr. Chairman.

Mr. Burgess. The chair thanks the gentleman. The gentleman yields back. The chair recognizes the gentlelady from Indiana, Mrs. Brooks, 5 minutes for questions, please.

Mrs. Brooks. Thank you, Mr. Chairman. Dr. Kolodny, I am going to followup. And I assume you heard from the last panel, from DEA, that I, too, am working on a bill, but slightly different. While fewer hours, it comes in part from the President's Commission on Combatting Drug Addiction Opioid Crisis, and it was top recommendation that all prescribers should be required to have some continuing medical

education. I know you agree with that.

Ours calls for 3 hours, but it is not just about preventing, you know, preventing the overdose, it is also about education on physicians and other practitioners, learning how to detect of their own patient base that they already have, not just the prevention of the addiction, but also, you know, what they, how they can learn more about just addiction writ large.

Do you believe that state licensing agencies are equipped to produce and manage education programs of this type? Because I know you are not in favor of other organizations producing that training. What about State licensing or agencies, possibly in conjunction with working with best practices from HHS?

Dr. Kolodny. You know, it took a while for policymakers on a State and Federal level to recognize that the opioid addiction epidemic was being fueled by very aggressive prescribing, that the medical community really needed to change course. And many State legislators have responded by passing laws mandating prescriber education on a State level. I don't believe those systems are working.

The way they typically work is that every doctor in the State who has a registration, whether or not they ever intend to prescribe an opioid, has to take a course on pain treatment. It is usually online. The content for these courses is awful. In many cases, the courses are taught by the same doctors who were teaching the courses that really got us into this mess.

I don't think that is the way to go. I think this should be done

on a Federal level linked to DEA registration with an opt-out for doctors who don't want to prescribe more than 3 days, let them opt out. But then they are not allowed to prescribe more than 3 days. That would overnight shrink the pool of doctors capable of prescribing aggressively. I like that you are thinking about addiction and we really do want to teach more than just how to prescribe these medicines. We need to also be teaching people who prescribe addictive drugs about addiction.

Mrs. Brooks. And I will probably be submitting for the record, because I have a couple other questions for another panelist about other model programs or ideas you might have on the specific types of courses and so forth.

Dr. Kan, my concern, and you have testified about the fact that so few people receive treatment but yet many people have medical professionals in their lives or they do see medical professionals. Would you say it is uncommon for primary care physicians or the physician that has prescribed the opioids to detect and to diagnose an addiction?

Dr. Kan. I would say that it is quite common. Dr. Kolodny made a comment earlier that I agreed with, that the change in opioids is going to cost in the billions of dollars. But the changes that we can have now is we need to educate the prescribers on how to identify problematic use.

For example, we know that anywhere from 15 to 45 percent of patients who are taking prescribed opioids for chronic pain demonstrate

aberrant behavior, meaning that they have a urine drug screen that is negative for the opioid. They may have something else in the drug screen or there is other problems.

I think that treating the opioid epidemic, one of the main emphasis that we see is that primary care needs to be taught how to do it. I think of buprenorphine a lot like insulin. If you look at the Type 2 diabetes disease model, it is almost a perfect analogue for opioid use disorder. I think of opioid use disorder with chronic exposure, whether for recreation or medication, changes the brain. And for some patients they need buprenorphine, just as some people who suffer from diabetes need insulin.

And I would argue to you that insulin is far more dangerous than buprenorphine.

Mrs. Brooks. Would you please share with me, though, aside from continuing the medical education, which is what I have been focused on in crafting a bill, what else can we do to better equip physicians, primary care, who are not trained addiction specialists as to what they should be doing?

Dr. Kan. I think what we need to equip them with is the access to the specialist. The greatest difficulty that a primary care provider sees, they don't know who to send the person to, because the addiction specialist they referred them to may be a cash practitioner or they may not have access to treatment.

So we need to educate a workforce that once the primary care provider identifies the person, then they can be sent to the specialist.

This is the Vermont hub and spoke model. Because they have hubs that are specially trained clinics, and when they stabilize, they go back to their primary care provider. It is a model that has been used in the city and county of San Francisco where I work part-time.

