AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

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

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED FIFTEENTH CONGRESS

SECOND SESSION

FEBRUARY 28, 2018

Serial No. 115–103



Printed for the use of the Committee on Energy and Commerce
energycommerce.house.gov

U.S. GOVERNMENT PUBLISHING OFFICE
30–411 WASHINGTON : 2019

COMMITTEE ON ENERGY AND COMMERCE

GREG WALDEN, Oregon
Chairman

JOE BARTON, Texas
Vice Chairman
FRED UPTON, Michigan
JOHN SHIMKUS, Illinois
MICHAEL C. BURGESS, Texas
MARSHA BLACKBURN, Tennessee
STEVE SCALISE, Louisiana
ROBERT E. LATTA, Ohio
CATHY MCMORRIS RODGERS, Washington
GREGG HARPER, Mississippi
LEONARD LANCE, New Jersey
BRETT GUTHRIE, Kentucky
PETE OLSON, Texas
DAVID B. MCKINLEY, West Virginia
ADAM KINZINGER, Illinois
H. MORGAN GRIFFITH, Virginia
GUS M. BILIRAKIS, Florida
BILL JOHNSON, Ohio
BILLY LONG, Missouri
LARRY BUCSHON, Indiana
BILL FLORES, Texas
SUSAN W. BROOKS, Indiana
MARKWAYNE MULLIN, Oklahoma
RICHARD HUDSON, North Carolina
CHRIS COLLINS, New York
KEVIN CRAMER, North Dakota
TIM WALBERG, Michigan
MIMI WALTERS, California
RYAN A. COSTELLO, Pennsylvania
EARL L. "BUDDY" CARTER, Georgia
JEFF DUNCAN, South Carolina

FRANK PALLONE, JR., New Jersey
Ranking Member
BOBBY L. RUSH, Illinois
ANNA G. ESHOO, California
ELIOT L. ENGEL, New York
GENE GREEN, Texas
DIANA DEGETTE, Colorado
MICHAEL F. DOYLE, Pennsylvania
JANICE D. SCHAKOWSKY, Illinois
G.K. BUTTERFIELD, North Carolina
DORIS O. MATSUI, California
KATHY CASTOR, Florida
JOHN P. SARBANES, Maryland
JERRY MCNERNEY, California
PETER WELCH, Vermont
BEN RAY LUJAN, New Mexico
PAUL TONKO, New York
YVETTE D. CLARKE, New York
DAVID LOEBSACK, Iowa
KURT SCHRADER, Oregon
JOSEPH P. KENNEDY, III, Massachusetts
TONY CARDENAS, California
RAUL RUIZ, California
SCOTT H. PETERS, California
DEBBIE DINGELL, Michigan

SUBCOMMITTEE ON HEALTH

MICHAEL C. BURGESS, TEXAS
Chairman

BRETT GUTHRIE, Kentucky
Vice Chairman
JOE BARTON, Texas
FRED UPTON, Michigan
JOHN SHIMKUS, Illinois
MARSHA BLACKBURN, Tennessee
ROBERT E. LATTA, Ohio
CATHY MCMORRIS RODGERS, Washington
LEONARD LANCE, New Jersey
H. MORGAN GRIFFITH, Virginia
GUS M. BILIRAKIS, Florida
BILLY LONG, Missouri
LARRY BUCSHON, Indiana
SUSAN W. BROOKS, Indiana
MARKWAYNE MULLIN, Oklahoma
RICHARD HUDSON, North Carolina
CHRIS COLLINS, New York
EARL L. "BUDDY" CARTER, Georgia
GREG WALDEN, Oregon *(ex officio)*

GENE GREEN, Texas
Ranking Member
ELIOT L. ENGEL, New York
JANICE D. SCHAKOWSKY, Illinois
G.K. BUTTERFIELD, North Carolina
DORIS O. MATSUI, California
KATHY CASTOR, Florida
JOHN P. SARBANES, Maryland
BEN RAY LUJÁN, New Mexico
KURT SCHRADER, Oregon
JOSEPH P. KENNEDY, III, Massachusetts
TONY CÁRDENAS, California
ANNA G. ESHOO, California
DIANA DEGETTE, Colorado
FRANK PALLONE, JR., New Jersey *(ex officio)*

CONTENTS

Page

Hon. Michael C. Burgess, a Representative in Congress from the State of Texas, opening statement 1
Prepared statement 3
Hon. Gene Green, a Representative in Congress from the State of Texas, opening statement 4
Prepared statement 5
Hon. Doris O. Matsui, a Representative in Congress from the State of California, prepared statement 6
Hon. Greg Walden, a Representative in Congress from the State of Oregon, opening statement 7
Prepared statement 9
Hon. Frank Pallone, Jr., a Representative in Congress from the State of New Jersey, opening statement 10
Prepared statement 12

WITNESSES

Susan A. Gibson, Deputy Assistant Attorney, Diversion Control Division, Drug Enforcement Administration 13
Prepared statement 16
Answers to submitted questions 246
Frank L. Fowler, Chief of Police, Syracuse Police Department 62
Prepared statement 64
Patrick M. Beardsley, Ph.D., Professor, Department of Pharmacology and Toxicology, Virginia Commonwealth University 67
Prepared statement 69
John Mulder, M.D., FAAHPM, HMDC, Director, Trillium Institute 80
Prepared statement 81
Ponni Subbiah, M.D., Chief Medical Officer, Indivior PLC 89
Prepared statement 91
David Y. Kan, M.D., President, California Society of Addiction Medicine 95
Prepared statement 97
Answers to submitted questions 254
Richard J. Nance, LCSW, Director, Utah County Department of Drug and Alcohol Prevention and Treatment 109
Prepared statement 111
Thomas J. Cosgrove, Partner, Covington and Burling LLP 136
Prepared statement 138
Answers to submitted questions [1] 259
Andrew Kolodny, M.D., Codirector, Opioid Policy Research, Brandeis University 141
Prepared statement 143
Answers to submitted questions 261
Richard N. Logan, Jr., Pharm.D., Owner, L&S Pharmacy 145
Prepared statement 147

SUBMITTED MATERIAL

Statement of Dr. Halberstadt, of the University of California, San Diego, submitted by Mr. Green 178
Statement of the College on Problems of Drug Dependence, submitted by Mr. Green 180
Statement of Hon. Brad Schneider, a Representative in Congress from the State of Illinois, submitted by Mr. Green 182
Statement of a public health group, submitted by Mr. Green 184

Page

Statement of the American Society of Addiction Medicine, submitted by Mr. Green 186
Statement of the Center for Lawful Access and Abuse Deterrence, submitted by Mr. Green 188
Statement of Catalent, submitted by Mr. Green 189
Statement of the Pharma & Biopharma Outsourcing Association, submitted by Mr. Green 191
Statement of the College on Problems of Drug Dependence, submitted by Mr. Green 194
Report from the Center for Budget and Policy Priorities, submitted by Mr. Green 196
Article entitled, "The Opioid Epidemic: A Crisis Years in the Making," The New York Times, October 26, 2017, submitted by Mr. Luján 204
Article entitled, "Inside the Story of America's 19th-Century Opiate Addiction," Smithsonian, January 4, 2018, submitted by Mr. Luján 213
Questions for the record from Representative David Kustoff, submitted by Mr. Burgess 216
Statement of Prime Therapeutics, submitted by Mr. Burgess 218
Statement of the National Association of Chain Drug Stores, submitted by Mr. Burgess 220
Statement of the University of Texas Health Science Center, submitted by Mr. Burgess 226
Statement of Catherine M. Davis, Ph.D., Hopkins Bayview Medical Center, submitted by Mr. Burgess 227
Statement of CVS Health, submitted by Mr. Burgess 229
Statement of Braeburn, submitted by Mr. Burgess 231
Statement of the American Hospital Association, submitted by Mr. Burgess ... 232
Statement of the Drug Policy Alliance, submitted by Mr. Burgess 238
Statement of Andrew C. Kruegel of Columbia University, submitted by Mr. Burgess 240
Statement of Hon. Mark DeSaulnier, a Representative in Congress from the State of California, submitted by Mr. Carter 245

---

[1] The committee did not receive a response to Mr. Cosgrove's submitted questions for the record by the time of printing.

COMBATING 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, DC.

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, Luján, 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.

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

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 fright-

ening 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 combating 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 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 safely 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:]

PREPARED STATEMENT OF HON. MICHAEL C. BURGESS

Our nation remains in the unrelenting grip of the opioid epidemic. While the latest report from the Centers for Disease Control and Prevention lists West Virginia, Ohio, New Hampshire, Pennsylvania, and Kentucky as the five States hardest hit, all of us know this crisis has ravaged other States, too. The statistics are heartbreaking: on average 115 Americans die every day from an opioid overdose—that is nearly 5 people per hour. I said it before and will say it again. Now more than ever, we must come together and strengthen our commitment to fight this scourge—it requires an all-hands-on-deck approach.

Today's hearing is the first of three legislative hearings on combating the opioid crisis. It is the product of the Member Day the Health Subcommittee held last October, where over 50 bipartisan Members of Congress—both on and off the Energy and Commerce Committee—shared their personal stories on how the opioid epidemic has devastated their communities while also offering 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 would like to welcome Susan Gibson, Deputy Assistant Attorney in the Diversion Control Division at the Drug Enforcement Administration (DEA). Ms. Gibson, we look forward to hearing your thoughts on the progress DEA has made to stem the flow of opioids through our neighborhoods and how these legislative proposals would strengthen the agency's efforts in what is now a public health emergency for the

country. On the next panel, we will hear from a cross-section of stakeholders representing local law enforcement, physicians, pharmacists, and hospices on one hand to anti-opioid researchers, manufacturers, and policy groups on the other. We also 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 that, as the title of our hearing indicates, seek help communities balance enforcement and patient safety.

Today, we will focus our attention specifically on the Controlled Substance Act. Over the last several months, the committee came to realize that some areas of this law required an update or clarification. For example, synthetic opioids, like fentanyl, has flooded U.S. cities and towns and pushed drug overdose deaths to levels never seen before. H.R. 2851, the Stop the Importation and Trafficking of Synthetic Analogues (SITSA) Act, authored by Rep. John Katko, will better equip law enforcement to get illicit synthetic drugs off our streets while modernizing scheduling guidelines for these drugs.

Another issue of critical importance is the growing risk of misuse and diversion of controlled substances. Reps. 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 safely dispose these drugs in patients' homes. Another bill, currently in discussion draft form, authored by Reps. Ryan Costello and Rick Nolan, will improve dispensing of implantable and injectable therapies that were developed to make misuse and diversion more difficult.

Next, we will examine two telemedicine bills that will improve access for patients. The Special Registration for Telemedicine Clarification Act, written by Reps. Buddy Carter and Cheri Bustos, would clarify telemedicine waivers and direct the Attorney General to issue regulations for health care providers to prescribe controlled substances through telemedicine in legitimate emergency situations. The Improving Access to Remote Behavioral Health Treatment Act, written by Rep. 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 obtain a DEA registration and qualify for the telemedicine exception under the Ryan Haight Act.

Lastly, the subcommittee will discuss two provider education bills. The first bill, H.R. 4275, the Empowering Pharmacists in the Fight Against Opioid Abuse Act, authored by Reps. Mark DeSaulnier and Buddy Carter, would help pharmacists detect fraudulent prescriptions through new educational materials. Another bill aims to improve doctors' understanding of pain management treatment guidelines and best practices, among other things, by mandating 12 hours of continuous medical education on these subjects every three years. This policy contained in H.R. 2063, the Opioid Preventing Abuse through Continuing Education (PACE) Act, authored by Rep. Brad Schneider, concerns me greatly because it seems to suggest that doctors are primarily at fault for the opioid epidemic. As we consider solutions critical to blunting this crisis, we must strike a careful balance before casting blame.

As I said earlier, an important aspect of today's hearing is to think through and debate the policies within these pieces of legislation. I believe what we accomplish here will set the tone for the next two hearings in our subcommittee.

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

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

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 com-

plex 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 nonelderly 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:]

PREPARED STATEMENT OF HON. GENE GREEN

Thank you, Mr. Chairman. I want to thank you for your work on addressing the opioid epidemic that has impacted countless families and communities in our country.

According to the National Institutes of Health, 115 Americans die every day after overdosing on opioids. The misuse and addiction to opioids, including prescription pain relievers, heroin, and synthetic opioids, such as fentanyl, is a serious national crisis that affects public health, as well as our social and economic welfare.

The pattern of lives ruined and lost due to the opioids epidemic must be reversed. The opioids epidemic is complex and multifaceted, however. There are no simple and quick fixes.

Ending this crisis will require better coordination of care, community involvement in 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 abuse.

In recent years, Congress has acted in this space. The Affordable Care Act expanded health care coverage to 20 million non-elderly Americans, giving access to the medical and behavioral attention opioid victims need to overcome addiction.

Any honest effort by Congress to address the opioids epidemic must include measures to stabilize and strengthen the exchanges, and make coverage accessible for

Americans who currently do not have health coverage, including the three 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 the 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 and secure these necessary funds.

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

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

Now, I would like to yield one-and-a-half minutes to my friend and colleague, Congresswoman Matsui of California.

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 Mrs. Matsui follows:]

PREPARED STATEMENT OF HON. DORIS O. MATSUI

Thank you for yielding. Mr. Chairman, as we continue this discussion, I hope we can work together in a bipartisan manner to effectively confront issues of access and affordability for addiction treatment.

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

We can all acknowledge that. while Controlled Substances should be carefully regulated, they also play a vital role in effective addiction treatment.

Accessing treatment continues to be a major hurdle in many communities. Today we're examining a discussion draft that I am working on with my colleague on the Committee, Rep. Gregg Harper, that looks at ways we can use telehealth to increase access to substance use treatment.

We are also examining a bill authored by my colleague, Rep. Brad Schneider that would require providers that 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. and the ACA. both of which have already played a crucial role in reducing the treatment gap. I look forward to continued discussions here. This conversation must be paired with significant resources to help patients and families who are suffering.

Thank you, I yield back.

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, expressing the support for the Senate companion for Tableting and Encapsulating Machine Regulation Act; a letter from Catalent and PBOA. 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. OK. Without objection, so ordered.

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

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.

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

Mr. WALDEN. 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. 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 toward 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 simply showed up, sat in the chair next to 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 con-

structive 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 Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

No community is immune to the opioid epidemic. It's ripping apart the very fabric of our neighborhoods. From Oregon to Ohio. From Connecticut to California. Our friends and our families are experiencing an epic tragedy—one that's claiming the lives of more than 100 Americans each and every single day.

Working together, we can help.

Congress must learn from the past. The Comprehensive Addiction and Recovery Act, or CARA, was an important milestone in helping States. The breakthrough 21st Century Cures Act—striking a fair balance of speeding up the availability innovative treatments and safeguarding necessary public health protections—is already delivering.

Lawmakers must acknowledge the present. In 2016, opioid overdose deaths—from both prescription and illicit drugs—were five times higher than in 1999. And as public officials representing our communities, we must plan for the future. This is why we're here today—to work towards our shared goal of combating the opioid crisis.

Each statistic is disturbing. Even more tragic, every number has a name. Like Mike.

At a roundtable I held in Oregon, a man named 'Mike' showed up. Literally, he just showed up. Mike didn't know anyone in the room. He'd heard of our meeting to discuss opioid abuse on the news and wanted to share his story.

Mike's son was injured in a 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 a cheaper opioid source: heroin. To this day, Mike's son still struggles with his addiction that began with opioid abuse.

Mike went on to speak about his sister who also suffered from addiction. A nurse, Mike commented that she found herself with easier access to the pills. 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. Mike came to the meeting—a roundtable I held with law enforcement and medical professionals—in hopes that sharing his stories could help ensure it doesn't happen to other families.

Mike, and the countless other folks who have fallen victim to this crisis, is the reason we're here today.

Today marks our first of three legislative hearings this Congress. We'll focus on equipping law enforcement with the necessary tools to fight the opioid epidemic with careful attention to not compromising important public health protections.

Getting illicit synthetic drugs off the streets, safely disposing of unused controlled substances, improving patient access to substance use disorder treatments and remote services, and helping providers and pharmacists better prevent addiction are among the handful of bills we'll review today.

It's important to acknowledge that this legislative hearing is the appropriate venue to ask tough questions and make constructive suggestions on how to improve these bills. Many of these bills are discussion drafts because they are admittedly in need of discussion. I look forward to feedback from each of our witnesses as well as both the Democratic and Republican members of this subcommittee.

In the coming weeks, this subcommittee will continue its hard work with legislative hearings related to public health and prevention efforts, as well as issues pertaining to insurance coverage. This is just the beginning and represents only a fraction of the ideas members from across the country have formulated to overcome this epidemic.

I'd like to thank our two panels of witnesses for being here today, and I look forward to your feedback on these important issues. I'd also like to thank my colleagues for staying in town to have this vital discussion. Combating the opioid crisis requires all-hands-on-deck, and I appreciate everyone's shared commitment in this effort.

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

Mr. WALDEN. 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.

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.

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

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 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 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—seemed to suggest that he didn't like the fact that 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 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, 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 they need to do this, they need to 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:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

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. This is a national crisis that is devastating families every day. Simply put, a lot more must be done.

That is why 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. These are serious issues that deserve serious consideration. I know Chairman Walden was thanking those who didn't go home and stayed, but frankly in my opinion no Member should have to choose to stay in Washington when we are not voting or go home. It is also completely unfair to all the witnesses who have flown here and will likely end up with less engagement by the time their panel ends. I get the feeling that the Republican leadership is just checking the box instead of giving members, staff and stakeholders the time to consider important issues like the opioid crisis.

Last Congress, we took bipartisan action to pass CARA and 21st Century Cures, both of which provided initial investments and steps to addressing this crisis. These laws are expanding access to treatment 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. I look forward to working to build on these efforts.

The legislative proposals we are examining today strive to address a number of discrete policy problems under the Controlled Substances Act that health care practitioners and law enforcement officials face in combatting the opioid and substance abuse crisis. For example, we are considering legislation from Congressmen 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. We also are considering legislation from Congressman Schneider that would require mandatory prescriber education as a condition of DEA licensure. This would ensure that all providers who treat patients for pain with opioids have training on the best practices for prescribing opioids, early detection of opioid addiction, and treatment and management of opioid-dependent patients.

We will also discuss how we can employ telemedicine in treating those suffering from substance use 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.

Finally we will consider two proposals that I continue to have strong concerns about. The first is H.R. 2851, which attempts to address the problem of illicit synthetic analogues. The second is a discussion draft that would propose scheduling tableting and encapsulating machines like controlled substances. While I recognize the importance of addressing illicit synthetic drugs and illegal importation of industrial pill presses, 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 look forward to hearing more from DEA and our witnesses today on these issues, and hope to work with my colleagues to address these concerns so that we can all support legislation that will help to address the opioid crisis.

Thank you, I yield back.

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 the 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:]

Department of Justice

STATEMENT OF

SUSAN A. GIBSON
DEPUTY ASSISTANT ADMINISTRATOR
OFFICE OF DIVERSION CONTROL REGULATORY
DIVERSION CONTROL DIVISION
DRUG ENFORCEMENT ADMINISTRATION

BEFORE THE

SUBCOMMITTEE ON HEALTH
ENERGY AND COMMERCE COMMITTEE
UNITED STATES HOUSE OF REPRESENTATIVES

FOR A HEARING ENTITLED

"COMBATING THE OPIOID CRISIS: HELPING COMMUNITIES BALANCE ENFORCEMENT AND PATIENT SAFETY"

PRESENTED

FEBRUARY 28, 2018

Statement of
Susan A. Gibson
Deputy Assistant Administrator
Office of Diversion Control Regulatory
Diversion Control Division
Drug Enforcement Administration

Before the
Subcommittee on Health
Energy and Commerce Committee
U.S. House of Representatives

For a Hearing Entitled
"Combating the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety"

February 28, 2018

INTRODUCTION

Chairman Walden, Ranking Member Pallone, and Members of the Committee: on behalf of the approximately 9,000 employees of the Drug Enforcement Administration (DEA), thank you for the opportunity to discuss potential legislation intended to help combat the opioid epidemic.

Drug overdoses, suffered by family, friends, neighbors, and colleagues, are now the leading cause of injury-related death in the United States, eclipsing deaths from motor vehicle crashes or firearms.[1] According to initial estimates provided by the Centers for Disease Control and Prevention (CDC), there were more than 64,000 overdose deaths in 2016, or approximately 175 per day. Over 34,500 (54 percent) of these deaths were caused by opioids. The sharpest increase in drug overdose deaths from 2015 to 2016 was fueled by a surge in overdoses involving fentanyl, fentanyl analogues, and synthetic opioids.[2]

Reports on the ongoing misuse of controlled prescription drugs (CPDs) and the growing use of heroin, fentanyl, and fentanyl analogues in the United States are at unprecedented levels. DEA has become increasingly alarmed over the proliferation of illicit fentanyl and its analogues, which have been added to heroin and other illicit substances and have also been encountered as counterfeit tablets resembling CPDs. Fentanyl and fentanyl analogues are potent synthetic opioids that present a serious risk of overdose and death by those who abuse these substances. The yearly market for illegal, non-medical prescription pain relievers is estimated to be over 11.5 million people, and if fentanyl and fentanyl analogues are introduced into even a small portion of the illicit opioids consumed, there is a likelihood overdoses will increase.[3] Fentanyl and fentanyl

[1] Rose A. Rudd, Noah Aleshire, Jon E. Zibbell, & R. Matthew Gladden. Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014 Morbidity and Mortality Weekly Report, 2016;64:1378-1382.
[2] CDC WONDER data, retrieved from the National Institute of Health website; http://www.drugabuse.gov as reported on NIDA's website.
[3] Center for Behavioral Health Statistics and Quality. (2017). 2016 National Survey on Drug Use and Health: Detailed Tables. Substance Abuse and Mental Health Services Administration, Rockville, MD

analogues can be absorbed through the skin, inhaled, or introduced into the body via mucous membranes (e.g., mouth, nose, eyes, etc.), which makes them particularly dangerous for public safety personnel who encounter these substances during the course of their daily operations. Fentanyl and fentanyl analogues represent the deadly convergence of the synthetic drug threat and the current national opioid epidemic.

On a broader scale, synthetic designer drugs, also known as New Psychoactive Substances (NPS) refer to man-made substances designed to mimic the effects of known licit and illicit controlled substances; while fentanyl and fentanyl analogues are scheduled, emerging NPS are oftentimes unscheduled and unregulated.[4] There are a variety of synthetic designer drugs, which are categorized based on the types of controlled substances they are intended to mimic: opioids (including fentanyl and fentanyl analogues), cannabinoids, cathinones, and hallucinogens known as phenethylamines. Other than synthetic opioids, the two most commonly used categories of synthetic designer drugs in the United States are synthetic cannabinoids and synthetic cathinones. NPS, including synthetic opioids, continue to pose a nationwide threat to the United States and tragically, overdoses and deaths attributable to those substances continue to occur.

SYNTHETIC DESIGNER DRUGS OVERVIEW

Fentanyl, Fentanyl Analogues, and Synthetic Opioids

Fentanyl is a Schedule II controlled substance produced in the United States and used widely in medicine; its classification in Schedule II indicates its widely accepted medical use but high potential for abuse. It is an extremely potent analgesic indicated for use as an anesthetic or for use as a serious pain control option in opioid tolerant patients.[5]

In 2016, almost 3.4 million Americans age 12 or older reported misusing prescription pain relievers within the past month.[6] This makes prescription opioid misuse more common than use of any category of illicit drug in the United States except for marijuana. The illicit market for prescription drugs is of considerable size. Counterfeit versions of such drugs are easier and cheaper to produce, which significantly increases the risk that fentanyl or fentanyl analogue-laced counterfeit pills will be produced to meet the demand. Widespread use of these substances will cause more overdoses across the nation.

According to the DEA National Forensic Laboratory Information System (NFLIS), from January 2013 through December 2016, federal, state, and local forensic laboratories identified

[4] On February 6, 2018, DEA published a final order in the Federal Register scheduling all fentanyl-related substances (i.e., fentanyl analogues) into Schedule I of the Controlled Substances Act on an emergency basis.The final order was made effective on the date of publication.

[5] Patients considered tolerant are those taking, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid.

[6] Substance Abuse and Mental Health Services Administration. (2017). Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health (HHS Publication No. SMA 17-5044, NSDUH Series H-52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/.

fentanyl in over 58,000 toxicology reports.[7] During 2016, there were 36,061 fentanyl reports compared to 1,042 reports in 2013,[8] an exponential increase over four years. The consequences of fentanyl misuse are often fatal and occur amongst a diverse user base. According to a November 2017 CDC Morbidity and Mortality Weekly Report on data from 10 states, fentanyl and fentanyl analogues were detected in 56.3 percent (5,152) of all drug overdose deaths in a 6-month period from July – December of 2016.[9]

Illicit fentanyl, fentanyl analogues, and their immediate precursors are often produced in China. From China, these substances are shipped through private couriers or mail carriers directly to the United States or alternatively shipped to transnational criminal organizations (TCOs) in Mexico, Canada, and the Caribbean using mail carriers or parcel delivery services. Once there, fentanyl or its analogues are prepared to be mixed into the heroin and cocaine supply domestically, or pressed into a pill form, and then moved to the illicit U.S. market where demand for prescription opioids and heroin remains at epidemic levels. In some cases, traffickers have industrial pill presses shipped into the United States directly from China and operate illegal fentanyl pill press mills domestically. Mexican TCOs have seized upon this business opportunity because of the profit potential, and have invested in growing their share of this market. Because of its high potency, one kilogram of illicit fentanyl purchased in China for $3,000 - $5,000 can generate upwards of $1.5 million in revenue on the illicit market.

Synthetic Cannabinoids and Synthetic Cathinones

Synthetic cannabinoids and their byproducts (sometimes sold under brand names such as K2 or Spice) continue to be a significant threat to public health and safety. These substances have a similar mechanism of action to that of delta-9-tetrahydrocannabinol (THC), the primary psychoactive constituent in marijuana, but they are much more powerful and significantly more toxic. Similar to fentanyl and its analogues, synthetic cannabinoids are sourced from chemical manufacturers and suppliers primarily in China. Products containing synthetic cannabinoids are typically prepared for packaging in the United States and marketed over the Internet or supplied to retail distributors before being sold to the public at retail stores (e.g., convenience stores, gas stations, and liquor stores). Laws governing the legality of the substances vary widely between states and the chemical components are frequently altered, making it an ongoing challenge for DEA to schedule these substances in a timely manner to protect the public.

Synthetic cathinones, often marketed to consumers as "bath salts" or "glass cleaner," can produce pharmacological effects that are substantially similar to cathinone, methcathinone, MDMA, amphetamine, methamphetamine, and cocaine. Whereas individuals consume stimulants for desired psychoactive effects such as euphoria, empathy, elevated mood, and

[7] U.S. Department of Justice, Drug Enforcement Administration, National Forensic Laboratory Information System, actual data queried on October 13, 2017.
[8] U.S. Department of Justice, Drug Enforcement Administration, National Forensic Laboratory Information System, actual data queried on October 13, 2017.
[9] O'Donnell JK, Halpin J, Mattson CL, Goldberg BA, Gladden RM. Deaths Involving Fentanyl, Fentanyl Analogs, and U-47700 – 10 States, July-December 2016. MMWR Morb Mortal Wkly Rep 2017; 66:1197-1202. DOI: http://dx.doi.org/10.15585/mmwr.mm6643e1

improved mental function,[10,11] patients who present to first responders and emergency departments with sympathetic stimulation have profoundly altered mental status. Altered mental status presents as severe panic attacks, agitation, paranoia, hallucinations, and violent behavior (e.g., self-mutilation, suicide attempts, and homicidal activity).[12] These substances are often labeled "not intended for human consumption" in an attempt to skirt the Government's utilization of the federal Controlled Substance Analogue Enforcement Act (Analogue Act). While the Department of Justice (DOJ) has had successful prosecutions under the Analogue Act, hundreds, if not thousands of these substances are sold to unsuspecting consumers in the meantime. Synthetic cathinones are widely available and have been encountered as a replacement for MDMA, a Schedule I controlled substance that is often referred to as "Molly."

Synthetic cathinones are usually snorted or swallowed in their powder or crystal forms. Many drugs in this class have been placed in Schedule I, either through legislative action or through DEA-initiated administrative action, to temporarily control the drug when the Administrator concludes that such action is necessary to avoid an imminent hazard to public safety. Unfortunately, when DEA initiates temporary control of a synthetic designer drug, those who produce and traffic the drug frequently alter the chemical composition of those drugs. These new substances, like the original substance, have serious adverse health effects including death and thus pose a severe public health threat.

Synthetic cannabinoids and synthetic cathinones are a significant area of concern for DEA. According to NFLIS, from January 2013 through December 2015, the 25 most frequently identified synthetic cannabinoids were identified in a total of 95,143 state and local forensic laboratory reports submitted to NFLIS. During the same period, state and local forensic laboratories reported finding the 20 most frequently identified synthetic cathinones a total of 51,824 times through the data submitted to NFLIS.[13] In 2016, synthetic cannabinoids were identified in 25,250 such reports.

CURRENT CHALLENGES WITH SYNTHETIC ANALOGUES

Traffickers Adapting to the Law

Even though fentanyl and fentanyl analogues, as well as NPS compounds have been controlled in Schedule I or Schedule II of the Controlled Substances Act (CSA), entrepreneurs procure new synthetic compounds with relative ease.[14] Over the past several years, DEA has

---

[10] L Karila and M Reynaud. GHB and synthetic cathinones: clinical effects and potential consequences. *Drug Testing and Analysis* 2010, 3: 552-559; JP Kelly. Cathinone Derivatives: A Review of their Chemistry, Pharmacology, and Toxicology. *Drug Testing Analysis* 2011, 3:439-453; JB Zawilska and J Wojcieszak. Designer cathinones – An emerging class of novel recreational drugs. *Forensic Science International* 2013, 231:42-53; JB Zawilska. Mephedrone and other cathinones. *Current Opinion in Psychiatry* 2014, 27: 256-262; CL German, AE Fleckenstein, and GR Hanson. Bath salts and synthetic cathinones: An emerging designer drug phenomenon. *Life Sciences* 2014, 97:2-8; PS Johnson, MW Johnson. Investigation of "bath salts" use patterns within an online sample of users in the United States. *Journal of Psychoactive Drugs* 2014, 46:369-378.

[11] M F Measham, K Moore, R Newcombe and Z Welch. Tweaking, bombing, dabbing and stockpiling: the emergence of mephedrone and the perversity of prohibition. *Drugs and Alcohol Today* 2010, 10:14-21; Psychonaut WebMapping Research Group. Ivory Wave report, Institute of Psychiatry 2010, King's College London: London, UK. [Paolo Deluca et al.]; EMCDDA. European Monitoring Centre for Drugs and Drug Addiction. Report of the risk assessment of mephedrone in the framework of the Council Decision on new psychoactive substances. Luxembourg: Publications Office of the European Union, 2011, doi: 10.2810/40800.

[12] EA Ross, M Watson and B Goldberber. "Bath salts" intoxication. *New England Journal of Medicine* 2011, 967-968.

[13] U.S. Drug Enforcement Administration, Diversion Control Division. (2016). *Synthetic Cannabinoids and Synthetic Cathinones Reported in NFLIS, 2013–2015*. Springfield, VA: U.S. Drug Enforcement Administration, accessed on March 8, 2017 at https://www.nflis.deadiversion.usdoj.gov/

[14] On February 6, 2018, DEA published a final order in the Federal Register scheduling all fentanyl-related substances (i.e., fentanyl analogues) in Schedule I on an emergency basis.The final order was made effective on the date of publication.

identified numerous fentanyl class substances and hundreds of designer drugs from at least eight different drug classes, the vast majority of which are manufactured in China.

Regarding NPS more broadly, clandestine chemists can easily continue developing/synthesizing new synthetic opioid, cannabinoid, and cathinone products that do not appear on any schedule of controlled substances. Data from the patent and scientific literature for structures with psychoactive effects have provided clandestine laboratory operators with a blueprint to produce hundreds of NPS for the illicit market. When DEA has taken an action to temporarily schedule a substance, traffickers begin selling new versions of their products made from new, noncontrolled substances. In addition, manufacturers provide traffickers with spurious chemical analyses that purport to document that the new product does not contain a controlled substance. Manufacturers and distributors will continue to stay one step ahead of any state or federal drug-specific banning or control action by introducing and repackaging new synthetic products that are not listed as such in any of the controlled substance schedules.

Importation vs. Domestic Production and Use of the Internet

Fentanyl, fentanyl analogues, synthetic cannabinoids, and synthetic cathinones are relatively inexpensive, available via the Internet and are often manufactured in China where they may be shipped (via U.S. mail or express consignment couriers) to the United States or alternatively shipped directly to transnational criminal organizations in Mexico, Canada, and the Caribbean. Once in the Western Hemisphere, fentanyl and fentanyl analogues in particular are combined with heroin and pressed into counterfeit pills made to look like controlled prescription drugs containing oxycodone or hydrocodone and sold online from anonymous darknet markets and even overtly operated websites. Similarly, bulk powders containing synthetic cannabinoids produced in China are imported into the United States where they are sprayed or otherwise applied onto plant matter, packaged into individual saleable units, and distributed for sale at gas stations and convenience stores, or sold directly to individuals via the Internet. The combination of the questionable legal status of these substances that are not specifically named in the CSA itself or by DEA through scheduling actions, the enormous volume of international parcel traffic by mail and express consignment couriers, and technological and logistical challenges of detection and inspection, make it extremely difficult for the U.S. Customs and Border Protection (CBP) to effectively address the threat at ports of entry and pave the way for non-cartel-affiliated individuals to undertake fentanyl trafficking. DEA is working with CBP to increase coordination on seized parcels.

Use of Freight Forwarders

Traffickers often use freight forwarders to ship fentanyl, fentanyl analogues, and other NPS from China. Several DEA investigations have revealed that the original supplier will provide the package to a freight forwarding company or individual, who transfers it to another freight forwarder, who then takes custody and presents the package to customs for export. The combination of a chain of freight forwarders and multiple transfers of custody makes it difficult for law enforcement to track these packages. Often, the package will intentionally have missing, incomplete, and/or inaccurate information.

Prosecutions Pursuant to the Analogue Act

A compound, including a fentanyl analogue, may be a "controlled substance analogue" pursuant to the CSA if it is found to have a substantially similar chemical structure to and substantially similar or greater depressant, stimulant, or hallucinogenic effect on the central nervous system as a Schedule I or II controlled substance, or is represented to have such an effect. Even if a particular substance is widely regarded as a "controlled substance analogue" under the CSA, each criminal prosecution must establish that fact anew. The primary challenge to preventing the distribution and abuse of a controlled substance analogue, as opposed to a controlled substance *per se*, is that the latter is specifically identified (by statute or regulation) as a controlled substance to which clear statutory controls automatically attach, while the former is not specifically identified (by statute or regulation) and is treated as a Schedule I controlled substance in a given case only once proven to meet the definition of a controlled substance analogue. In addition to proving a material is a controlled substance analogue, prosecutors must also prove that the substance was intended for human consumption. Accordingly, each prosecution requires expert testimony to obtain a conviction, even if the same substance was determined by a jury to meet the criteria of the analogue definition in a prior case. This holds true even if a prior conviction was in the same District Court or even in front of the same judge. This process is workable, but resource-intensive for DEA, federal prosecutors serving in United States Attorney's Offices, the defense bar, and the court system.

The above considerations, along with the increasing volume and variety of designer drugs available today and the sophisticated methods and routes of distribution, render the Analogue Act a cumbersome and resource-intensive tool to prevent manufacturing, trafficking, and abuse of designer drugs. Furthermore, clandestine manufacturers are continually introducing unique substances that have abuse liability but do not meet the legal definition of an analogue. That said, agents, chemists, pharmacologists, and prosecutors have worked together tirelessly to make the Analogue Act work, with many successful prosecutions to show for it. The Synthetic Drug Abuse Prevention Act of 2012 (SDAPA) approach to control specific, known, synthetic substances in some instances by a description of chemical characteristics, was a swift and effective contribution to the overall effort to combat the designer drug threat.[15] DEA will continue to identify ways to better combat the designer drug threat.

The Drug Control Process under the CSA is Reactive and Requires Evidence of Harm

The CSA provides the Attorney General (delegated to the DEA Administrator) with a mechanism to bring new drugs of abuse under CSA control and subject them to a regulatory scheme to protect the public. Through an interagency process, determinations about placement in the CSA are dictated by the following eight enumerated scientific factors:[16] the state of current scientific knowledge about the substance; its pharmacological effect; its risk to the public health; its psychic or psychological dependence liability; whether the substance is an immediate precursor of a controlled substance; its actual or relative potential for abuse; its history or current pattern of abuse and its scope; and the scope, duration, and significance of use. In this process, the Secretary of Health and Human Services (HHS) is responsible for any

[15] P.L. 112-144 – Food and Drug Administration Safety and Innovation Act, Subtitle D, Section 1151, titled "Synthetic Drug Abuse and Prevention Act of 2012.

[16] The eight factors are enumerated in 21 U.S.C. § 811(c).

scientific and medical considerations about a substance and the DEA Administrator considers a recommendation made by the HHS Secretary along with other relevant facts to determine whether there is substantial evidence to warrant control. These scheduling evaluations by both HHS and DEA require extensive collection and evaluation of scientific, medical, law enforcement, and other data. The acquisition of this data is often an arduous and time-consuming process which often relies heavily on actual evidence of harm to the public.