I already had my DEA x-waiver, but I was required to get it because the model that they use is they have extensive treatment and then goes back to the primary care provider once somebody is stabilized. As they destabilize, go back to the hub.

Mrs. Brooks. Thank you. My time is up. I yield back. Thank you all for your work.

Mr. Burgess. The chair thanks the gentlelady. The gentlelady yields back. The chair recognize the gentleman from Virginia, Mr. Griffith, 5 minutes for questions, please.

Mr. Griffith. Thank you very much, Mr. Chairman. Mr. Nance, let me just say thank you for your testimony that you have given thus far on telemedicine. It is a very important field for us to get in and explore.

My district is in the east, but it is a very rural district. And while we don't have the miles that you have, sometimes getting around the mountain, particularly when the weather is not the best or when people are having problems to begin with, as you pointed out, can be a problem. And so I agree with many of the things that you say and appreciate your testimony here today on that. I mean, appreciate everybody's testimony today. It has been very informative.

Dr. Beardsley, if I night just briefly. You talk about drugs and

compounds may be structurally similar. And we heard some comments earlier today about the long history of opioids, and sometimes we treat one opioid with another opioid. And so I am just kind of curious, the naloxone, are you absolutely certain that that doesn't have an addictive problem down the road? Do you think that works for us no matter what?

Mr. Beardsley. I am absolutely certain that naloxone does not have addictive properties.

Mr. Griffith. Because it is the antidote, as you said earlier.

Mr. Beardsley. It is an antagonist, right, to opioids that are abused. That is an antidote, more or less it reverses their effects.

Mr. Griffith. Yeah. I appreciate it. That takes me to you, Mr. Logan, if I might. One of your recommendations is to allow pharmacists to prescribe naloxone.

Can you explain the differences you have seen in terms of access to reversal drugs in the States that currently allow this compared to those that do not. And how has increased access improved patient treatment?

Mr. Logan. There is a long answer to that question.

Mr. Griffith. Can I get a shorter one?

Mr. Logan. You can.

Mr. Griffith. You can send a written longer one, if you would like.

Mr. Logan. Naloxone is a life-saving drug. When it is used, it is in a life or death situation. If it is not used there is no treatment

thereafter. In that instance, the more we distribute the easier it is to get, whether provided by a healthcare professional, an EMS, or a family member. It doesn't matter. We have got to get it in the hands of the people who need it. And as of now, if I am not mistaken, naloxone is available through pharmacies in every State.

Mr. Griffith. Okay. You referenced a Virginia program, Virginia's Medicaid Addiction Recovering Treatment Services has a new benefit for Medicaid patients which benefit includes coverage for SBRT (ph) provided by pharmacies. And I wrote that down. I am bad with all those names, too. But could you explain how that program works and specifically, how it has worked in Virginia and what good that does?

Mr. Logan. I am going to defer to NCPA for that answer. I can tell you about what is happening in Missouri.

Mr. Griffith. All right. Tell me what is happening in Missouri.

Mr. Logan. Not much.

Mr. Griffith. Okay. But it seems like what they are looking for is giving the pharmacists the authority to -- and they will send me a written response -- but giving the pharmacists the authority to say, Hey, we think this person might have a problem. And instead of having law enforcement swoop in, have some education and try to get treatment for that individual first. Is that your understanding of the program?

Mr. Logan. The whole goal of the program is to keep addiction addiction and not make addiction criminal. We don't want a person who is ill being treated in the legal system. From both sides of my life, my pharmacy healthcare side and my law enforcement side, we want those

people properly assigned and properly treated.

Mr. Griffith. Absolutely. And so do we. And I appreciate you on that.

Dr. Beardsley, back to you. I know earlier you were scratching your head a little bit. That is what us lawyers call conditional relevancy. I was setting up his question but asking you something. And you were like, why is he asking me that.

But now I am going to ask you questions directly to you and that is, you talked about how adding a new drug to your existing schedule I registration may take months. Now for the folks back home who are watching this in the middle of the night or right now, you have to get permission to do -- you do schedule I registration, to do research on some of the more dangerous drugs, or at least the ones that are on schedule I, isn't that correct?