When the DEA Administrator concludes that control of a substance is necessary to avoid an "imminent hazard to public safety," the DEA Administrator may initiate temporary control of that substance for a period of two years, subject to possible extension for up to one year,[17] during which time the interagency conducts the above mentioned scientific review for permanent placement under the CSA.[18]

DEA believes a coordinated response by public health and law enforcement and other stakeholders remains the most effective response to this problem. Further, DEA will continue to share information and engage stakeholders to decrease the demand for NPS.

DEA RESPONSE TO THE THREAT OF FENTANYL, FENTANYL ANALOGUES AND OTHER SYNTHETIC DRUGS

Scheduling by Administrative Rulemaking: Temporary Control

DEA continues to utilize its regulatory authority to place many synthetic substances into the CSA pursuant to the aforementioned temporary scheduling authority. Once a substance is temporarily placed in Schedule I, DEA moves towards permanent control by requesting a scientific and medical evaluation and scheduling recommendation from HHS and gathering and analyzing additional scientific data and other information collected from all sources, including poison control centers, hospitals, medical examiners, treatment professionals, and law enforcement agencies, in order to consider the additional factors warranting its permanent control. Since March 2011, DEA has utilized this authority on nineteen occasions to place 56 synthetic designer drugs temporarily (emergency control) into Schedule I, including 17 fentanyl analogues. In comparison, over the first 25 years (1985-2010) after Congress created this authority, DEA utilized it a total of 13 times to control 25 substances. In addition, on February 6, 2018, DEA temporarily placed Schedule I controls on "fentanyl related substances" which includes any substance structurally related to fentanyl based on specific chemical changes not otherwise controlled in any other schedule.[19]

Significant Enforcement Efforts

The DEA Special Operations Division (SOD) Heroin/Fentanyl Task Force (HFTF) Working Group consists of several agencies using a joint "whole of government" approach to counter the fentanyl/opioid epidemic in the United States. The HFTF consists of personnel from

[17] The procedure for the temporary control of a substance is enumerated in 21 U.S.C. § 811(h).
[18] Temporary control of a substance may be extended for a period of 1 year if DEA receives the Secretary's scientific and medical evaluation and scheduling recommendation within the 2-year temporary control period.
[19] 83 FR 5188 (Feb. 6, 2018).

DEA, U.S. Immigration and Custom Enforcement (ICE) Homeland Security Investigations (HSI) and CBP; supplemented by the Federal Bureau of Investigation (FBI), and the U.S. Postal Inspection Service. HFTF uses every resource available, including support from the multi-agency Organized Crime Drug Enforcement Task Forces (OCDETF) and the OCDETF Fusion Center (OFC), the Department of Justice's Criminal Division, the Department of Defense (DOD), Intelligence Community (IC), and other government entities, and provides field offices (all agencies) with valuable support in their respective investigations.

The HFTF mission aims to:

- Identify, target, and dismantle command and control networks of national and international fentanyl and NPS trafficking organizations.
- Provide case coordination and de-confliction on all domestic and foreign investigations to ensure that multi-jurisdictional, multi-national, and multi-agency investigations and prosecutions have the greatest impact on targeted organizations.
- Provide direct and dynamic operational and investigative support for domestic and foreign field offices for all agencies.
- Identify new foreign and domestic trafficking, manufacturing, importation, production, and financial trends utilized by criminal enterprises.
- Analyze raw intelligence and documented evidence from multiple resources to develop actionable leads on viable target(s) involved in possible illicit pill production and/or distribution networks.
- Educate overall awareness, handling, trafficking trends, investigative techniques, and safety to domestic and foreign field offices for all law enforcement, DOD, IC, and governmental agencies.
- Facilitate, coordinate, and educate judicial districts during prosecutions of fentanyl and other NPS related cases.

Close interagency cooperation via the HFTF has led to several large enforcement actions, including two separate OCDETF investigations centered in North Dakota and Southern Mississippi that resulted in the first-ever indictments in September 2017 of two Chinese nationals responsible for the manufacturing, importation, and distribution of illicit fentanyl and other NPS in the United States. On October 17, 2017, the Deputy Attorney General and the DEA Acting Administrator announced the indictments of the Chinese nationals, who were the first manufacturers and distributors of fentanyl and other opiate substances to be designated as Consolidated Priority Organization Targets (CPOTs). CPOT designations are of those who have "command and control" elements of the most prolific international drug trafficking and money laundering organizations operating in the world.

In addition, SOD's HFTF played an integral role in the July 2017 seizing of assets and shutting down of the largest criminal marketplace on the Internet, AlphaBay. As outlined by the Attorney General and the DEA Acting Principal Deputy Administrator in July, AlphaBay operated for over two years on the dark web and was used to sell deadly illegal drugs, stolen and fraudulent identification documents and access devices, counterfeit goods, malware and other computer hacking tools, firearms, and toxic chemicals throughout the world. The international operation to seize AlphaBay's infrastructure was led by the United States and involved cooperation between law enforcement authorities in Thailand, the Netherlands, Lithuania,

Canada, the United Kingdom, and France, as well as the European law enforcement agency, Europol. Multiple interagency OCDETF investigations into AlphaBay revealed that numerous vendors, including many in China, sold illicit fentanyl and heroin on the site, and that there had been a substantial number of overdose deaths across the country attributed to such purchases.

China: Government Action and Cooperation

Recognizing that synthetic drugs are manufactured in China, Attorney General Sessions and Deputy Attorney General Rosenstein both requested that China take action during meetings with then-State Councilor Guo Shengkun of the Chinese Ministry of Public Security. Deputy Attorney General Rosenstein met with Guo in Beijing, China on September 25, 2017, followed by a meeting with the Attorney General in Washington, D.C. on October 3 and October 4, 2017.

The Attorney General and the Deputy Attorney General's efforts built on long-standing working-level engagements with the Chinese on a number of levels. For example, DEA has maintained a liaison presence in the People's Republic of China, with an office in Beijing, for the last three decades. DEA is currently working to staff a second office to be located in Guangzhou. DEA's office in Beijing has direct engagement with drug control officials from China's Ministry of Public Security, Narcotics Control Bureau (NCB). DEA's well-established relationship with Chinese drug control authorities is the primary bilateral conduit for addressing the threat resulting from the shipment of illicit fentanyls, their precursors, and other synthetic drugs from China to the United States and elsewhere.

At a higher policy level, the U.S. Government has also engaged China through an interagency working forum that operates under the U.S.-China Joint Liaison Group (JLG). The JLG is chaired by DOJ, the Department of State's Bureau of International Narcotics and Law Enforcement Affairs, and the Department of Homeland Security. DEA and the NCB participate in the Counter Narcotics Working Group (CNWG) and the BDIWG within the JLG framework that are chaired, respectively, by DOJ and DEA on the U.S. side, and the Ministry of Public Security on the Chinese side. DEA and the NCB share drug-related intelligence and trends through the Bilateral Drug Intelligence Working Group (BDIWG), led by DEA's Intelligence Division. This annual engagement was established through a memorandum of agreement between DEA and the NCB in 2002.

Engagement in the efforts mentioned above has resulted in positive actions by the Government of China taken over the last year. These actions are a step in the right direction, but much more needs to be done. Since 2014, the DOJ, DEA, and Chinese officials have met regularly to discuss bilateral efforts to counter the threat to the United States from synthetic drugs, including illicit fentanyl and its analogues. For the past four years, representatives from China's National Narcotics Laboratory have met with DEA experts to exchange information on emerging substances, trafficking trends, and drug sampling standards. This dialogue fosters information exchange about new substances of abuse in the United States to be considered for control in China. A larger and more formal bilateral exchange between legal and (especially) scientific experts took place in Beijing in May 2017. Plans are underway for DEA to welcome its scientific counterparts to Washington in early spring 2018.

A key moment in enhanced cooperation on synthetic drugs came in October 2015, when, following similar discussions, China implemented domestic control on 116 NPS, including a number of fentanyl analogues, and streamlined its procedures to control additional substances. In total, China has scheduled 138 different NPS.

On March 1, 2017, China's National Narcotics Control Commission announced scheduling controls on four fentanyl-class substances: carfentanil; furanyl fentanyl; valeryl fentanyl; and acryl fentanyl. This announcement followed ongoing collaboration between DOJ and the Government of China, and reaffirms an expanding collaborative commitment to countering illicit fentanyl. On July 1, 2017, China announced implementation of controls on U-47700. While not a fentanyl class substance, U-47700 is a powerful synthetic opioid that has been trafficked and abused in the United States and a substance that DEA placed in Schedule I on a temporary basis following significant evidence of abuse.

After requests by Administration officials, including the Attorney General and Deputy Attorney General, and in accordance with its obligations under the 1988 U.N. Convention, on December 28, 2017, China's Ministry of Public Security announced scheduling controls on two fentanyl precursor chemicals, NPP and 4ANPP. The scheduling controls took effect on February 1, 2018. Implementation of Chinese controls on all of these substances, and the effect that prior control efforts have had on the availability of these substances in the United States, is encouraging and affirms the need for the continued collaborative commitment between DEA and the NCB.

In 2018, DEA will continue to engage the Chinese on the control of emerging fentanyl analogues and other NPS. We are further encouraged that the Chinese are willing to engage in discussions and technical exchanges with DEA regarding scheduling fentanyl as a class. Officials from the NCB indicated that their scheduling process is long and complicated, that China has always scheduled one drug at a time, pursuant to its law, and that any change in that process would be groundbreaking for China. In spite of the complexity of this process, and the fact that domestic abuse of fentanyl and related substances has not been a problem in China, they have continued to show an understanding of the problem and a willingness to listen and at least discuss class scheduling.

Recent Major Synthetic Cannabinoid and Cathinone Enforcement Operations

Over the past six years, DEA has conducted two primary, national efforts (Operation Log Jam and Project Synergy) related to countering the threat from synthetic cannabinoid and cathinone operations, in addition to all other synthetic investigations executed by DEA field offices.

DEA's Operation Log Jam launched in 2011 and culminated in a nationwide takedown on July 25, 2012. This DEA SOD Operation resulted in multiple OCDETF Operations throughout the United States, including 25 federal districts. This operation was coordinated by DEA in cooperation with HSI, FBI, CBP, and the Internal Revenue Service (IRS). The goals of this operation included the targeting of manufacturers, wholesale distributors, and retail distributors of designer drug products, the development of information on foreign-based sources

of supply, raising public awareness of the dangers associated with the use of these drugs, and the development of leads for a Phase II initiative (Project Synergy).

Operation Log Jam resulted in 100 arrests, the execution of 300 search warrants and 80 consent searches, and the identification of 38 manufacturing sites. Law enforcement seized 196 kilograms of raw synthetic cathinones, 722 kilograms of raw synthetic cannabinoids, 167,187 packets of synthetic cathinones ready for distribution, 4,852,099 packets of synthetic cannabinoids ready for distribution, 4,766 kilograms of plant material treated with synthetic cannabinoids ready to be packaged, 21,933 kilograms of untreated plant material, over $45,000,000 in U.S. currency and bank accounts, 88 vehicles, 77 firearms, additional assets valued at $5,688,500, and 1,096 gallons of acetone.

Project Synergy, the second phase of a national cooperative effort in combating synthetic designer drug distribution, has resulted in multiple OCDETF operations in at least 13 federal districts. Project Synergy has resulted in nationwide take downs in 2013, 2014, and 2015 by DEA, HSI, FBI, CBP, IRS, and domestic law enforcement departments in 45 states, and international partners in Australia, New Zealand, Canada, and Barbados. Over 400 individuals were arrested and authorities seized assets valued at nearly $75 million. In addition to curbing the flow of synthetic drugs into the country, Project Synergy III continued to reveal the flow of millions of dollars in U.S. synthetic drug proceeds to countries in the Middle East.

OTHER AREAS OF DEA FOCUS TO COMBAT THE OPIOID EPIDEMIC

Medication Assisted Treatment (MAT)

DEA plays an important part in the U.S. government's drug control strategy, which includes enforcement, treatment, and prevention. It is important to consider medication assisted treatment (MAT) as a part of any successful strategy to combat the opioid epidemic. It is imperative to determine how to best balance access to MAT against the potential for the diversion of the FDA-approved drugs to be used in the treatment of substance abuse disorder, such as buprenorphine.

As you are aware, the Comprehensive Addiction and Recovery Act (CARA) (P.L. 114-198) was enacted to address the opioid epidemic. One of CARA's important provisions expands access to MAT by authorizing certain mid-level practitioners (i.e., nurse practitioners and physicians assistants) to dispense or prescribe schedule III, IV, or V controlled substances that are FDA-approved for the treatment of opioid use disorder. This prescribing authority was previously limited to physicians only. In February 2017, the Substance Abuse and Mental Health Services Adminstration (SAMSHA) began providing waivers to qualifying practicioners and DEA published regulations in January 2018 to implement this provision.

Telemedicine and the Ryan Haight Act

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 was signed into law in October 2008 and authorized DEA-registered practitioners to prescribe controlled substances listed in Schedules II - V using telemedicine under seven distinct circumstances when

the prescriber is otherwise unable to fulfill the in-person medical evaluation required under the CSA.

DEA's implementing regulations (published in April 2009) lay out the following requirements that must be met in order for a practitioner to prescribe controlled substances using telemedicine: 1) the prescribing practitioner who is at a location remote from the patient must be acting in the usual course of his/her professional practice; 2) the practitioner's activity must be done in accordance with applicable federal and State laws; 3) the practitioner must be communicating with the patient (or health care professional who is treating the patient) using multimedia communications equipment referred to in section 1834(m) of the Social Security Act; and; 4) the patient must be physically located at a DEA-registered hospital or clinic or must be in the physical presence of a DEA-registered practitioner.

There is confusion over whether a doctor authorized to treat opioid use disorder utilizing MAT can perform these services utilizing telemedicine. Some have sought the assistance of the Secretary of the Department of Health and Human Services (HHS) to use his authority to authorize telemedicine for MAT pursuant to a public health emergency declaration. We are working closely with HHS, the Department of Veterans Affairs and other federal partners to identify opportunities to improve access to MAT as DEA continues the drafting process to implement regulations regarding special registration for telemedicine.

Proper Medication Disposal

On September 9, 2014, DEA issued a final rule, titled "Disposal of Controlled Substances." These regulations implement the Secure and Responsible Drug Disposal Act of 2010 and expand upon the previous methods of disposal by including disposal at drop-boxes in pharmacies and law enforcement agencies, mail back programs, and drug deactivation systems if they render the product irretrievable. Through these regulations, DEA continues to focus its national attention on the misuse of prescription drugs and related substance use disorders (SUDs), and promotes awareness that one source of these drugs is often the home medicine cabinet, as 53% of persons aged 12 or older who misused pain relievers in the past year bought or took the pain relievers from a friend or relative, or that friend or relative gave it to the user for free.[20] These regulations provide a safe and legal method for the public to dispose of unused or expired CPDs. As of February 12, 2018, 3,450 DEA registrants have become "authorized collectors."

Since 2010, DEA has held its National Drug "Take Back" Initiative (NTBI) to provide a convenient and safe option to dispose of unused, expired, and/or unwanted prescription drugs. DEA's most recent NTBI was held on October 28, 2017. As a result of all fourteen National Take Back Days, DEA, in conjunction with its state, local, and tribal law enforcement partners, has removed over 9 million pounds (4,508 tons) of medications from circulation. DEA is conducting its fifteenth National Drug Take Back Day on April 28, 2018.

[20] Substance Abuse and Mental Health Services Administration. (2017). Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health (HHS Publication No. SMA 17-5044, NSDUH Series H-52). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/.

Tableting and Encapsulating Machines

In December 2016, DEA concluded several years of regulatory work to implement a 2014 Executive Order (E.O. 13659) which aimed to streamline federal import and export processes by utilizing a government-wide system called the International Trade Data System (ITDS). As part of that effort, DEA amended its regulations pertaining to domestic transactions and import/export transactions involving tableting and encapsulating machines (21 C.F.R. 1310.05(a)(4)). The rule became effective on January 30, 2017 and regulated persons were required to comply no later than July 30, 2017. The information below outlines the CSA's regulatory requirements pertaining to the trade of pill presses.

Domestic Transactions: Previously in 21 C.F.R 1310.05(a)(4) and (b), regulated persons who engaged in a domestic regulated transaction in a tableting or encapsulating machine were required, whenever possible, to make an oral report to the DEA Divisional Office in advance of the transaction, followed by a written report. The new rule makes the oral reporting mandatory and mandates the electronic filing of a written report (DEA Form 452). In addition, the amended regulations require regulated persons to orally report domestic regulated transactions in a tableting machine or an encapsulating machine when an order is placed rather than at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved. The written report (DEA Form 452) is required to be filed within 15 calendar days after the order has been shipped by the seller.

Import/Export Transactions: An electronic report filing (DEA Form 452) is required to be submitted to DEA 15 calendar days before the anticipated date of arrival at the port of entry or port of export. In addition, the importer or exporter may not initiate an import or export transaction involving a tableting machine or encapsulating machine until the regulated person has been issued a transaction identification number from DEA. The importer or exporter may proceed with the import or export of the machine(s) as soon as the transaction identification number has been issued. In addition, these new regulations require electronic filing of return information, specifying the particulars of the transaction, for tableting and encapsulating machines imported or exported within 30 calendar days after actual receipt of a tableting or encapsulating machine, or within 10 calendar days after receipt of a written request by DEA to the importer.

CONCLUSION

Synthetic opioids, cannabinoids, cathinones, and phenethylamines will continue to pose a nationwide threat. Synthetic drug producers modify and experiment with chemical formulas in search of new psychoactive substances. Once a new drug is formulated, the Internet and social media are used to market its arrival on the scene, allowing for its fast adoption and use. Due to the changing nature of the chemical formulas for synthetic designer drugs, distributors are able to reap significant profits before legislative and regulatory controls of these specific psychoactive substances are implemented. Sadly, it is likely the United States will continue to see overdoses and deaths as a result of synthetic drug use.

Additionally, the United States continues to be affected by a national opioid epidemic, which has been spurred, in part, by the rise of nonmedical prescription opioid use and the large

number of people with active SUDs who are not currently in treatment. It is likely that this demand will continue to be met in part by counterfeit prescription opioids which are being laced with fentanyl, fentanyl analogues, and other synthetic opioids (e.g., U-47700), and that Mexican-based TCOs will push to expand their profits. DEA will continue to address this threat by pursuing the Mexican-based TCOs which have brought tremendous harm to our communities. Additionally, DEA's Diversion Control Division will use all criminal and regulatory tools possible to identify, target, disrupt, and dismantle individuals and organizations responsible for the illicit distribution of pharmaceutical controlled substances in violation of the CSA. Finally, DEA is committed to looking at all available options to combat the opioid epidemic and will continue to work with the Committee to provide legislative assistance on bills aiming to attack this public health emergency.

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 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 synthetic 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, 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 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. Yes, 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.

Mr. WALDEN. 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." 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.

Mr. WALDEN. 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 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——

Mr. WALDEN. 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 tremendously. 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.

Mr. WALDEN. 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, 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, purchasing this stuff thinking it is a legal alternative to the actual substance.

Mr. WALDEN. Exactly. And "because it is natural," that was the argument her son made.

Ms. GIBSON. Absolutely.

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——

Mr. WALDEN. 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.

Mr. WALDEN. 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.

Mr. WALDEN. 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 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. Yes.

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 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—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 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, they can track it. They can find if it is delayed even 1 day, they are not going to be there to pick it up, 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, 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 are you interacting with where—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 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. 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 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?

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, 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. 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 controlled 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 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 participants 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 FDA's 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 controlled 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 controlled 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. Yes, 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 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, 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 combating the epidemic. And I would think DEA's 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, 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.

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. Being from Ohio, we are, unfortunately, right in the middle of this. We have seen some 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,

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, there are 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, 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 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. OK. This is the heroin-fentanyl task force that you mentioned in your testimony. I 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. OK. 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 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 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 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 informa-

tion, 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. I have 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. The little smiley face, frowny face on the patient's chart. 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 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 "fifth vital sign," which was pain.

That is not a defense of practitioners, but it also is the truth. And I think 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, we have some, not only in areas where we have the international shipping, that is a huge issue, but my parents stayed down in the 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, 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 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. Yes.

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. Yes, just do your best to tell everybody what the rules are. 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 scheduled for a day when we thought we would be having votes. But having said that, 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, 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. Ms. Gibson, when I hear you talking about the struggles with telemedicine and how are we listing these substances and so on, it is just really clear there are 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 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 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 OK 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——

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, yes. Choice, yes.

Ms. GIBSON. OK. Sorry, I am a simple girl from Pennsylvania. 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, 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. OK. 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. Luján for 5 minutes for questions, please.

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

Ms. GIBSON. Sir, way too long.

Mr. LUJÁN. Do you know when it started?

Ms. GIBSON. 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. LUJÁN. 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. LUJÁN. 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——

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

Mr. LUJÁN. 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. LUJÁN. 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 appears at the conclusion of the hearing.]

Mr. LUJÁN. Thank you, Mr. Chairman.

Mr. BURGESS. The gentleman's time is expired. The gentleman yields back. The chair recognizes 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 the 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, dentists, 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. OK. Well, welcome.

Ms. GIBSON. Thank you.

Mrs. BROOKS [continuing]. 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 [continuing]. Or a valid license——

Ms. GIBSON. Yes.

Mrs. BROOKS [continuing]. 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 they're 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 homed 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, 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. OK. 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. OK. And with that, Mr. Chairman, I will yield back.

Mr. BURGESS. The Chair thanks the gentleman. The gentleman yields back. The Chair recognizes 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, 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 THC and cannabidiol. 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, yes, they say they are doing research at the DEA, but we have a hard time getting approval.

And I note with some interest that in our next panel, we have a witness, Dr.Beardsley, who in 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 put into a Schedule I or Schedule A, as the Katko bill would have it do, that we not just immediately take 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 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, 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-a-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 through telemedicine 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 [continuing]. 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. 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. OK. 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 prac-

ticing 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 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, 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 simply a 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.

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 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. OK. Yes or no.

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 for being here today. 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 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. OK. 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. OK. 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 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 on.

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 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 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 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 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:]

Testimony

Chief Frank Fowler

Committee on Energy and Commerce

2/28/2018

Thank you Chairman Walden, Ranking Member Pallone, and distinguished Members of the Committee on Energy and Commerce. I am here today to paint you a picture of community that has been ravaged by synthetic drug abuse. Beginning in 2013, the Syracuse Police Department (SPD) responded to an increase in the use and subsequent overdoses of synthetic marijuana (spike). SPD implemented various means of tracking the problem in addition to the police enforcement efforts. In 2015, Syracuse saw the largest number of overdoses from use of synthetic marijuana; the largest number of overall calls for service, calls for service 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 street, new chemical formulations of "spike" were being put in

circulation. In addition, all the SPD could do to someone selling this dangerous drug was to give them an appearance ticket for local law violation.

This is just one example of the dangerous synthetic compounds that are flooding our streets. Toxic, synthetic drugs are designed to mimic street drugs like marijuana, LSD, cocaine, ecstasy and other hard drugs. They can be more potent than the real thing and often times are more deadly. In addition, these drugs are not simply effecting 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, introduced by Congressman John Katko. This bill takes a big step towards eradicating these harmful substances and protecting our communities.

SITSA will give my officers the tools they need to target synthetic substances and the criminals who distribute and traffic them. Under this bill, a drug such as "spike" could be temporarily or permanently

added to a new schedule under the Controlled Substances Act in as little as 30 days after the chemical compound has been identified. The abuses of 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 the need for a solution. H.R. 2851 is that solution. I urge this committee to pass this bill and give us the tools we need to combat this deadly epidemic.

Thank you again for the opportunity be here, I welcome your questions.

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:]

STATEMENT
OF
PATRICK M. BEARDSLEY, PH.D.
PROFESSOR,
DEPARTMENT OF PHARMACOLOGY & TOXICOLOGY
VIRGINIA COMMONWEALTH UNIVERSITY
RICHMOND, VA

BEFORE THE
SUBCOMMITTEE ON HEALTH OF THE
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES

"

"COMBATTING THE OPIOID CRISIS:
HELPING COMMUNITIES BALANCE ENFORCEMENT AND PATIENT SAFETY"
FEBRUARY 28, 2018

Mr. Chairman and Members of the Health Subcommittee, 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 the regulatory control of drugs to insure public safety, and the necessity for researchers to have access to controlled drugs to further science. The Controlled Substances Act 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. I would also like to end my statement by identifying a few ways that would enable research with synthetic opioids, and drugs of abuse more generally, to be more efficient, far

less costly, and bring much relief from the bureaucratic burden of conducting research with them.

It is my opinion that the Attorney General has been able to effectively regulate all synthetic opioids that are known to be a current problem via the historical process identified by the Controlled Substances Act (the CSA). Effective February 6, 2018, 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. The few non-fentanyl synthetic opioids that have been identified as abused in recent years have been previously included in Schedule I. Because most, if not all currently abused synthetic opioids are currently scheduled under the CSA, it is unclear how the introduction of Schedule A will help address the *current* problems with abused synthetic opioids.

Regarding the fentanyls that have now all been included in Schedule I, it is unclear whether they will be transferred into Schedule A if SITSA is passed. Considering 13 fentanyls are explicitly identified in SITSA to be included in

Schedule A, this appears to be the likely outcome. How would public health be enhanced transferring these compounds from Schedule I conditions to Schedule A conditions?

SITSA also adds yet another level of bureaucracy to researchers who work with drugs of abuse by the addition of yet another category of drugs, Schedule A, and the associated requirements in order to study them. SITSA indicates that a separate registration for engaging in research with a Schedule A substance shall not be required for researchers who hold Schedule I registrations. Registrants with only a schedule II-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* Schedule A substance. 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. If similar delays that are now impeding research with Schedule I drugs transfer to Schedule A drugs, SITSA provides nothing to the researcher

that will hasten our understanding of synthetic opioids through science, and will likely only impede that progress.

Under SITSA, the Attorney General also has the power to place a compound in Schedule A based only upon a drug's structure, and in the absence of pharmacological information commonly provided by HHS and NIDA. This can result in misclassifications of drugs and missed opportunities for discovering medications we need for confronting the opioid crisis. Determining scheduling solely 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. Banning a compound just based upon structural similarity to an abused compound may inadvertently ban an antidote to the abused compound.

Injudicious scheduling could be particularly counter-productive in the discovery of treatments for over-dose. There have been numerous reports that overdose with some fentanyls can be refractive to the ability of naloxone to revive respiration often requiring multiple initial and subsequent naloxone treatments. Just as naloxone is a particularly effective antagonist to morphine's

effects, perhaps an antagonist based upon fentanyl's structure would be more effective than naloxone. Research directed at that possibility will be chilled if potential antagonists are preemptively classified in Schedule A as *abused drugs* just based on structure. This problem is compounded by an absence of a mechanism in SITSA for removing a drug from Schedule A once it is scheduled.

Several ways 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.

Requiring only one registration per researcher would greatly facilitate the research process with Schedule I drugs. In my district, multiple DEA registrations are now required for a researcher if he conducts research in more than one laboratory if the laboratories are in different buildings. This requirement only became policy about five years ago, and before then only a single registration was required. I conduct controlled substance research in four buildings that are close to each other on my campus. I am required to have separate controlled substance registrations for each building. That means I am

required to have four Schedule I, four Schedule II-V, and four Commonwealth of Virginia controlled substance registrations. The bureaucratic burden of maintaining location-specific records for one set of registrations is challenging, for four it makes research untenable.

Allowing one registrant to supply controlled substances to an entire unit would maximize efficiency, minimize costs, and still insure public safety. For decades prior to 2013, it had been permitted that one person, the chair of my department, was allowed to dispense controlled substances to other faculty within the department. Requirements changed in 2013 that required all faculty that conducted research with controlled substances to obtain their own sets of registrations. In my department that meant over 20 faculty now had to obtain their own registrations, and for anyone who had multiple laboratories in different buildings, it required that they individually obtain multiple sets of registrations. This change involved an enormous cost of time and money, and it is elusive how public safety had been enhanced by it.

Clarifying the registration application process, and setting limits to the duration of an application's review would facilitate and encourage more research with the drugs of abuse. The process for applying for a registration can be

confusing. In my state, the Commonwealth of Virginia, an applicant is instructed that he or she needs a federal registration before applying for a state registration, but DEA instructions indicate a state registration is needed before applying for a federal registration. It's only by trial-and-error that one learns that a state registration is needed before applying for a federal registration to conduct research with Schedule II-V drugs, but a federal registration is needed before applying for a state registration to conduct research with Schedule I drugs. Once a proper federal application is submitted, it can take a year or longer to obtain an approved registration. This confusion in the application process, and the delay in obtaining an approved registration, inhibits researchers, especially younger researchers, from commencing research with the drugs of abuse and from dedicating careers to their study. If law dictated a reasonable and maximal amount of time provided the DEA for the review process, timelier drug abuse research would be conducted and more researchers would be conducting drug abuse research.

Shortening the delay between application and approval for adding a new drug to an existing Schedule I registration would eliminate the most inhibiting factor associated with conducting research with Schedule I drugs. It can take

over four months to add a new compound to a Schedule I registration. A protocol has to be written and submitted detailing the dose and number of doses to be administered and the quantity of drug needed. Drug needs are often impossible for a researcher to estimate. For instance, I conduct what is called drug self-administration research in which laboratory animals are allowed to self-dose themselves with a test substance. This procedure is the major procedure for pre-clinically assessing the abuse potential of a drug, and for evaluating medications for treating drug abuse disorders. The researcher doesn't know beforehand if the laboratory subject will self-administer the test drug or not, that is the objective of the test procedure. Consequentially, the researcher finds it impossible to estimate drug needs, proving extremely difficult to prepare the needed protocol. After the application and protocol is submitted, months can go by before being approved to use the drug. In one instance, it took over four months to get cannabidiol added to my Schedule I registration, and this drug has no abuse potential and no street value.

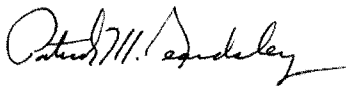
Being able to add an entire class of drugs to a Schedule I registration would greatly benefit timely research, and minimize the costs and the unnecessary bureaucratic burden associated with adding individual drugs. I

thought this was going to be the case when all fentanyls (except those previously scheduled) were added to Schedule I on February 6, 2018. However, when I went to apply to add that category to my Schedule I registration, I was instructed that if I wanted to conduct research with any fentanyl previously scheduled, or one individually scheduled in the future, I had to go through the typical process of adding it to my registration as well. Therefore, adding fentanyls as a class would only give me rights to conduct research with unscheduled fentanyls, and I could be prosecuted if I conducted research with a fentanyl that had been individually listed, even if I had been approved for a "group fentanyl" category. If a researcher could be approved to conduct research with a class of compounds, especially considering that the DEA has now shown it can schedule entire classes of compounds, this would save thousands of dollars exhausted in the bureaucratic processing of individual drug applications, and more importantly, would inspire spontaneous and creative research.

I have tried to identify a few concerns I have with SITSA as a researcher, and concluded with a few suggestions of how research with the synthetic opioids, and drugs of abuse more generally, can be facilitated. Thank you and I welcome

your questions.

Sincerely,



Patrick M. Beardsley, Ph.D.

Professor, Dept of Pharmacology & Toxicology,
Institute for Drug and Alcohol Studies,
& Center for Biomarker Research and Personalized Medicine
Virginia Commonwealth University
410 N. 12th. St.; Smith Bld. Rm. #756
Richmond, VA 23298-0613
tel: 804 8285185

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 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 1½ 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 to answer any questions or concerns that someone might have about this issue.

[The prepared statement of Dr. Mulder follows:]



NATIONAL ASSOCIATION FOR HOME CARE & HOSPICE
228 Seventh Street, SE, Washington, DC 20003 • 202/547-7424 • 202/547-3540 fax

Denise Schrader, RN MSN NEA-BC
Chairman of the Board

William A. Dombi, Esq.
President

TESTIMONY OF JOHN ADRIAN MULDER, MD, FAAHPM, HMDC

Director, Trillium Institute

Grand Rapids, MI

before the

House Committee on Energy and Commerce

Subcommittee on Health

at a hearing on

"COMBATING THE OPIOID CRISIS: HELPING COMMUNITIES BALANCE ENFORCEMENT AND PATIENT SAFETY"

February 28, 2018

Chairman Burgess, Ranking Member Green, and Members of the Committee: My name is John Adrian Mulder, MD, FAAHPM, HMDC. I am the Medical Director of the Trillium Institute in Grand Rapids, MI, which provides education on palliative care and end of life issues to medical and lay communities, and navigation services to those dealing with advanced and terminal illnesses. I also serve as Chief Medical Consultant for Hospice and Palliative Care at Faith Hospice, which is part of Holland Home, also located in Grand Rapids. Holland Home is Michigan's largest non-profit provider of senior services and employs over 1,400 people who serve more than 4,000 individuals daily.

Holland Home is an active member of the National Association for Home Care & Hospice (NAHC), the largest national organization representing home health, home care, and hospice organizations of all types; we are also active with the Michigan HomeCare & Hospice Association, which I serve as a board member. Trillium Institute is also a member of the American Academy of Hospice and Palliative Medicine, the National Hospice and Palliative Care Organization, the Center for the Advancement of Palliative Care, and the Coalition to Transform Advanced Care.

As a hospice and palliative care physician who has been caring for patients at the end of life for over 30 years, and on behalf of NAHC, I am honored to present testimony in support of H.R. 5041, The Safe Disposal of Unused Medication Act, which would authorize employees of a hospice program to handle controlled substances in the residence of a deceased hospice patient in order to assist in their disposal. We thank Representative Walberg, as well as Representatives Dingell and Hudson, for their efforts to develop this legislation. I also bring thanks from the Michigan HomeCare & Hospice Association and its strong endorsement for your legislation.

Approximately 98 percent of hospice care days are provided in a patient's place of residence. A high proportion of patients are dispensed medications to address terminal, intractable pain. Most of these drugs are opioids or otherwise classified as controlled substances, and heavily regulated by the federal government. With some frequency, medications that were prescribed for use by a hospice patient will go unused. This can happen for a number of reasons, including when a patient dies or when the hospice initiates medication changes.

In recent years, and particularly since the Drug Enforcement Administration's (DEA's) issuance of final regulations implementing the *Secure and Responsible Drug Disposal Act of 2010*, many questions have arisen regarding the appropriate role of hospice professionals relative to destruction of controlled substances in patient's homes. Under current law, unless a state or locality has enacted legislation that otherwise allows hospices to dispose of unused medications, hospice staff may not handle or destroy such medications in the home. As a result, it is frequently the case that hospice home visiting staff -- who may be the last professional to visit the home in connection with a patient's death -- must leave dangerous medications with a high risk for diversion and misuse by those for whom the drug was never intended in the home environment. These circumstances create a significant challenge for hospice personnel.

Strict adherence to existing federal law means that a hospice may only educate the patient or family in proper disposal methods and/or provide approved mail-back pouches, and supply information about community "drop boxes" or "drug take back" days. This presumes that a willing and able individual with proper authority to dispose of a patient's property is available. This is frequently not the case. Further, not all hospices have access to supplies of mail-back pouches, and public "drop boxes" and "take back" days are few and far between. Some have suggested that hospices call local authorities to come into the home to seize leftover medications. Hospice provider experience indicates that local police and sheriffs' offices are not sufficiently staffed to fulfill this function.

A moderate sized hospice caring for 2,000 patients a year will prescribe approximately 1 million pills per year, the majority of which will be controlled substances. These are typically prescribed in limited quantities – 7-14 day supply at a time – but since it is impossible to predict precisely when a hospice patient will die, there will always be medications left over when death occurs. Similarly, it is not always possible to predict how well a patient will tolerate a medication or dosage, so prescription changes frequently occur during the course of treatment. This yields potentially tens of thousands of pills in need of disposal, and at risk for misuse or diversion.

It should be noted that hospice providers are extremely sensitive to the potential for diversion of medications intended for terminally ill patients. Hospice personnel keep close track of medication supplies in the home and where diversion by family members is suspected the hospice will frequently take steps to address the issue by reducing the amount of medication dispensed, providing lock boxes, alerting the pharmacy of their concern and, in some cases, the local authorities.

Given the growing public health threat posed by widespread misuse of controlled substances, a number of states have enacted or are in the process of developing legislation that would permit hospice organizations to authorize certain home visiting staff to participate in the destruction of unused controlled medications. While these efforts are laudable, there is significant variation among these laws, which ultimately diminishes the ability of the federal government to oversee activities in this area, and does little to ensure that hospices nationwide adhere to a distinct set of standards for destruction of controlled substances in the home.

It is for this reason that we applaud the introduction of H.R. 5041. Under this legislation, Medicare-certified hospice providers may authorize licensed employees that are acting within the scope of their employment to handle controlled substances for the purpose of disposal after the patient has died. In order to be qualified to authorize such destruction, hospices would be required to:

- Have in place written policies and procedures for assisting in the disposal of the controlled substances of the deceased individual
- Have provided a copy of those written policies and procedures to the patient or patient representative and family at the time that the medications are ordered
- Have discussed the policies and procedures with the patient or representative at the time that the medications are ordered and
- Have documented in the patient's clinical record that the written policies and procedures were provided and discussed.

We are gratified to see that the legislation gives hospice providers the option to decide whether or not to authorize employees to assist in destruction of controlled substances in the home. Some hospices are concerned that requiring their staff to assist in the destruction of unused medications could pose a personal risk to those employees or a potential liability risk to the hospice, so we believe it is vital that hospices be given the opportunity to make that choice on behalf of their organizations. We also strongly support the bill's provision that exempts hospice employees from the Drug Enforcement Administration's registration requirements that would otherwise apply. These requirements are complex and would be prohibitively expensive for most community hospices to meet.