Mr. Beardsley. That is correct.

Mr. Griffith. And so could you tell us how, so we can all better understand, how taking months to get the schedule I registration for a researcher can gum the process.

Mr. Beardsley. Well, it interrupts the research process if you have to wait for months in order to get approved for using a drug.

The initial process for even applying to have a schedule I drug added to your registration is lengthy for the researcher himself. It takes several hours to prepare a protocol. And that also has research costs in terms of downtime. In my case, I do research in four laboratories, very close together in similar -- buildings are very

close together. And yet I have to have four schedule I registrations, four Schedule two to five registrations, and four commonwealth of Virginia registrations to do that research. That all adds cost and hampers research.

Mr. Griffith. Cost, time, and makes it harder to come up with good results, isn't that correct?

Mr. Beardsley. Well, it ends up creating a bureaucratic morass that can almost make research untenable.

Mr. Griffith. Well, I appreciate that. My time is up and I appreciate all of you. And I yield back.

Mr. Burgess. The gentleman yields back. The chair thanks the gentleman. The chair recognizes the gentleman from Georgia, Mr. Carter, 5 minutes for questions, please.

Mr. Carter. Thank you, Mr. Chairman. Mr. Chairman, before I start, I want to compliment you and staff. This is an outstanding panel. I mean, seriously, we got boots on the ground. So often, with all due respect, we only have people from academia. But this is truly boots on the ground. And I just can't tell you, I am so impressed. I am sorry I had to leave a little earlier to go meet with another group, but let me get started because I got a lot I want to go through.

I am going to start with you, Dr. Kan. I want to ask you, because telemedicine -- I have got a bill that we are considering with telemedicine -- but specifically with the Ryan Haight Act, it limits expanded access to buprenorphine. And I am just wondering if you can speak to that, very quickly, about how we could do away with that so

that we could be able to prescribe it, if we needed to, but because of this act, as I understand it, we are not able to?

Dr. Kan. If we amend it to the recommendation that we can rely on another provider, that would be extremely helpful. With my company, we rely on emergency department physicians. We pair with emergency departments to identify, get them started on buprenorphine and quickly matriculated into care.

The short version of it is that the drug dealers are open 24/7.

Mr. Carter. Right.

Dr. Kan. We need to be ready to do the same.

Mr. Carter. Right. Mr. Nance, you mentioned this also in your testimony, about the limitations that Ryan Haight Act is causing us on that. Can you comment on that very quickly?

Mr. Nance. Can you ask me a more specific question?

Mr. Carter. Particularly, as I understand it, it limits the expanded access to treatment with some of the drugs that we need to be treating this opioid addiction with, like buprenorphine.

Mr. Nance. Yeah, the whole point of my testimony is that, especially in rural and frontier areas --

Mr. Carter. Absolutely.

Mr. Nance. -- you have very, very few licensed providers who will actually be willing to provide buprenorphine. My friend at the DEA in Utah says we have 503 licensed trained buprenorphine prescribers. Only 125 of them are actually practicing and prescribing buprenorphine. But if you go on the buprenorphine treatment binder on their website,

there are only about 70 listed.

Mr. Carter. Right.

Mr. Nance. So you have got a huge potential labor pool out there but they are just reluctant to do it because they are not familiar with --

Mr. Carter. But specifically with telemedicine, if we were able to have the physician be able to prescribe it then, as I understand it, and they can't because of the Ryan Haight Act.

Mr. Nance. Right. It is very, very difficult. You have to have that first face-to-face. If we can get the community behavioral health centers included as a kind of separate definition inside the Ryan Haight Act, then we can open up a lot of potential buprenorphine services to the patients in those extreme --

Mr. Carter. Okay. Let me move on. Mr. Logan, I wanted to ask you. Did you all ever get the PDMP in Missouri?

Mr. Logan. I keep getting asked these questions with long answers.

Mr. Carter. Okay. I need you to make it real quick. Yes or no.

Mr. Logan. We have an executive order signed that examines prescriptions written and adjudicated through a third-party insurance.