We believe H.R. 5041 represents a common-sense, real-world approach to allowing hospice agencies to authorize their personnel to safely handle controlled substances in a patient's residence for the sole purpose of assisting in their proper disposal after a hospice patient's death. It is our belief that the legislation could be further strengthened by extending authority to destroy the medications to instances under which medications for a living patient have been changed (leaving unused medications in the home that could be diverted for misuse) and to specify the disciplines to which the authority would apply (including RNs, LPNs, social workers, physicians, nurse practitioners and physician assistants) so that

there is no confusion over which personnel would be permitted to destroy the medications. We at NAHC, along with our associates at the National Hospice and Palliative Care Organization (NHPCO), have worked collaboratively with the sponsors of H.R. 5041 and we look forward to continuing discussions with you on these issues going forward.

Additional Issues.

While I have the opportunity, there are other issues related to prescribing of controlled substances that have emerged in a number of states that have serious implications for the comfort and relief of terminally ill patients and the practice of hospice and palliative medicine. One relates to drug shortages, including supplies of opioids and other pain medications. Throughout the nation, hospices are hearing from their supply houses that they should prepare for widespread shortages as the result of the temporary shutdown of production in Puerto Rico (as the result of Hurricane Maria) and the DEA's reduction in production quotas. We fully appreciate that a vital step in reducing the prevalence of opioid abuse is to reduce overproduction of these medications, thereby limiting the amount that may be available for diversion. However, hospice and hospital providers must have timely and affordable access to medications that are necessary to treat their patients effectively. A hallmark of palliative care is ensuring that we do all that we can to address unnecessary and debilitating pain, and many hospices are fearful that they will be unable to do that in future months.

We would encourage the DEA and the Food and Drug Administration, and other appropriate federal agencies, to ensure that they have a process in place to closely track supply needs, anticipate potential shortages and quickly address them in a way that does not threaten continuity of care or increase the cost of effective care delivery.

Further, many states have enacted, or are developing, legislation that would place additional limitations on prescribing practices for controlled substances. While we agree that these actions are warranted to

help address the growing opioid crisis, some states are placing limitations on the circumstances under which controlled substances can be prescribed without giving consideration to the special needs of terminally ill patients. Of particular concern are provisions that require a prescriber to have a "bona fide" relationship, and more specifically how they define such a relationship. Many of these emerging laws require that a complete history and physical be conducted prior to prescribing a controlled substance, and that the patient again be evaluated before dosing changes are made, or additional medications prescribed.

While there may be clinical circumstances in non-terminal situations in which this may be appropriate, in hospice and palliative care, it is essential that patients have access to medications as quickly as possible in order to control pain and other symptoms that are frequently problematic at the end of life. Moreover, these patients have been heavily engaged in the healthcare system at the time of their hospice admission with complex regimens put in place by their physicians. To require additional hands-on physician intervention to simply maintain their current pain medications is onerous, time consuming, duplicative, and will delay the provision of care. There is no other area of medical practice in which patient care is as carefully scrutinized or monitored. Nurse case managers are in the home at the bedside, communicating with hospice physicians in real time, and facilitating the relationship that effectively manages the plan of care.

In recent months there have been several states in which physicians and hospice providers have had to negotiate with state legislators and regulators to ensure that exceptions to these restrictive laws are enacted to allow effective care of hospice patients. While regulation of prescribing practices is, for the most part, the domain of the state, the issue has emerged with sufficient frequently that I believe it is useful for this committee to be aware of this concern.

In a similar vein, many hospices are finding that in growing numbers community physicians are hesitant to prescribe pain medications for patients with advanced or terminal illness because of the intense

scrutiny that prescribing practices are receiving throughout the Nation. While I believe that these fears may not be well-founded – and clearly, it is not the intention of legislators that hospice patients suffer – this is an issue that is a growing concern in my field. I am very concerned that we could be facing the reality of dying patients being forced into situations of preventable suffering as a result of legislative efforts, that while reasonably conceived, will fail to protect the most vulnerable and prone to suffering. I would also parenthetically note that it is not patients at the end of life, nor hospice physician prescribers, who have influenced the current opioid misuse and addiction issues.

As indicated at the start of this testimony, I am appreciative of the opportunity to discuss these issues with you today. In the course of my palliative work, 15 years ago I was asked to consult with the DEA and the FBI in investigating opioid diversion cases and abuse cases. I have appreciated the opioid challenges that are permeating our communities, and yet understand the need to meet the pain needs of patients at the end of life. I would be pleased to answer any questions that you may have, and, along with representatives of the National Association for Home Care & Hospice (NAHC), welcome the opportunity to serve as a resource to members and staff of the committee.

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:]



Dr. Ponni Subbiah, MD, MPH

Chief Medical Officer, Indivior PLC

Statement to the House Energy and Commerce Subcommittee on Health

Hearing on

Combating the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety

February 28, 2018

Good morning. Thank you, Chairman Burgess and Ranking Member Green, for the privilege to address the Subcommittee and for recognizing the importance of combatting the current opioid crisis. I am Dr. Ponni Subbiah, a neurologist and Chief Medical Officer at Indivior. Indivior is a global specialty pharmaceutical company. Our core focus is addiction medicine. We have a 20-year legacy of commitment to our vision that all patients have access to evidence-based treatment for the chronic condition and co-occurring disorders of addiction. We developed the first buprenorphine-based opioid use disorder treatment for patients in the United States. Today, we have a global portfolio of treatments for opioid addiction and a pipeline of product candidates to address unmet patient needs for this disorder and other chronic conditions, 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. Addiction is often punished and criminalized.

Even when people want to stop using illicit drugs, cravings and withdrawal symptoms can be so intense that generally there is only a small window of time when a person is emotionally and physically able to pursue treatment. The healthcare system, however, does not always encourage

treatment during that window due to structural barriers to care. This is one of many reasons that the majority of those who need help go untreated. For this reason, Indivior believes that any patient in need of approved treatments for opioid use disorder should have access to the medically-assisted treatment (MAT) prescribed by their health care professional. Several government agencies have noted that MAT has recognized track records of success.

Indivior's core guiding principle - focus on patient needs to drive decisions - inspired our research and development team to develop SUBLOCADE™ which received FDA approval on November 30, 2017. SUBLOCADE is the first once-monthly Schedule III buprenorphine extended-release injection for subcutaneous use. In the face of the growing addiction crisis, FDA granted the product Fast Track approval and Priority Review designation. It is indicated for the treatment of moderate to severe opioid use disorder in patients as part of a complete treatment plan that includes counselling 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 (REMS) program. The goal of the REMS is to mitigate serious harm or death that could result from intravenous self-administration by the patient. All healthcare settings and pharmacies that order and dispense SUBLOCADE must be certified and establish processes and 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 towards recovery is different, access to additional treatment options is critical. SUBLOCADE represents one such option that we believe will be essential to addressing the needs of patients, families and communities battling the opioid epidemic.

New innovations are expanding medication-assisted treatment options. Government policies impacting these treatments must adapt to ensure patients have access to all evidence-based treatment options.

Historically, buprenorphine treatments have been daily, oral medications and the Controlled Substances Act allows for dispensing of these medications directly to patients. However, as stated earlier, SUBLOCADE, as required by our risk management program, 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 has evolved from a traditional 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 the administering provider. For example, current long-acting injectable treatments used for schizophrenia utilize both these distribution methods to ensure optimal patient access to these medications.

Based on this, we agree with Representatives Costello and Nolan, the sponsors of the *Ensuring Patient Access to Substance Use Disorder Treatments Act of 2018*, that the law needs to be clarified so that these next generation buprenorphine products can also be accessed directly by healthcare providers through a specialty pharmacy restricted delivery system as well as a traditional buy and bill system.

We agree with the Committee that there is a role for Congress, and the Administration, to update laws to allow for new medical technologies. We support the proposed legislation to remove any ambiguity in the current law to ensure that patients with opioid use disorder and their providers have the same level of access to these innovative treatments as they do to other injectable products. We believe this technical clarification will ensure the safest distribution channels for these new treatments.

Thank you again for the opportunity to address the Committee.

All of us together can transform addiction from a human crisis to a recognized and highly treated disease. We stand ready to support the Committee's work however we can. I would be happy to answer any of your questions. Thank you for your leadership and consideration.

-END

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 significantly 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 in-

volving 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:]



ASAM The Voice of Addiction Medicine
American Society of Addiction Medicine

Testimony of David Kan, MD, DFASAM
Before the Energy and Commerce Committee Subcommittee on Health
February 28, 2018

Executive Summary

My name is Dr. David Kan, and I'm the President of the California Society of Addiction Medicine, a Chapter of the American Society of Addiction Medicine (ASAM), which represents more than 5,000 of our nation's addiction specialist physicians and other clinicians.

My testimony today will focus on the following facts:

1. Addiction involving opioid use can be successfully treated with a combination of medications and psychosocial interventions, and we have published standards and guidelines that detail best practices for the use of these medications.
2. There are significant barriers to access these effective medications, resulting in a significant addiction treatment gap in our country.
3. Changes to the Controlled Substances Act to facilitate the use of telemedicine and new medication formulations can expand access to evidence-based treatment options and help close the addiction treatment gap.

Opioid addiction is taking a devastating toll on our families, friends, and neighbors across the country, but there is hope when patients can access effective treatment services. ASAM is honored today to offer its thoughts and expertise on how we can close the treatment gap, improve the quality of care, and ultimately save lives.

Introduction

Chairman Burgess and Ranking Member Green, thank you very much for inviting me to participate in this important hearing. I'm grateful to you and the other Members of the Subcommittee for your leadership in addressing the epidemic of opioid addiction currently ravaging our country.

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, myself as a practicing addiction specialist physician, and my patients. I am board-certified in both Addiction Medicine and General and Forensic Psychiatry, and I'm the Medical Director of Bright Heart Health, which provides telemedicine addiction treatment services in 21 states across the United States, and of which I have a 3.5% ownership interest. I have dedicated my entire career to treating patients with opioid addiction and have spent more than a decade treating addiction at the Veterans Administration Medical Center in San Francisco, where I used telemedicine to treatment patients. I am also a faculty member at the UCSF Department of Psychiatry.

Established in 1954, ASAM is a national medical specialty society of more than 5,000 physicians and allied health professionals who specialize in the treatment of addiction. Its mission is to increase access to and improve the quality of addiction treatment; to educate physicians, other health care providers and the public; to support research and prevention; and to promote the appropriate role of the physician in the care of patients with addictive disorders.

My testimony today will focus on the following three facts:

1. Addiction involving opioid use can be successfully treated with a combination of medications and psychosocial interventions, and we have published guidelines that detail best practices for the use of these medications.
2. There are significant barriers to access these effective medications, resulting in a significant addiction treatment gap in our country.
3. Changes to the Controlled Substances Act to facilitate the use of telemedicine and new medication formulations can expand access to evidence-based treatment options and help close the addiction treatment gap.

Addiction Involving Opioid Use Can Be Treated Successfully

The medical literature is clear, and as a practicing addiction specialist with more than a decade of experience I can confirm, that addiction involving opioid use can be treated successfully with a combination of medication and psychosocial interventions.

There are currently three medications that are FDA-approved to treat opioid addiction: methadone, which has been used in highly regulated opioid treatment programs since the 1960s; buprenorphine, which has been used since 2002 by specially trained physicians in their offices; and naltrexone, which is not a controlled substance and can be administered by any licensed prescriber. Given the bills being considered by the Subcommittee today, I will focus my remarks on the safety and effectiveness of buprenorphine, although it is important to note that all three medications have been proven to be safe and clinically effective for the treatment of addiction involving opioid use.

The benefits of buprenorphine in the treatment of opioid dependence and opioid use disorder are well documented. A 2013 review of the scientific literature found substantial, broad and conclusive evidence for the effectiveness of all three medications.[1] Several studies of office-based treatment with buprenorphine found it improves treatment engagement; reduces cravings, illicit opioid use, and mortality; and improves psychosocial outcomes. Compared to full opioid agonists like methadone, buprenorphine offers an improved safety profile, with significantly lower related overdose deaths and adverse events after treatment discharge.[2,3,4] Moreover, the direct health care savings per opioid dependent patient per year exceed $20,000,[5] with total economic savings stretching beyond just health care costs to the criminal justice and social services sectors as well.

Finally, we have clear standards of care for clinicians treating patients with addiction, as well as comprehensive guidelines for how to use medications effectively in the clinical care of persons with addiction involving opioid use. ASAM's *Standards of Care for the Addiction Specialist Physician*, which apply to any physician assuming the responsibility for caring for patients with addiction and related disorders, address expected physician competencies and actions with the ultimate purpose of improving patient outcomes. ASAM's *National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use* was developed to promote evidence-based clinical treatment of opioid use disorder and to assist clinicians in the decision-making process for prescribing medications to patients with opioid use disorder. It offers specific clinical recommendations on the assessment and diagnosis of opioid use disorder, treatment options, managing withdrawal, initiating medication treatment, and psychosocial treatment.[6] I will return to the Standards and the Guideline's recommendations shortly when I discuss the in-person physical examination requirement stipulated by the Ryan Haight Act.

There are Significant Barriers to Access these Medications Leading to a Major Treatment Gap

Despite the strong evidence base for the use of buprenorphine and the clinical guidance available, very few eligible patients are offered medication to help treat their disease. Indeed, a 2015 study published in the Journal of the American Medical Association found that 80% of Americans with opioid addiction don't receive treatment.[7] Part of the treatment gap is attributable to lack of access to DATA-waived clinicians who can prescribe buprenorphine. A 2015 study co-authored by the Assistant Secretary for Mental Health and Substance Use Dr. McCance-Katz that estimated national and state need and capacity for opioid agonist medication-assisted treatment (both methadone and buprenorphine) found that, "among states and the District of Columbia, 96% had opioid abuse or dependence rates higher than their buprenorphine treatment capacity rates." The authors concluded, "Significant gaps between treatment need and capacity exist at the state and national levels. Strategies to increase the number of [opioid agonist-MAT] providers are needed."[8]

Other barriers preventing patients from accessing this life-saving treatment include transportation difficulties, limited hours of operation, and few prescribers who accept Medicaid or Medicare. Individually, these barriers prevent access. However, patients often encounter multiple barriers making access to treatment next to impossible.

- Whether rural or urban, many individuals struggle with attending appointments due to functional ability and transportation issues related to bus schedules, costs of travel, and ability to adjust work and life schedules around appointments.
- Many providers only offer limited hours or weekday schedules. Many individuals seeking treatment for addiction involving opioid use are employed by retail, restaurant,

construction, or similar industries with limited flexibility to attend frequent medication and behavioral health appointments in accordance to their treatment plan.

- Finally, the scarcity of Medicaid-eligible and enrolled practitioners and programs that could provide medications for the treatment of addiction involving opioid use to Medicaid patients limits geographic access for Medicaid beneficiaries with addiction involving opioid use, requiring long commutes and/or Medicaid-paid transportation, whose costs are rising substantially as a result. Many physicians choose to offer cash only practices, restricting access to care to only individuals who can pay out-of-pocket.

Changes to the Controlled Substances Act to Facilitate Treatment Via Telemedicine and New Medication Formulations Can Help Close the Treatment Gap

While not a silver bullet that will solve our current opioid addiction crisis or fully close the treatment gap, making smart and targeted changes to the Controlled Substances Act to facilitate treatment with buprenorphine for addiction involving opioid use via telemedicine and the use of new implantable and injectable buprenorphine formulations are steps this Congress should take to expand treatment access.

Telemedicine

Telemedicine provides significant opportunities to reach more patients in urban, peri-urban, and rural communities. However, the current restrictions on internet prescribing under the Ryan Haight Act and the seven, specific "practice of telemedicine" exceptions it provides for are of limited utility for expanding access to treatment with buprenorphine for addiction involving opioid use via telemedicine. As you know, the Ryan Haight Act generally requires an "in-person medical evaluation" in the physical presence of the prescribing clinician for the prescription to be

considered valid. The "practice of telemedicine" exceptions to this requirement provide for circumstances in which the patient is being treated by, and physically located in, a DEA-registered hospital or clinic, or in which the patient is being treated by and in the physical presence of another DEA-registered practitioner. It generally does not allow for circumstances in which a patient may have received a medical evaluation by another qualified practitioner but is not physically present in a DEA-registered hospital or clinic or with another DEA-registered practitioner.

ASAM's Standards of Care and National Practice Guideline make it clear that patients presenting for treatment of addiction involving opioid use should receive a physical examination by a qualified and appropriately licensed healthcare professional as part of a comprehensive assessment process. However, they specifically allow for this examination to be conducted by a healthcare professional other than the prescriber, as long as the prescriber "ensure[s] that a current physical examination is contained within the patient medical record before a patient is started on a new medication for the treatment of his/her addiction."[9] **Accordingly, ASAM recommends that the requirement for an in-person physical exam by the prescribing clinician be revised to allow for the physical exam to be conducted by another appropriately licensed healthcare professional and documented in the patient's medical record.** Completion of the patient's medical history should include screening for concomitant medical conditions, including infectious diseases (hepatitis, HIV, and tuberculosis [TB]), acute trauma, and pregnancy. Initial laboratory testing should also include a complete blood count and liver function tests.

Additionally, ASAM recommends limiting this exception to the in-person physical exam requirement for patients who will be treated with buprenorphine for opioid addiction only to those physicians who hold "additional certification" or who practice in a "qualified practice setting" per

the definitions in the 2016 SAMSHA rule that raised the DATA-2000 prescribing limit. Specifically, only physicians who hold board certification in addiction medicine or addiction psychiatry by the American Board of Addiction Medicine or the American Board of Medical Specialties, or certification by the American Society of Addiction Medicine, or those who practice in settings that provide professional coverage for patient medical emergencies when the practice is closed, provide access to case management services, are registered with their state PDMP, and are able to accept third-party insurance, should be allowed to prescribe buprenorphine via telemedicine with an in-person evaluation conducted by another appropriately licensed healthcare professional and documented in the patient's medical record.

These changes would allow for highly skilled addiction specialists to treat patients who might otherwise face insurmountable geographic, logistical, or financial barriers to in-person treatment, and would make progress toward closing the addiction treatment gap while still ensuring patients are receiving high-quality care from competent healthcare providers.

New Formulations

Secondly, ASAM encourages Congress to move expeditiously 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 requiring the clinician to rely on the "buy and bill" method for obtaining and being reimbursed for the medications.

Foremost to ASAM's mission is a goal to increase access to and improve the quality of addiction treatment. The introduction and use of novel addiction medications supports this goal. Addiction patients, like all patients, should have available to them a robust and varied array of treatment

options, as no one treatment modality is appropriate or therapeutic for everyone. The recent approval of implantable and injectable buprenorphine formulations expands treatment options for patients. No product will be suitable for all patients, and many will still be best-served by oral formulations, other medications, or no medication at all, but they may help improve treatment adherence and reduce diversion among certain patients for whom they are indicated. However, these options are only valuable if patients can access them. A change to the Controlled Substances Act, as has been proposed in Senate bill 916, would facilitate access to these new products by allowing them to be delivered to administering practitioners on a patient-by-patient basis rather than requiring the practitioners anticipate demand, buy the medication in advance, store it on site, and hope they estimated the correct number of doses needed to meet demand and avoid waste. This is not a new pathway for medication delivery but would allow for these controlled substances to be delivered as many non-controlled substances are already. It is a technical, common-sense fix to the law that will expand treatment access while potentially reducing the buprenorphine diversion, and ASAM urges this Subcommittee to advance a bill to approve it.