Mr. Carter. Okay.

Mr. Logan. And prescribes blame to over-prescribers.

Mr. Carter. Okay. You really needed -- for a long time 49 out of 50 States had it. Missouri was the only one who didn't have it. And it needs to go across State lines. As you pointed out earlier in

your testimony, you are right on the State line. And you are going get prescriptions as I did, in my pharmacy from many States. So that is why it is so very important.

I wanted to mention just a couple of other things. Mr. Cosgrove, you mentioned a number of companies, pharmaceutical manufacturers are moving overseas. Is that because of our tax laws? We changed that just recently, so I hope that we have resolved that.

Mr. Cosgrove. Well, I am not an expert in tax law.

Mr. Carter. Right.

Mr. Cosgrove. I do know that the manufacturing costs overseas for a number of reasons --

Mr. Carter. Okay.

Mr. Cosgrove. -- are dramatically lower than --

Mr. Carter. Well, if it is because of manufacturing costs. But if it is because of the tax problems, then we have resolved that problem with the Tax Cuts and Jobs Act. So I want to make sure we understand that.

Dr. Subbiah, you mentioned about the new drug that you had. I just wanted to ask you very quickly. You haven't used specialty pharmacies, only practitioners can be injected. Was that mandated by the FDA or did the company decide that is the way that you wanted to go? Because access is a big problem when we are talking about these kinds of drugs, and obviously, that is going to limit access there.

Dr. Subbiah. So this was in discussion with the FDA. It is part of our risk evaluation mitigation strategy program.

Mr. Carter. Okay.

Dr. Subbiah. Because a lot of doctors, some of them do not want to do the buy-in bill, and so there had to be another way in a restricted distribution system. So if a doctor in Utah wanted to prescribe Sublocade, they can contact one of the specialty pharmacists that we are working with.

Mr. Carter. Right.

Dr. Subbiah. And they will get a named patient for prescription that will be sent to that doctor for use only in that patient.

Mr. Carter. Okay. And one last thing. Dr. Mulder, thank you. I was a hospice consultant pharmacist for many years. And quite often in Congress, we have the tendency to overreact and overdo it. And you pointed out something that is very important. There are people out there who truly need these drugs. We need to make sure that they are going to be able to get them and have access to them. So thank you for pointing that out.

Mr. Mulder. Amen.

Mr. Carter. Yes. Thank you, Mr. Chairman. I yield back.

Mr. Burgess. The gentleman yields back. The chair thanks the gentleman. And does the gentleman from Michigan wish to be recognized for questions?

Mr. Walberg. Yes, Mr. Chairman.

Mr. Burgess. You are recognized for 5 minutes.

Mr. Walberg. Thank you. Thanks again for letting me sit in this panel. And specifically, I would add to my colleagues' comments -- and

compliments to you, Dr. Mulder. It is a tough field that you are in. And it is a compassion field, and we want to make sure that we do things right. But I am delighted that you are also thinking along the line of how do we carry on our impact with end-of-life issues, with human beings in need, but also make sure that what we use and use appropriately, doesn't end up causing problems for others down the road.

In our home State of Michigan, Mr. Mulder, we have seen real challenges with diversion and misuse of leftover medications that have contributed to the opioid crisis. Hospices and hospice personnel could play a key role in helping ensure these drugs are properly disposed of, but current DEA regulations appear to pose an obstacle.

Could you please describe the current challenge that hospice personnel face when an individual passes away and there is remaining unused medication? How does the current law specifically prevent hospice personnel from destroying this unused medication to ensure that it is not diverted to another purpose?

Dr. Mulder. Well, it somewhat has to do with kind of the take-back provisions in which, if they are going to receive these medications, whether for the purpose of, you know, distributing them somewhere else or to, of destroying them, it is a reverse distributor process. And they have to be licensed by the DEA as a reverse distributor to be able to take those medications in. I think I am using the right terminology. The pharmacists can correct me if I am not.

But when that came into effect then, they by law, can't take those

medications. They really are not allowed to do anything with that. And that is the primary limitation.

Mr. Walberg. Is that the same problem in an actual hospice, physical hospice facility?

Mr. Mulder. No, it really isn't. And part of that has to do with how those facilities are licensed. And that may vary from State to State but that does not exist, for example, we have a, you know, our hospice operates in a facility. We do not have that same restriction.

Mr. Walberg. Okay. In your opinion, what type of licensing should a hospice worker have to be able to destroy unused medication? Is that something that needs to be further clarified in my bill, H.R. 5041?

Mr. Mulder. Yes. Well, for sure, physicians, physician assistants, nurse practitioners, and registered nurses, I would put at the top of my list as those who already have licensure and could, I think, very logically be certified to be able to manage that process.

Mr. Walberg. So they have the background, they have the training, they have the certification. If indeed they are retired and volunteer services, would that carry over?

Mr. Mulder. I probably would not extend that to volunteers. Volunteers, although they function in many capacities as a, you know, kind of a surrogate employee at the hospice, the relationship is different, the financial relationship is different, the regulatory relationship is different. And I probably would be reluctant to subscribe that particular task. That is my own personal view, though,

to a volunteer.

Mr. Walberg. Okay. Well thank you. I appreciate the entirely panel and sitting in, but appreciate, Dr. Mulder, your points. I yield back.

Mr. Burgess. The gentleman yields back. The chair thanks the gentleman. The chair would observe that I had delayed my questioning to allow other members to pose their questions and then catch planes, or trains, or automobiles, whatever they needed to do.

Dr. Mulder, I really was encouraged to hear you use the term, we are going to miss some episodes of preventible suffering. And it worries me, too.

Mr. Mulder. Thank you.

Mr. Burgess. One of my very first hearings in this committee, and it was a long time ago, but it is why are doctors not prescribing enough pain medicine to the point that some others have made on this panel. I have seen the pendulum swing both ways. And I do worry that we live in the land of unintended consequences here in the United States House of Representatives.

So it worries me that some of the things that we are perhaps contemplating today are going to put more people into the realm of preventible suffering that is not prevented, and I worry about that. So thank you for what you do in bringing that to our attention as well.

Mr. Mulder. Well, thank you for your comments and we will be looking forward to the diligence of this committee to make sure that doesn't happen.

Mr. Burgess. Yeah, ever hopeful.

Mr. Logan, first off, I want you to know that in the appropriations bill for Labor, Health and Human Services that the House of Representatives passed in September -- now, the Senate has never taken any action, so it hasn't become law -- but the bill that we passed in September actually did carve up some dollars for people who don't have a PDMD available so that it would be available.

I am a big believer in PDMPs. I think they are useful. I worry about burdening people with too much, too many inputs that they have to put in their electronic health record but at the same time -- or too many queries of a database, but still, this is one that I think can be very useful.

But let me just ask you. I mean, you described a situation where your pharmacy is, and you are on a big highway, that is the crossroads of the Nation and people come from all over the country with prescriptions they have received somewhere else and then they present them to you. Did I understand that correctly?

Mr. Logan. Yes, you did.

Mr. Burgess. And I got the impression, I may have been overcalling it, but I got the impression that you felt that sometimes -- I don't want to infer anything. Do you feel that sometimes the prescription perhaps is overly generous with the amount of medication that is dispensed?

Mr. Logan. Any time I see multiple prescriptions for multiple people in one vehicle in quantities of excess of 180 oxycodone, I think

that is excessive, yes.

Mr. Burgess. So with your keen powers of observation, you are able to deduce that that may be an overprescribing situation?

Mr. Logan. Thank God it don't take no rocket scientist.

Mr. Burgess. And that kind of is the point. Our representative from the agency, from the DEA, I don't think is here any longer, but I was under the impression every time I wrote a triplicate prescription for a controlled substance that it goes into -- whether I had a PDMP or not -- it goes into a database. Somebody is monitoring that. Maybe someone at my State level, maybe someone at the Federal level.

So it is not a surprise that these prescriptions are going out the doors or the pills are going out the doors. I had this very conversation with Secretary Azar two weeks ago when he was here. CMS has a lot of data at its disposal. It knows who under their care, in Medicare or Medicaid, is receiving an untoward number of pills. And it also knows the pharmacies to which it is reimbursing payment where an untoward number of pills are going out. Is that not recently to assume?