Thank you, again, for the opportunity to present here today. ASAM looks forward to a continued collaboration on this and other addiction-related issues, and I look forward to your questions.

###

[1] Chalk M, Alanis-Hirsch K, Woodworth A, Kemp J, and McClellan T. FDA Approved Medications for the Treatment of Opiate Dependence: Literature Reviews on Effectiveness & Cost- Effectiveness. 2013. Available at: http://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addiction-treatment_final

[2] Schwartz RP, Gryczynski J, O'Grady KE, et al. Opioid Agonist Treatments and Heroin Overdose Deaths in Baltimore, Maryland, 1995–2009. *American Journal of Public Health*. 2013;103(S):917-922. doi:10.2105/AJPH.2012.301049.

[3] Paone D, Tuazon E, Stajic M, et al. Buprenorphine infrequently found in fatal overdose in New York City. *Drug Alcohol Depend*. 2015 Oct 1;155:298-301. doi: 10.1016/j.drugalcdep.2015.08.007. Epub 2015 Aug 15.

[4] Bell JR, Butler B, Lawrence, A. et al. Comparing overdose mortality associated with methadone and buprenorphine treatment. *Drug Alcohol Depend*. 2009;104(1): 73 – 77. doi: 10.1016/j.drugalcdep.2009.03.020

[5] Tkacz J, Volpicelli J, Un H, and Ruetsch C. Relationship between buprenorphine adherence and health service utilization and costs among opioid dependent patients. *J Subst Abuse Treat*. 2014 Apr;46(4):456-62. doi: 10.1016/j.jsat.2013.10.014. Epub 2013 Nov 12.

[6] Kampman K and Jarvis M. American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. *J Addict Med* 2015;9: 1–10.

[7] Saloner B and Karthikeyan S. Changes in Substance Abuse Treatment Use Among Individuals With Opioid Use Disorders in the United States, 2004-2013. *JAMA*. 2015;314(14):1515-1517.

[8] Jones CM, Campopiano M, Baldwin G, and McCance-Katz E. National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment. *Am J Public Health*. 2015 Aug;105(8):e55-63. doi: 10.2105/AJPH.2015.302664. Epub 2015 Jun 11.

[9] Kampman K and Jarvis M. American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. *J Addict Med* 2015;9: 1–10.

Appendix: ASAM Position on Other Bills under Consideration

Bill	ASAM Position
H.R. 2063, the Opioid Preventing Abuse through Continuing Education (PACE) Act of 2017	The dramatic increase in the prescription of opioid medications has played a significant role in rise of opioid addiction and development of the opioid overdose epidemic in the United States. To address this epidemic, we must take a comprehensive approach to strengthening treatment, prevention, and recovery services for patients with addiction, including strategies to ensure safe and responsible prescribing of opioids. This bill would help reduce unnecessary exposure to addictive medications by requiring prescribers to be educated on safe prescribing practices and addiction, and ASAM is pleased to endorse it. In addition, ASAM offers these additional recommendations for consideration: • Make the new training requirement a condition of registration to prescribe or dispense benzodiazepines in addition to opioids for the treatment of pain. • Streamline federal efforts to promote safe opioid prescribing by incorporating the recommendations included in the CDC Guideline for Prescribing Opioids for Chronic Pain. There is no need for duplicative federal recommendations on opioid prescribing; in fact, duplicative efforts may only confuse practitioners and

	further clutter an already-crowded educational space on this topic. • Offer a "test-out" option that would give practitioners the opportunity to demonstrate their knowledge and "test-out" of this mandatory training requirement.

Mr. BURGESS. Thank you, Dr. Kan.

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

STATEMENT OF RICHARD J. NANCE

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:]

Statement by Richard Nance, LCSW
Director of Utah County's Department of Drug and Alcohol Prevention and Treatment

on

Combatting the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety

before

Committee on Energy & Commerce,
Subcommittee on Health

U.S. House of Representatives
February 28, 2018

Summary

The National Council for Behavioral Health appreciates and affirms the importance of the Ryan Haight Act. This Act is as important today as it was when it was passed in 2008. Our goal is to enable regulated community mental health and drug and alcohol treatment centers – facilities that are staffed by regulated and licensed healthcare professionals – to be able to comply with the Ryan Haight Act and in order to provide care to patients in need. The issue is that DEA's narrow interpretation of the Ryan Haight Online Pharmacy Consumer Protection Act is limiting community mental health and addiction treatment centers' ability to provide patients speedy and safe treatments that involve controlled substances for substance use disorder (SUD) and mental health conditions by utilizing telemedicine.

The reason is simple: Legitimate community mental health and addiction treatment centers are currently unable to register with DEA as a "hospital or clinic" as required by the Ryan Haight Act because DEA has interpreted "hospital or clinic" to mean a state-licensed medical facility. The problem is that many community mental health and addiction treatment centers are not licensed as state medical facilities as DEA's interpretation requires; instead these legitimate patient care centers may be state-licensed but county-run, county-licensed, or even run by/through the local government itself. To comply with the Ryan Haight Act, these centers are asking for additional regulation and oversight by DEA so they can provide Americans access to SUD and other mental health therapies via telemedicine, as medically appropriate.

The Harper/Matsui draft legislation does just that, enabling community mental health and addiction treatment centers to register with DEA to provide care via telemedicine. The Carter/Bustos draft also provides for a mechanism to expand access to telemedicine treatments and will have the most impact if enacted in conjunction with the Harper/Matsui draft.

Statement

Chairman Burgess, Ranking Member Green, and Members of the Health Subcommittee, thank you for the opportunity to testify on an issue that is impacting community addiction and mental health treatment centers' ability to provide patients speedy and safe treatments for substance use disorder (SUD) and mental health conditions by utilizing telemedicine. Medically appropriate treatment for SUD and mental health conditions sometimes involves controlled substances. Unfortunately, today thousands of community addiction and mental health treatment centers across the country are unable to use telemedicine that results in the issuance of a prescription for a controlled substance due to the DEA's narrow interpretation of the Ryan Haight Online Pharmacy Consumer Protection Act (Ryan Haight Act).

I appreciate the opportunity to speak for the 2,900 National Council for Behavioral Health member organizations that provide front-line addiction and mental health treatment across the country. We deeply appreciate Congress's interest in creating a pathway to enable legitimate community addiction and mental health treatment centers to register with DEA such that they may provide treatment for Americans in need.

About the National Council for Behavioral Health

The National Council for Behavioral Health is the unifying voice of America's health care organizations that deliver mental health and addictions treatment and services. Together with our 2,900 member organizations

serving over 10 million adults, children and families living with mental illnesses and addictions, the National Council is committed to all Americans having access to comprehensive, high-quality care that affords every opportunity for recovery.

I am a Licensed Clinical Social Worker in Utah, and have been Director of Utah County's Department of Drug and Alcohol Prevention and Treatment (UCaDDAPT) since 1998. UCaDDAPT provides a comprehensive range of drug and alcohol prevention and treatment services, including medication-assisted treatment for substance use disorders (SUD), such as opiate addiction and abuse, as well as for co-occurring SUD and mental health disorders. UCaDDAPT also contracts for methadone treatment services. Utah County has a population of over 600,000, and UCaDDAPT serves over 2,000 people per year. Over 40% of these are now being seen for opiate use disorders, and at any given time about 30% of those are receiving MAT in addition to counseling services.

LEGISLATION IS NEEDED TO ENABLE COMMUNITY ADDICTION AND MENTAL HEALTH TREATMENT CENTERS TO USE TELEMEDICINE TO PROVIDE TREATMENT INVOLVING CONTROLLED SUBSTANCES

The Problem

Thanks to ever-expanding technological advances, telemedicine has the potential to improve access to care, while reducing costs and increasing patient and provider convenience. **Unfortunately, today my center and many other legitimate community addiction and mental health treatment centers are unable use telemedicine to connect patients in our center with DEA-registered doctors.** Here is why:

The Controlled Substances Act, as amended by the Ryan Haight Act, allows for the issuance of a prescription for a controlled substance without a prior in-person patient medical evaluation in limited circumstances, known as telemedicine exceptions. The most common way for such telemedicine to be permitted is when the

patient being treated is located in a DEA-registered hospital or clinic and is being treated by a DEA-registered provider located off-site. See 21 U.S.C. 829(e)(3)(A). In order to register, DEA requires that hospitals or clinics be licensed by a state. See *Appendix A*, DEA Registration Form 224, Section 4. The state licensure requirement is not in statute, rather is a result of DEA's administrative application of the Act. The problem is, many community addiction and mental health treatment centers are unable to use telemedicine that results in a prescription for a controlled substance because they are not "state-licensed" according to DEA's interpretation. Many community addiction and mental health centers are licensed, certified, or otherwise formally overseen and recognized by their state, county, or municipality but do not meet the DEA's narrow interpretation.

The National Council believes community mental health or addiction treatment facilities that are **licensed, operated, authorized, or otherwise recognized by a state, county or municipality** should be able to register with DEA for purposes of complying with the Ryan Haight Act.

Especially given the opioid epidemic, the National Council continues to believe remote prescribing of controlled substances without a prior in-person medical evaluation should be limited to patients located in a DEA-registered facility, including community addiction and mental health treatment centers registered under the two draft bills sponsored by Representatives Harper and Matsui and by Representatives Carter and Bustos. Our concerns with removing the registration requirement and/or allowing patients to receive prescriptions for controlled substances via telemedicine while at their home or otherwise not in a care setting as currently permitted under the Act are outlined later in this statement.

About Community Addiction and Mental Health Treatment Centers

In general, community addiction and mental health treatment centers are facilities that treat patients for mental health, substance use disorder, and other behavioral health needs. These centers, for the most part, do not dispense controlled substances.[1]

There is no federal definition of a community mental health center or of an addiction treatment center applicable in all 50 states to clinics that serve patients from all payer sources. Rather, states, counties, and in some cases municipalities determine what qualifies as a legitimate center and how to regulate them. Sometimes centers are required to have state licenses; sometimes states establish and run the centers themselves as parts of the government; in other cases, centers are regulated by county or municipal governments. For example:

1. **In Utah:** Community mental health and addiction treatment (MH/SUD) centers are overseen by the State Department of Human Services Office of Licensing. Utah has a county government-based addiction and mental health system, which means addiction and mental health services are services are delivered directly by county government, or are contracted out to one or more MH/SUD providers that are also under the purview of the state licensing department and are overseen by governing boards comprised of elected county government officials.
2. **In Texas –** Community mental health centers (known as Community Centers) are governmental entities authorized in Texas statute and required by Texas law to treat individuals with severe and persistent mental illness throughout Texas. In their capacity as units of Texas government they do not require any additional state license to perform their state-mandated tasks. These centers are a critical component of the Texas health care system and already meet the intent of registration by virtue of their statutory authorization to perform the functions of Community Mental Health Centers with

[1] While rare, we are aware of at least one center that does dispense: the Josephine County, Oregon Health Department is the local behavioral health authority, and they operate a licensed methadone program – thus dispense controlled substances.

regard to psychiatric medications. The Texas Council of Community Centers represents 39 centers across Texas that were established by Texas statute and has spent multiple years working with DEA on behalf of its membership to secure DEA registration, with no resolution to date. See *Appendix B* for a discussion of these efforts.

3. **In Georgia –** Community mental health centers (known as Community Service Boards) are quasi-governmental entities authorized in Georgia statute and required by Georgia law to treat individuals with severe and persistent mental illness. In their capacity as instrumentalities of Georgia government, they do not require any additional state license to perform their state-mandated tasks. These centers are a critical component of the Georgia health care system and they are already registered under Georgia law with regard to controlled substances. The CSBs of the Georgia Association of Community Service Boards are concerned about access to vital psychiatric services in schools (as delivered by school-based clinics in partnership with Community Service Boards) and rural areas.

4. **In Missouri –** Community mental health centers operate across 25 service areas reaching the entire state. These providers are non-profit entities serving in a quasi-governmental role as administrative agents of the state responsible for a comprehensive array of mental health and addiction services in their catchment area. Though these centers do not have a state licensure number, they are certified and monitored by the state, are subject to detailed administrative rules outlining their certification criteria and obligations, and are closely overseen by a system of regional managers.

The authorizing governmental body (e.g. states, counties) can determine the scope of services that are able to be provided in these centers and the professional qualification requirements of the centers' on-site staff.

1. **Types of Providers On-Site in Centers:** Community addiction and mental health treatment centers may not always have doctors or psychiatrists on-site at all times. In these cases, it is common for centers to be staffed by social workers, nurses, counselors and other state-licensed mental health or addiction professionals that do not have prescribing authority. Staff at community addiction and mental health

treatment facilities are regulated by state and local laws, including any requirements for licensure (e.g. state nursing licenses, social worker licenses), education, and professional conduct.

2. **Scope of Services Provided in Centers:** The types of services provided by community addiction and mental health treatment centers vary, but we do know that roughly 75% of the National Council's 2,900 member organizations offer addiction treatment services. The number of organizations that strictly provide mental health treatment services without any addiction services is very slim.

   For example, Hill Country MHDD Centers serve 19 Texas counties and provide mental health, individual developmental disability, substance use disorder, and early childhood intervention services. These centers need the ability to register with DEA such they can bring in an addictionologist, addiction psychiatrist or child psychiatrist via telemedicine to prescribe to a patient on-site, when medically appropriate.

The Impact on Patients During the Opioid Epidemic and Beyond

The inability of legitimate community addiction and mental health treatment centers to use telemedicine has a direct impact on the lives of Americans. As this Committee understands, the demand for addiction and mental health services far exceeds current system capacity to serve patients. Telemedicine is a vital opportunity to extend both addiction and mental health treatment services to more patients, particularly those living in rural and frontier areas that lack qualified providers.

There are only four medications commonly used to treat opiate use disorders. One of these – naloxone – is only used for emergency reversal of opiate overdoses. Naltrexone – in oral or long acting injection form works well for some patients, but not for all. The other two – methadone and buprenorphine (also delivered as Suboxone, a formulation that includes buprenorphine combined with naloxone) – are controlled substances and a form of opiate medication themselves. Methadone is the longstanding gold standard for opiate addiction

treatment, but methadone treatment programs are subject to tight licensing, accreditation, and DEA oversight standards. These standards make the establishment of methadone treatment programs in rural and frontier areas economically non-viable. Buprenorphine/Suboxone can be prescribed by DATA 2000 certified physicians, but for several reasons, there are few Suboxone prescribers in rural and frontier areas. In Utah, there are over 400 Suboxone prescribers on the DEA's list, however, many of these are not actively prescribing Suboxone. Of the remainder, many choose not to solicit new Suboxone patients, but only use their certification to prescribe to existing patients in their own practices. There are 506 registered buprenorphine prescribers in Utah and 28 American Board of Addiction Medicine (ABAM)-certified physicians in practice (however, some of these only do pain management). Only 72 Suboxone prescribers can be found on the Suboxone.com website for Utah.

Here is a real-world example from my practice in Utah: A patient at one of our rural licensed community mental health or addiction treatment centers is in crisis and needs addiction treatment involving a prescription for a controlled substance as part of his/her medication-assisted treatment (MAT). MAT is a highly effective, evidence-based treatment for opioid addiction that combines the use of medication with counseling and mental therapies.

As common with community addiction and mental health treatment centers, my center is staffed with social workers, nurses, counselors and other mental health professionals, including a full time ABAM certified addictionologist. Due to shortages of providers and the rural and frontier nature of most of the rest of the state, many other community addiction and mental health centers do not regularly have DEA-registered doctors or psychiatrists on site who are certified, competent, or willing to prescribe MAT for opiate use disorders.

But thanks to advances in technology, we do have the technical ability to connect the patient to a DEA-registered psychiatrist via telemedicine. The problem is that because my center is licensed by our state Department of Human Services (not licensed by our state Department of Health as DEA requires of medical clinics), we are unable to register with DEA such that the Ryan Haight Act's telemedicine exception for "treatment in a hospital or clinic" would apply.

As such, we cannot provide the patient his/her needed care; rather we must wait for a DEA-registered doctor to "go on the road." If we take Bluff, Utah, as an example, it can take up to ten hours round-trip including an overnight stay – to do the required face-to-face physical evaluation of the patient prior to writing the prescription. If Suboxone treatment is indicated, this requires the patient to fill the prescription then return to the office for a medically supervised induction process that takes up to 4 hours. For Dr. Elina Chernyak in my office to provide this service, she must forego seeing up to 48 – 60 of our own patients to see one in the rural setting – if the patient actually keeps the appointment. People in active opiate addiction are often disorganized, physically ill, and cognitively impaired to the point that they may be unable to keep or even remember their appointment.

In the context of the opioid epidemic, the costs of this inefficiency can tragically be measured in lives lost from speedy access to MAT. We can also measure the cost in terms of dollars, as just for my Utah center alone we estimate it costs $490 in travel, lodging, and per diem and $1,400 in physician time to have Dr. Chernyak drive out to the center to do an in-person patient medical evaluation, prescribing, and Suboxone induction. In the winter in Utah, this could easily double or even have to be cancelled for safety reasons depending on road conditions. This is to see perhaps one patient, versus the 48 – 60 that she could see if she stayed in her office in Provo. Continuing care could be conducted via telemedicine procedures.

If the law were changed to permit our clinics to register with DEA, instead of this inefficient and high-cost workaround, we could provide consumers with more responsive, timely access to care. Currently, to evaluate and initiate Suboxone treatment, Dr. Chernyak must drive often quite lengthy distances for the first face-to-face visit, with continuing patient care and consulting with the clinical staff being done via a secure HIPAA-compliant telehealth platform called Zoom.

In contrast, when Suboxone is prescribed via telemedicine, we would follow a version of Vermont's hub and spoke model. The hub would be our office in Provo where our DEA-certified addiction medicine doctor – Dr. Chernyak – has her full-time office. The spokes could be one or more rural or frontier community MH/SUD health center(s) or federally qualified health center sites. At present we have contracts with Northeastern Counseling Center and Mountainlands Community Health Center in Vernal and Roosevelt, Utah that could serve as the spokes in this model. In addition to counselors and therapists, both these centers employ nursing staff who can monitor patients' first use of the medication (known as "induction") and immediately address any adverse reactions in partnership with the prescribing physician via telemedicine. Having a medical professional in the room with the patient is the standard practice for first-time use, or induction, of Suboxone and is in accordance with national best practices and guidelines established by ASAM. This is the only way we would consider practicing addiction medicine using Suboxone. We would never consider it advisable to see a patient over a non-secure platform such as Facetime when the patient was using the Wi-Fi at Starbucks, for instance.