Mr. Logan. An inordinate number of these prescriptions are cash. There is no claim generated for them. So what you deal with at a payor level is paid claims. PDEs we call them. If there is no cash claim, if there is no PDMP, it never happened.

Mr. Burgess. Well, back to the point of the PDMP, why I thought it was important to put the money forward on that. This committee actually authorized a bill, it was called NASPER well over 10 years

ago, that was to provide that type of help. It got tied up in the appropriations process, and although it was authorized on several occasions, it was never funded. So I tried to correct that last September so that it would be funded.

But I guess the point I am getting at is it is not a surprise that there are some people who are overprescribing, and you can know who they are. You have brought up a point that I had not actually considered, which was the cash transaction, but still, the pharmacy has a record of the pills that they, I mean, are you not required to account for every controlled substance dose that comes through your shelves?

Mr. Logan. Absolutely. The pharmacist's duty of care is to determine the legality of the prescription. Are all the numbers on it? Is it filled out correctly. But also the legitimacy of the prescription. Is there a valid prescriber-patient relationship? Have there been diagnostic tests done to justify what we are talking about. A lot of times, the pharmacist has to go on gut feeling on the legitimacy. And the independent pharmacist is in a unique position. We determine our own destiny.

We can say yes, we will fill it. No, we won't. We are where the buck stops. There are people who work for companies that may not have the discretion to determine the legality and legitimacy and go strictly on the legality of the prescription.

Mr. Burgess. And I guess the point I was getting at, at some level, that data is available, because whether it be an independent

pharmacist or a chain pharmacy, all of those dosages of those control substances have to be accounted for somewhere.

Mr. Logan. In either controlled substance inventory mandated by DEA or purchases through wholesalers.

Mr. Burgess. Correct. So it is knowable if a location is receiving an unusual or an untoward amount of product, is that --

Mr. Logan. Absolutely.

Mr. Burgess. And Dr. Kolodny, obviously you and I do see things a little bit differently on some of the approaches, but I will say this: I mean I look at our doctors as our allies in this, not our adversaries. I think if we treat our doctors as allies, they will be our allies, if we treat them as adversaries, they will be our adversaries.

We, I think, sometimes unnecessarily complicate the lives of our physicians to the point where some of them will just give up and we will have preventable pain that doesn't get prevented or that doesn't get treated. So I just worry that putting the onus on a practicing physician to do some mandatory training, I don't know that that is going to solve the problem when the problem is as big as what Mr. Logan describes, Dr. Logan describes at his crossroads pharmacy. And yet, that data is known. Somebody knows that those bills are going out the door, right?

Dr. Kolodny. Yes. And I think we do agree that doctors are not to blame. I think that doctors were responding to brilliant marketing. And that is why we are seeing litigation from counties and States across the country and why the Department of Justice and Attorney General

Sessions announced yesterday that the Federal Government is going to be helping out. There is an understanding that the medical community has been deceived about the risks and benefits of these drugs.

The pill mill doctors, we have to try and stop them because they are killing a lot of people, but they are really not the root of the problem. The bigger problem are the well-meaning doctors and dentists who are inadvertently creating customers for these doctors. We have to stop those doctors because they kill people. But this epidemic will not end unless we prevent more people from becoming opioid-addicted.

Mr. Burgess. And here is where we disagree. I practiced in the 1980s and 1990s. I can rarely remember writing a prescription for more than 12 doses of a controlled substance. I had a surgical practice, and someone who was operated on was going to need pain relief. I recognized that. It did seem like in the old days we could allow for a refill on a prescription. And that may be a State function in Texas, but it seems like that went away at some point. And I don't know if that led to the conclusion that people are going to write larger numbers of pills so they don't get a telephone call on the weekend. I don't know. I am inferring that. I have no data to back that up.

But it just seems like the world changed somewhere between the late 1990s and the end of the first decade of the 21st century.