National Council Support for Federal Legislation

The National Council appreciates the efforts this Committee, including Representatives Carter, Harper and Matsui, for putting forward draft legislation that would support the ability of legitimate clinics to register with DEA for purposes of complying with the Ryan Haight Act. Benefits of this approach include:

1. Giving DEA transparency into and jurisdiction over the practices of health care locations not otherwise registered with the DEA under Section 303(f) but which nonetheless have patients on-site that need treatment via telemedicine involving the issuance of a prescription for a controlled substance.
2. Balancing the burden that is placed on the health care provider with a corresponding onus on the center where the patient is located. Providers already must be registered with DEA in order to prescribe controlled substances.
3. Continuing DEA jurisdiction over both parts of the treatment – the provider and the center – which both benefits the Agency's enforcement abilities and is consistent with the Ryan Haight Act's "belt and suspenders" approach of allowing telemedicine treatment in a hospital or clinic registered with the DEA.

As for how to accomplish this goal, we defer to Congressional leaders on the best approach but share some considerations:

1. Section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f) does not capture what community addiction and mental health treatment centers do. These centers typically do not dispense controlled substances and do not conduct research. Accordingly, we fear that the addition of community addiction and mental health treatment centers to Section 303(f) will not solve our problem.
2. As an alternative, Paragraph (54) of section 102 of the Controlled Substances Act (21 U.S.C. 102) could be amended to make clear that legitimate community addiction and mental health treatment centers shall be eligible to register with DEA just like state licensed hospitals and clinics currently can. For example:

"(i) while the patient is being treated by, and physically located in—

"(I) a hospital or clinic registered under section 303(f); or

"(II) a community mental health or addiction treotment center registered for purposes of this subparograph."

Plus at the end:

"The Attorney General shall register community mental health or addiction treatment facilities that are licensed, *operated, authorized, or otherwise recognized by a State, county, or municipal government for purposes of treatment via the practice of telemedicine as described in subparagraph (A)"*

3. We appreciate the draft Harper/Matsui bill allows centers to use telemedicine to treat patients for all types of addiction and mental health conditions, not just SUD. While the opioid epidemic is the nation's most pressing public health issue and the subject of this hearing, the National Council wishes to emphasize the importance of allowing community addiction and mental health treatment centers to use telemedicine to treat other mental health conditions too, not just SUD. There are two reasons for this:

    a. There is a legitimate public health need to improve access to mental health services generally. According to federal health authorities, there are roughly 4,000 areas nationwide where there is only one psychiatrist for every 30,000 patients. Further, the American Academy of Child and Adolescent Psychiatrists, (AACAP) reports there are approximately 8,300 practicing child and adolescent psychiatrists in the U.S. — and over 15 million youths in need of one. Telemedicine can be part of the solution to this provided shortage, but currently the Ryan Haight Act limits mental health providers' ability to treat mental illness because of restrictions on stimulants that are commonly used in psychiatric treatment for both children and adults.

    b. Many treatment centers provide both addiction and mental health services, and not all states certify, recognize or otherwise authorize addiction and mental health treatment centers in the same way. In some states there are two separate certifications (one for mental health

treatment services and another for addiction treatment services), while other states provide a single certification for community providers offering both types of services. Therefore, to be inclusive of the full universe of community providers who offer addiction treatment services, the legislation cannot narrow the scope to simply "addiction" providers as this would exclude many of the organizations who currently provide both addiction and mental health care.

4. We also support the approach outlined in the Carter/Bustos draft, which requires DEA to act swiftly to implement a "special registration" and note that we continue to believe that the patient who is being treated by telemedicine should be located in a DEA-registered facility. It is our hope that such a special process would be inclusive enough to apply to community addiction and mental health treatment clinics, though we fear that if the registration process is implemented too narrowly it could continue to exclude these treatment providers. It is possible that DEA could implement the "special registration" in such a way as to still require "state licensure" of hospitals and clinics, or to otherwise draft regulations that would continue to exclude legitimate community addiction and mental health treatment centers from being able to use telemedicine for controlled substance treatment. If that were to occur, centers that are licensed, operated, authorized, or otherwise recognized by a State, county, or municipal government would still be shut out from being able to provide effective health care options to patients in need. The Carter/Bustos draft bill will have the most impact if enacted in conjunction with the Harper/Matsui draft bill that clearly specifies community mental health and addiction providers as a category of centers eligible to register with DEA.

5. We support requiring patients to be treated via telemedicine while located in a DEA-registered location (hospital, clinic, center). The draft Harper-Matsui bill simply makes clear that legitimate community addiction and mental health treatment centers shall be eligible to register with DEA just like hospitals and clinics.

Allowing patients to receive prescriptions for controlled substances via telemedicine outside of a legitimate care setting would erode the Ryan Haight Act and invite rogue online pharmacies posing as telemedicine providers into the market. The National Council worries rogue actors would see this as a market opportunity to offer controlled substances based on a prescription issued via "telemedicine," but instead of providing real patient care, rogue sites would simply sell prescriptions on demand for controlled substances. Such a result is opposite of Congress's intent, of course, and contrary to the Ryan Haight Act itself, but a foreseeable consequence of allowing online prescribing of controlled substances to patients outside of legitimate care settings. As true when the Ryan Haight Act was passed in 2008, illegal online dispensing/prescribing of controlled substances is still a problem today:

a. In February 2018 the National Association of Boards of Pharmacy (NABP) reported that 54% of the online pharmacy websites they surveyed were selling controlled substances. This is a substantial jump from the 13% of all sites NABP has reviewed and listed as "Not Recommended" in the past nine years that were selling controlled substances.

b. The Alliance for Safe Online Pharmacies estimates that there are roughly 30,000 active online drug sellers operating at any one time. If NABP's finding that 54% of sites sell controlled substances holds true for the full online pharmacy market, that would mean more than 15,000 sites offer controlled substances at any one time.

c. The U.S. Senate Permanent Subcommittee on Investigations January 2018 report evidences how easy it is to buy illicit, mail-order opioids online. Investigators for the Subcommittee posed as would-be online buyers, entering terms like "fentanyl for sale" into Google and used payment information to track more than 500 US-linked transactions from these illegal sites.

d. Just last week a group of Senators led by Ryan Haight Act sponsor Senator Feinstein and Judiciary Chairman Senator Grassley sent a letter to Google, Microsoft, Pinterest and Yahoo discuss the rise illegal online sale of controlled substances.

Therefore, the National Council urges Congress to not authorize online prescribing of controlled substances to patients not located in a DEA-registered facility—whether an existing DEA-registered facility or a center registered pursuant to the Harper/Matsui or Carter/Bustos bills—as such risks making the opioid epidemic worse.

Conclusion

Thank you again for considering my testimony in support of the draft Harper/Matsui and Carter/Bustos bills that would enable legitimate community addiction and mental health treatment centers to register with DEA to be able to use telemedicine that involves issuance of a prescription for a controlled substance. Changing this law will have immediate and measurable impact on the lives of countless Americans seeking treatment options for mental health conditions and substance use disorder. I appreciate your time and attention to this important public health issue.

Appendices

- Appendix A: DEA Registration Form 224, for hospitals and clinics
- Appendix B: Memo from Texas Council of Community Centers describing previous efforts to register community mental health centers with DEA, drafted April 2016

Form-224

APPLICATION FOR REGISTRATION
Under the Controlled Substances Act

APPROVED OMB NO 1117-0014
FORM DEA-224 (04-12)
FORM EXPIRES: 01/31/2015

INSTRUCTIONS

Save time - apply on-line at *www.deadiversion.usdoj.gov*

1. To apply by mail complete this application. Keep a copy for your records.
2. Mail this form to the address provided in Section 7 or use enclosed envelope.
3. The "MAIL-TO ADDRESS" can be different than your "PLACE OF BUSINESS" address.
4. If you have any questions call 800-882-9539 prior to submitting your application.

IMPORTANT: DO NOT SEND THIS APPLICATION AND APPLY ON-LINE.

DEA OFFICIAL USE :

Do you have other DEA registration numbers?

☐ NO ☐ YES

MAIL-TO ADDRESS Please print mailing address changes to the right of the address in this box.

FEE FOR THREE (3) YEARS IS $731
FEE IS NON-REFUNDABLE

SECTION 1 APPLICANT IDENTIFICATION

☐ Individual Registration ☐ Business Registration

Name 1 (Last Name of individual -OR- Business or Facility Name)

Name 2 (First Name and Middle Name of individual - OR- Continuation of business name)

PLACE OF BUSINESS Street Address Line 1

PLACE OF BUSINESS Address Line 2

City State Zip Code

Business Phone Number Point of Contact

Business Fax Number Email Address

DEBT COLLECTION INFORMATION

Mandatory pursuant to Debt Collection Improvements Act

Social Security Number (*if registration is for individual*)

Provide SSN or TIN. See additional information note #3 on page 4.

Tax Identification Number (*if registration is for business*)

FOR Practitioner or MLP ONLY:

Professional Degree : *select from list only*

Professional School :

Year of Graduation :

National Provider Identification:

Date of Birth (*MM-DD-YYYY*):

SECTION 2 BUSINESS ACTIVITY

Check one business activity box only

☐ Central Fill Pharmacy	☐ Practitioner (DDS, DMD, DO, DPM, DVM, or MD)	☐ Ambulance Service
☐ Retail Pharmacy	☐ Practitioner Military (DDS, DMD, DO, DPM, DVM, or MD)	☐ Animal Shelter
☐ Nursing Home	☐ Mid-level Practitioner (MLP) (DOM, HMD, MP, ND, NP, OD, PA, or RPH)	☐ Hospital/Clinic
☐ Automated Dispensing System (ADS)	☐ Euthanasia Technician	☐ Teaching Institution

FOR Automated Dispensing System (ADS) ONLY:

DEA Registration # of Retail Pharmacy for this ADS

An ADS is automatically fee-exempt. Skip Section 6 and Section 7 on page 2. You must attach a notorized affidavit.

SECTION 3 DRUG SCHEDULES

Check all that apply

☐ Schedule 2 Narcotic	☐ Schedule 3 Narcotic	☐ Schedule 4
☐ Schedule 2 Non-Narcotic (2N)	☐ Schedule 3 Non-Narcotic (3N)	☐ Schedule 5

☐ Check this box if you require official order forms - for purchase of schedule 2 controlled substances.

SECTION 4

STATE LICENSE(S)

MANDATORY

Be sure to include both state license numbers

You MUST be currently authorized to prescribe, distribute, dispense, conduct research, or otherwise handle the controlled substances in the schedules for which you are applying under the laws of the **state** or jurisdiction in which you are operating or propose to operate.

State License Number ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ Expiration Date / / MM - DD - YYYY

What state was this license issued in? _____

State Controlled Substance License Number ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ Expiration Date / / MM - DD - YYYY

What state was this license issued in? _____

SECTION 5

LIABILITY

IMPORTANT

All questions in this section must be answered.

	YES	NO
1. Has the applicant ever been **convicted of a crime** in connection with controlled substance(s) under state or federal law, or been excluded or directed to be excluded from participation in a medicare or state health care program,or is any such action pending? Date(s) of incident MM-DD-YYYY: ☐☐-☐☐-☐☐☐☐	☐	☐
2. Has the applicant ever surrendered (for cause) or had a **federal** controlled substance registration revoked, suspended, restricted, or denied, or is any such action pending? Date(s) of incident MM-DD-YYYY: ☐☐-☐☐-☐☐☐☐	☐	☐
3. Has the applicant ever surrendered (for cause) or had a **state** professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending? Date(s) of incident MM-DD-YYYY: ☐☐-☐☐-☐☐☐☐	☐	☐
4. If the applicant is a **corporation** (other than a corporation whose stock is owned and traded by the public), association, partnership, or pharmacy, has any officer, partner, stockholder, or proprietor been **convicted of** a crime in connection with controlled substance(s) under state or federal law, or ever surrendered, for cause, or had a **federal** controlled substance registration revoked, suspended, restricted, denied, or ever had a **state** professional license or controlled substance registration revoked, suspended, denied, restricted or placed on probation, or is any such action pending? Date(s) of incident MM-DD-YYYY: ☐☐-☐☐-☐☐☐☐ *Note: If question 4 does not apply to you, be sure to mark 'NO'. It will slow down processing of your application if you leave it blank.*	☐	☐

EXPLANATION OF "YES" ANSWERS

Applicants who have answered "YES" to any of the four questions above **must provide a statement to explain each "YES" answer.**

Use this space or attach a separate sheet and return with application

Liability question # _____ Location(s) of incident: _____

Nature of incident:

Disposition of incident:

SECTION 6 **EXEMPTION FROM APPLICATION FEE**

☐ Check this box if the applicant is a federal, state, or local government official or institution. Does not apply to contractor-operated institutions.

Business or Facility Name of Fee Exempt Institution: **Be sure to enter the address of this exempt institution in Section 1.**

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Form - 224 APPLICATION FOR REGISTRATION SUPPLEMENTARY INSTRUCTIONS AND INFORMATION

SECTION 1. APPLICANT IDENTIFICATION - Information must be typed or printed in the blocks provided to help reduce data entry errors. A physical address is required in address line 1; a post office box or continuation of address may be entered in address line 2. Fee exempt applicant must list the address of the federal or state fee exempt institution.

Applicant must enter a valid social security number (SSN), or a tax identification number (TIN) if applying as a business entity. ***Debt collection information is mandatory pursuant to the Debt Collection Improvement Act of 1996.***

The email address, point of contact, national provider id, date of birth, year graduated, and professional school are new data items that are used to facilitate communication or as required by inter-agency data sharing requirements. They are requested in order to facilitate communication or as required by inter-agency data sharing requirements.

Practitioner must enter one degree from this list: DDS, DMD, DO, DPM, DVM, or MD.
Mid-level practitioner must enter one degree from this list: DOM, HMD, MP, ND, NP, OD, PA, or RPH.

SECTION 2. BUSINESS ACTIVITY - Indicate only one. Practitioner or mid-level practitioner must enter the degree conferred, and are requested to enter the last professional school of matriculation and the year graduated.

Automated dispensing system (ADS) must provide current DEA registration number of parent retail pharmacy or hospital, and attach a **notarized** affidavit in accordance with 21 CFR Part 1301.17. Affidavit must include:

1. Name of parent retail pharmacy or hospital and complete address
2. Name of Long-term Care (LTC) facility and complete address
3. Permit or license number(s) and date issued of State certification to operate ADS at named LTC facility
4. Required Statement:
   This affidavit is submitted to obtain a DEA registration number. If any material information is false, the Administrator may commence proceedings to deny the application under section 304 of the Act (21 U.S.C. 8224(a)). Any false or fraudulent material information contained in this affidavit may subject the person signing this affidavit, and the named corporation/partnership/business to prosecution under section 403 of the Act (21 U.S.C 843).
5. Name of corporation operating the retail pharmacy or hospital
6. Name and title of corporate officer signing affidavit
7. Signature of authorized officer

SECTION 3. DRUG SCHEDULES - Applicant should check all drug schedules to be handled. However, applicant must still comply with state requirements; federal registration does not overrule state restrictions. Check the order form box only if you intend to purchase or to transfer schedule 2 controlled substances. Order forms will be mailed to the registered address following issuance of a Certificate of Registration. The following list of drug codes are examples of controlled substances for narcotic and non-narcotic schedules 2, 3, 4, and 5. Refer to the CFR for a complete list of basic classes.

SCHEDULE 2 NARCOTIC	BASIC CLASS	SCHEDULE 3 NARCOTIC	BASIC CLASS	SCHEDULE 4	BASIC CLASS
Alphaprodine (Nisentil)	9010	Buprenorphine (Buprenex, Temgesic, Subutex	9064	Alprzolam (Xanax)	2882
Anileridine (Leritine)	9020	Codeine combo product up to 90 mg/du (Empirin)	9804	Barbital (Veronal, Plexonal, Barbitone)	2145
Cocaine (Methyl Benzoylecgonine)	9041	Dihydrocodeine combo prod 90 mg/du (Compal)	9807	Chloral Hydrate (Noctec)	2465
Codeine (Morphine methyl ester)	9050	Ethylmorphine combo product 15 mg/du	9808	Chlordiazepoxide (Librium, Libritabs)	2744
Dextropropoxyphene (bulk)	9273	Hydrocodone combo product (Lorcet, Vicodin)	9806	Clorazepate (Tranxene)	2768
Diphenoxylate	9170	Morphine combo product 50 mg/100ml or gm	9810	Dextropropoxyphene du (Darvon)	9278
Diprenorphine (M50-50)	9058	Opium combo product 25 mg/du (Paregoric)	9809	Diazepam (Valium, Diastat)	2765
Ethylmorphine (Dionin)	9190	**SCHEDULE 3 NON-NARCOTIC**	**BASIC CLASS**	Diethylpropion (Tenuate, Tepanil)	1610
Etorphine Hydrochloride (M-99)	9059	Anabolic Steroids	4000	Difenoxin 1mg/25ug atropine SO4/du (Motofen)	9167
Glutethimide (Doriden, Dorimide)	2550	Benzphetamine (Didrex, Inapetyl)	1228	Fenfluramine (Pondimin, Dexfenfluramine)	1670
Hydrocodone (Dihydrocodeinone)	9193	Butalbital (Fiorinal, Butalbital w/aspirin)	2100/2165	Flurazepam (Dalmane)	2767
Hydromorphone (Dilaudid)	9150	Dronabinol in sesame oil w/soft gelatin capsule	7369	Halazepam (Paxipam)	2762
Levo-alphacetylmethadol (LAAM)	9648	Gamma Hydroxbutyric Acid preps (Zyrem)	2012	Lorazepam (Ativan)	2885
Levorphanol (Levo-Dromoran)	9220	Ketamine (Ketaset)	7285	Mazindol (Sanorex, Mazanor)	1605
Meperidine (Demerol, Mepergan)	9230	Methyprylon (Noludar)	2575	Mebutamate (Capla)	2800
Methadone (Dolophine, Methadose)	9250	Pentobarbital suppository du & noncontrolled active ingred. (FP-3, WANS)	2271	Meprobamate (Miltown, Equanil)	2820
Morphine (MS Contin, Roxanol)	9300	Phendimetrazine (Plegine, Bontril, Statobex	1615	Methohexital (Brevital	2264
Opium, powdered	9639	Secobarbital suppository du & noncontrolled active ingredients	2316	Methylphenobarbital (Mebaral)	2250
Opium, raw	9600	Thiopental (Pentothal)	2100/2329	Midazolam (Versed)	2884
Oxycodone (Oxycontin, Percocet)	9143	Vinbarbital (Delvinal)	2100/2329	Oxazepam (Serax, Serenid-D))	2835
Oxymorphone (Numorphan)	9652			Paraldehyde (Paral)	2585
Opium Poppy / Poppy Straw	9650	**SCHEDULE 5**	**BASIC CLASS**	Pemoline (Cylert)	1530
Poppy Straw Concentrate	9670	Codeine Cough Preparation (Cosanyl, Pediacof)	9050	Pentazocine (Talwin, Talacen)	9709
Thebaine	9333	Difenoxin Preparation (Motofen)	9167	Phenobarbital (Luminal, Donnatal)	2285
SCHEDULE 2 NON-NARCOTIC	**BASIC CLASS**	Dihydrocodeine Preparation (Cophene-S)	9120	Phentermine (Ionamin, Fastin, Zantryl)	1640
Amobarbital (Amytal, Tuinal)	2125	Diphenoxylate Preparation (Lomotil, Logen)	9170	Prazepam (Centrax)	2764
Amphetamine (Dexedrine, Adderall)	1100	Ethylmorphine Preparation	9190	Quazepam (Doral)	2881
Methamphetamine (Desoxyn)	1105	Opium Preparation (Kapectolin PG)	9809	Temazepam (Restoril)	2925
Methylphenidate (Concerta, Ritalin)	1724			Triazolam (Halcion)	2887
Pentobarbital (Nembutal)	2270			Zolpidem (Ambien, Ivadal, Stilnox)	2783
Phencyclidine (PCP)	7471				
Phenmetrazine (Preludin)	1631				
Phenylacetone	8501				
Secobarbital (Seconal)	2315				

Form - 224 APPLICATION FOR REGISTRATION - CONTINUED - SUPPLEMENTARY INSTRUCTIONS AND INFORMATION

SECTION 4. STATE LICENSE(S) - Federal registration by DEA is based upon the applicant 's compliance with applicable state and local laws. Applicant should contact the local state licensing authority prior to completing this application. If your state requires a separate controlled substance number, provide that number on this application.