Dr. Kolodny. You are absolutely right. In fact we know exactly what year the prescribing began to take off. It happened in 1996. And it wasn't just OxyContin that starts to take off in 1996. Hydrocodone, hydromorphone, morphine, the fentanyl patch. Starting in 1996 is when

the prescribing really begins to explode.

In 2014, the fall 2014, we put Vicodin into a more restrictive category where it couldn't be phoned in easily and where you couldn't write refills. And that may have had an influence on the quantity in a prescription, but the overall impact of that change was a dramatic reduction in the number of hydrocodone pills that were prescribed.

So I think the bigger part of the problem was starting in 1996, a multifaceted campaign that was very effective that told doctors that we need to prescribe more. And many doctors are still very badly misinformed. I think in an ideal world, we would not have to make doctors take a training course. We could rely on doctors. But in this situation, doctors are not able to accurately weigh the risks versus the benefit for the patient in front of them.

Mr. Burgess. I disagree with that. I mean, that is our job. That is what we do. That is what we were trained to do. So you and I are going to fundamentally disagree on that. I will just conclude with the observation, I have gone way over time, but since I am the chairman, I can do that.

I don't know that any of the doctors who are writing those prescriptions that Mr. Logan gets presented with at 2:00 or 3:00 in the morning, I don't know if -- I mean, you may force them to take a continuing education course, but I don't think it is going to alter their behavior in the least.

And I also agree with you that some of the courses that are available, I, in fact, took for my CME last August, I did an online

course on opiate use and proper prescribing. One thing I have learned to do over the years is how to take a test. I disagreed with the philosophic premise that was coming out of this large medical school in the east, but I was able to answer the questions the way they wanted and got what my goal was, which was my continuing education hours.

You all have been very generous with your time today and I do appreciate it.

Mr. Green, do you have a followup?

Mr. Green. Yes, Mr. Chairman. I am not going to ask for the full 6 minutes that you took but I just want to ask, is anybody --

Mr. Burgess. You see, I aggregated all of the extra time that was taken on your side of the dais.

Mr. Green. Well, I just want to ask other witnesses, if you have any short statements in response to the chair or any of the stuff we did, because our solution, our efforts are to try a find a solution, and the balance, what we can do. Because we know we have an epidemic, but I have also seen overkill and that is what some of the testimony is, but we also know we need to deal with this issue. And does anybody have anything else for what the chair responded to?

Yes, Doctor.

Dr. Subbiah. I think the main thing I think you heard from all of us is that it requires a multi-pronged approach. It is going to require the treatment, it is going to require telemedicine. It is going to require education. And I think all of those are going to be very important. It is very encouraging today that you did allow all

of us to give those different perspectives. So thank you.

Mr. Burgess. That is what a hearing is all about.

Mr. Green. Yeah. And let me -- one thing. I had a constituents in our district who worked for many years in construction and he needed an opioid. And one of the chain drug stores, Walgreens that I work with all the time, because they help do immunizations in my area. The independent pharmacist has the right to decide that. And so I asked the regional director, I said, well, could this fellow go to another Walgreens? He said well, that pharmacist might decide not to. We ended up finding his medication, probably not at the most reputable pharmacy that we should have.

So there is an issue about people who really need it just to survive because of their lifestyle or their work, you know. As we get older, we find out that where we fell down and we are 30 years, when you are 65 you all of a sudden say, hey, that hurts. So, but anyway, thank you, Mr. Chairman.

Mr. Burgess. The chair will not refer to you as an enabler.

I do want to thank all our witnesses again for being here today, and for the time you have invested. As you can see, this is an important topic. And as the chairman, said we are going to have multiple hearing on this.

I would like to submit statements from the following for the record: Congressman David Kustoff, Prime Therapeutics, National Association of Chain Drug Stores, the University of Texas, Johns Hopkins University, CVS Health, Braeburn.

[The information follows:]

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

Mr. Burgess. Pursuant to committee rules, I remind members they have 10 business days to submit additional questions for the record, and I ask the witnesses to submit those responses within 10 business days upon receipt of said questions.

Without objection, the subcommittee is adjourned.

[Whereupon, at 5:12 p.m., the subcommittee was adjourned.]