SECTION 5. LIABILITY - Applicant must answer all four questions for the application to be accepted for processing. If you answer "Yes" to a question, provide an explanation in the space provided. If you answer "Yes" to several of the questions, then you must provide a separate explanation describing the date, location, nature, and result of each incident. If additional space is required, you may attach a separate page.

SECTION 6. EXEMPTION APPLICATION FEE - Exemption from payment of application fee is limited to federal, state or local government official or institution. The applicant's superior or agency officer must certify exempt status. The signature, authority title, and telephone number of the certifying official (other than the applicant) must be provided. The address of the fee exempt institution must appear in Section 1.

SECTION 7. METHOD OF PAYMENT - Indicate the desired method of payment. Make checks payable to "Drug Enforcement Administration". Third-party checks or checks drawn on foreign banks will not be accepted. **FEES ARE NON-REFUNDABLE.**

SECTION 8. APPLICANT'S SIGNATURE - Applicant **MUST** sign in this section or application will be returned. Card holder signature in section 7 does not fulfill this requirement.

Notice to Registrants Making Payment by Check

Authorization to Convert Your Check: If you send us a check to make your payment, your check will be converted into an electronic fund transfer. "Electronic fund transfer" is the term used to refer to the process in which we electronically instruct your financial institution to transfer funds from your account to our account, rather than processing your check. By sending your completed, signed check to us, you authorize us to copy your check and to use the account information from your check to make an electronic fund transfer from your account for the same amount as the check. If the electronic fund transfer cannot be processed for technical reasons, you authorize us to process the copy of your check.

Insufficient Funds: The electronic funds transfer from your account will usually occur with 24 hours, which is faster than a check is normally processed. Therefore, make sure there are sufficient funds available in your checking account when you send us your check. If the electronic funds transfer cannot be completed because of insufficient funds, we may try to make the transfer up to two more times.

Transaction Information: The electronic fund transfer from your account will be on the account statement you receive from your financial institution. However, the transfer may be in a different place on your statement than the place where your checks normally appear. For example, it may appear under "other withdrawals" or "other transactions." You will not receive your original check back from your financial institution. For security reasons, we will destroy your original check, but we will keep a copy of the check for record-keeping purposes.

Your Rights: You should contact your financial institution immediately if you believe that the electronic fund transfer reported on your account statement was not properly authorized or is otherwise incorrect. Consumers have protections under Federal law called the Electronic Fund Transfer Act for an unauthorized or incorrect electronic fund transfer.

ADDITIONAL INFORMATION

No registration will be issued unless a completed application has been received (21 CFR 1301.13).

In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The OMB number for this collection is 1117-0014. Public reporting burden for this collection of information is estimated to average 12 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information.

The Debt Collection Improvements Act of 1996 (31 U.S.C. §7701) requires that you furnish your Taxpayer Identification Number (TIN) or Social Security Number (SSN) on this application. This number is required for debt collection procedures if your fee is not collectible.

PRIVACY ACT NOTICE. Providing information other than your SSN or TIN is voluntary; however, failure to furnish it will preclude processing of the application. The authorities for collection of this information are §§302 and 303 of the Controlled Substances Act (CSA) (21 U.S.C. §§822 and 823). The principle purpose for which the information will be used is to register applicants pursuant to the CSA. The information may be disclosed to other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes, State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes, and persons registered under the CSA for the purpose of verifying registration. For further guidance regarding how your information may be used or disclosed, and a complete list of the routine uses of this collection, please see the DEA System of Records Notice "Controlled Substances Act Registration Records" (DEA-005), 52 FR 47208, December 11, 1987, as modified.

Your Local DEA Office

CONTACT INFORMATION
All offices are listed on web site
(800, 877, and 888 are toll-free)

INTERNET
www.deadiversion.usdoj.gov

TELEPHONE
HQ Call Center (800) 882-9539

WRITTEN INQUIRIES:
DEA
Attn: Registration Section/ODR
P.O. Box 2639
Springfield, VA 22152-2639

Texas Council
of Community Centers

BACKGROUND HIGHLIGHTS

On April 15, 2014, the Texas Council was notified of an unfolding DEA issue at one of our Community Mental Health Centers (CMHCs) regarding a determination by a Drug Enforcement Agency (DEA) official that the Center's DEA registered psychiatrist was out of compliance with the Ryan Haight Act (RHA) relating to prescribing controlled substances via tele-medicine. This raised substantial concern not only for the cited CMHC, but for CMHCs across the state, the majority providing tele-psychiatry services.

Several attorneys surrounding the situation determined this DEA determination was a misunderstanding or misinterpretation of the RHA, noting the act exempts prescribing via tele-medicine. However, Texas Council legal counsel ultimately advised Texas CMHCs to accept the DEA determination and move toward resolution.

1. Following multiple communications and a June 24, 2014 meeting in East Texas with representatives from Texas CMHCs, Texas Department of Public Safety (TDPS) and the Drug Enforcement Agency (DEA), agreement was reached that Texas CMHCs should register their clinics with the DEA in order to realize the tele-medicine exemption cited in the RHA.

   NOTE: TDPS had previously determined that Texas CMHCs were exempt from registration requirements due to their governmental status, but in the course of deliberations with CMHCs and the DEA, they came to understand why the registration was necessary due to the negative impact on Texas tele-psychiatry practices as a result of the Ryan Haight Act.

2. As the registering authority in Texas, TDPS agreed to expedite Texas CMHC registrations and instructed the initial Texas CMHCs to register as Hospitals/Clinics on Form 224. On June 30, 2014, the first Texas CMHC submitted the registration as instructed by TDPS (see attached). In July, Mr. Richard Boyd, DEA Registration Section Chief, denied the registration with the stated reason that the "license" number provided on the application was "invalid and therefore DEA determined your application to be defective and is withdrawn. Please resubmit your application once you have the proper state authority".

   NOTE: the Texas Council was not able to obtain from DEA officials (or locate) a regulatory requirement for an entity to be licensed in order to receive DEA registration. In multiple exchanges with Mr. Boyd he referenced the need for evidence of "the state authority" for CMHCs. Texas Council legal counsel provided Mr. Boyd with the statutory authority of Texas CMHCs and advised him that TDPS conveyed this authority to the DEA by registering the Texas CMHCs, but this was not accepted by Mr. Boyd.

3. Another round of communications culminated in a September 9, 2014 meeting in Houston between Texas Council legal counsel, representatives of the Texas Health and Human Service Commission (HHSC), DEA representatives (Mr. Boyd joined by conference call) and other stakeholders impacted by the application of Ryan Haight Act on tele-psychiatry in Texas. From this meeting, Texas Council legal counsel understood the DEA would accept a letter from state officials describing the related authority of Texas CMHCs. Thus began a lengthy endeavor to

obtain a state agency letter describing the authority of Texas CMHCs, an endeavor that began with an educational process with Health and Human Services Commissioner and Department of State Health Services attorneys (who initially believed a registration path could be identified).

4. After several months of dialogue between Texas Council, HHSC officials, HHSC legal counsel (and, we understand, Mr. Boyd), on January 12, 2015 the HHSC Executive Commissioner issued a letter to the DEA describing the statutory authority of Texas CMHCs (see attached).

   Referenced Statute: http://www.statutes.legis.state.tx.us/Docs/HS/htm/HS.534.htm#534.001

5. The e-mail exchanges below, between Sonja Gaines, Texas HHSC Associate Commissioner for Mental Health Coordination, and Mr. Boyd, DEA Section Chief, begins with Mr. Boyd's response to the January 12, 2015 letter from Texas HHSC Executive Commissioner. As per this exchange, Mr. Boyd indicates that evidence of the "state authority" for Texas CMHC can only be met if the state puts in writing that Texas CMHCs are hospitals operating without a license (with licensure waived by the state). He would not accept that the Hospital/Clinic category was the closest category TDPS (as the DEA registering authority in Texas) had available in their on-line registration and that Texas CMHCs used this category to apply for registration of their tele-psychiatry clinics at the instruction of TDPS.

6. Although Mr. Boyd contends that he made clear all along that "state authority" meant licensed hospital, others involved in the various communications with Mr. Boyd never understood this was what he required in order to register the Texas CMHCs. This realization by the Texas Council effectively ended the quest for a letter from a state agency that would satisfy Mr. Boyd as the state agencies were clearly not in a legal position to state that Texas CMHCs are operating as "hospitals without licenses". This realization also effectively ended Texas Council hopes that we could register Texas CMHCs under current DEA regulations, as applied by Mr. Boyd.

7. On July 20, 2015 the Texas Council was notified that the DEA issued a notice of intent (excerpted below) to amend registration requirements to permit a special registration for "Practice of Telemedicine".

Title: •Special Registration to Engage in the Practice of Telemedicine

Abstract:

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (the Act) (Pub. L. 110-425) was enacted on October 15, 2008, and amended the Controlled Substances Act by adding various provisions to prevent the illegal distribution and dispensing of controlled substances by means of the Internet. Among other things, the Act required an in-person medical evaluation as a prerequisite to prescribing or otherwise dispensing controlled substances by means of the Internet, except in the case of practitioners engaged in the practice of telemedicine. The definition of the "practice of telemedicine" includes seven distinct categories that involve circumstances in which the prescribing practitioner might be unable to satisfy the Act's in-person medical evaluation requirement yet nonetheless has sufficient medical information to prescribe a controlled substance for a legitimate medical purpose in the usual course of professional practice. One specific category within the Act's definition of the "practice of telemedicine" includes "a practitioner who has obtained from the [DEA Administrator] a special registration under [21 U.S.C. 831(h)]." 21 U.S.C. 802(54)(E). The Act also specifies certain criteria that DEA must consider when evaluating an application for such a registration. However, the Act contemplates that DEA must issue regulations to effectuate this special registration provision. The DEA proposes to amend the registration requirements to permit such a special registration.

SELECT E-Mail Exchanges

[Texas HHSC Associate Commissioner Sonja Gaines & DEA Section Chief, Richard Boyd]

From: Gaines,Sonja (HHSC) [mailto:Sonja.Gaines@hhsc.state.tx.us]
Sent: Friday, February 06, 2015 7:30 PM
To: Danette Castle <dcastle@txcouncil.com>; Carvan Adkins <cadkins@toase.com>
Subject: Fwd: New Pending app W15007375B

Mr. Boyd got back with me. The dialogue is very promising. HHSC attorneys are actively engaged and working through me to get to a resolution. You can see the dialogue about waiving centers as hospitals. That may not be viable - attorneys working on an alternative I can present to Boyd.

More next week!

SONJA GAINES,MBA| ASSOCIATE COMMISSIONER
Mental Health Coordination |4900 N. Lamar Blvd. | Austin, Texas 78751
Office: 512.487.3417 Cell: 512-720-2086| sonja.gaines@hhsc.state.tx.us

---

From: "Gaines,Sonja (HHSC)" <Sonja.Gaines@hhsc.state.tx.us>
Date: February 6, 2015 at 11:31:09 AM PST
To: "Boyd, Richard A." <Richard.A.Boyd@usdoj.gov>
Subject: Re: New Pending app W15007375B

Great-we will work on a communication and hopefully get back with you by next week. Again, thank you so much for your clarification and assistance.

You have been a huge help.

SONJA GAINES,MBA| ASSOCIATE COMMISSIONER
Mental Health Coordination |4900 N. Lamar Blvd. | Austin, Texas 78751
Office: 512.487.3417 Cell: 512-720-2086| sonja.gaines@hhsc.state.tx.us

---

On Feb 6, 2015, at 11:27 AM, "Boyd, Richard A." <Richard.A.Boyd@usdoj.gov> wrote:

Yes- we would be able to use that letter in lieu of state license for proof that the state understands they will be operating as a DEA registered hospital and the state license is waived.

Richard Boyd
Section Chief
DEA Registration and Program Support

From: Gaines,Sonja (HHSC) [mailto:Sonja.Gaines@hhsc.state.tx.us]
Sent: Friday, February 06, 2015 2:24 PM
To: Boyd, Richard A.
Subject: Re: New Pending app W15007375B

Mr. Boyd,

Thanks so much for your assistance and the clarification.

Dr. Janek is the Executive Commissioner over DSHS as well as other state agencies. Would a communication from Dr.Janek regarding the referenced written waiver a a hospital ,meet the outcome you outlined below?

SONJA GAINES,MBA| ASSOCIATE COMMISSIONER
Mental Health Coordination |4900 N. Lamar Blvd. | Austin, Texas 78751
Office: 512.487.3417 Cell: 512-720-2086| sonja.gaines@hhsc.state.tx.us

---

On Feb 6, 2015, at 10:53 AM, "Boyd, Richard A." <Richard.A.Boyd@usdoj.gov> wrote:

Ms.Gaines- thank you for your prompt response.

DEA issues a DEA registration predicated upon state authority (21USC 823). For hospitals in TX that requires a DPS license and a license from DSHS and if they have a pharmacy on the premises, than a state license from the BOP.

The Community Centers are attempting to register with DEA without the state licenses as state authorized hospitals in order to conduct telemedicine, which requires, as an exception to the initial face to face dr/patient consultation, for the telemedicine to be conducted in a DEA registered hospital.

This was all explained to them in the Sept video conference we had and DEA even offered that if they get DSHS to provide DEA with written waiver for getting a DSHS license as a hospital, DEA can use that as the state authority. I hope that helps

Richard Boyd
Section Chief
DEA Registration and Program Support

-----Original Message-----
From: Gaines,Sonja (HHSC) [mailto:Sonja.Gaines@hhsc.state.tx.us]
Sent: Thursday, February 05, 2015 10:00 PM
To: Boyd, Richard A.
Subject: Re: New Pending app W15007375B

Mr. Boyd,

Thank you for your communication. Texas HHSC is committed to working with DEA to solve this registration dilemma. I have no doubt that the Texas Community Centers should be registered with DEA just as they are already registered with the Texas Department of Public Safety. You are correct that they are not hospitals, however, it is my understanding that DPS instructed the community centers to check the hospital box on the DPS form as that is the closest business activity label available on the DPS application.

These Community Centers are in fact governmental entities required by Texas law to treat individuals with severe and persistent mental illness throughout Texas. In their capacity as units of Texas government they do not require any additional state license in order to perform their state mandated tasks. These centers are a critical component of the Texas health care system and they are already registered under Texas law with regard to controlled substances. It is critical that they be registered with the DEA in order to comply with federal law. We just need to figure out how to make that happen.

You stated in your email communication that Commissioner Janek did not mention a waiver from the Texas hospital licensing requirements. As these centers are not required to be licensed as hospitals there is nothing to be waived by HHSC. I am unclear regarding your request for language waiving a requirement that does not exist under Texas law. HHSC is committed to working with DEA toward a viable solution to this registration dilemma, but I need your help in understanding why Commissioner Janek's January 12, 2015 letter was not sufficient for your purposes. Your assistance with what the letter needs to say is appreciated.

Thank you,

SONJA GAINES,MBA| ASSOCIATE COMMISSIONER Mental Health Coordination |4900 N. Lamar Blvd. | Austin, Texas 78751
Office: 512.487.3417 Cell: 512-720-2086| sonja.gaines@hhsc.state.tx.us

---

-----Original Message-----
From: Boyd, Richard A. [mailto:Richard.A.Boyd@usdoj.gov]
Sent: Thursday, February 5, 2015 9:59 AM
To: Gaines, Sonja (HHSC)
Cc: Sullivan, Lisa D.; Carter, Ruth A.; Mullins, Robert E.; Giacoppo, Maureen; Adams, Carolyn B.
Subject: FW: New Pending app W15007375B

Ms. Gaines- your name was listed on Dr Janek's letter as the POC for the attached issue. After reading the attached , I believe some pertinent facts were omitted in the discussion surrounding the issuance of a DEA registration for the state MH/MR facilities.

Several MH/MR have submitted DEA applications as a hospital to obtain a DEA registration as a Texas hospital. All of these applications have been denied since there was no state licenses issued to those facilities by the DSHS, DPS and the BOP. All of the 1,378 hospitals in Texas have those licenses, including other state operated facilities.

The federal Controlled Substance Act 21 USC 823 requires that the entity registering with the DEA, for a DEA registration. to obtain state authority before the DEA can issue a registration. Numerous discussions /email have reiterated this requirement to the MH/MR facilities and their attorney. To date these facilities have not properly registered with the Texas authorities to recognize their authority to operate as a hospital under Texas law. Since these facilities have no state licensure, DEA cannot issue a DEA registration for the MH/MR as hospitals.

Dr Janek correctly pointed out that the MH/MR must comply with all applicable laws and regulatory requirements regarding controlled substances. To date MH/MR has failed to comply with both state and federal requirement to obtain a DEA registration. The attached letter contains no waiver of Texas requirements to be licensed as a hospital.

Please let me know if you have any other questions.

Richard Boyd
Section Chief
DEA Registration and Program Support

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 synthetic 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 of 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 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:]

Testimony of Thomas Cosgrove, Covington & Burling LLP (Feb. 28, 2018)
Before the House E&C Health Subcommittee on the "Tableting and Encapsulating Machine Regulation Act of 2018"

Thank you to Chairman Burgess, Ranking Member Green and Members of the Subcommittee for the opportunity to testify today. My name is Thomas Cosgrove, and until late last year, I was an official at the Food and Drug Administration (FDA) responsible for Current Good Manufacturing Practices (CGMP) enforcement and compliance within the Center for Drug Evaluation and Research (CDER). In that role, I was responsible for ensuring manufacturing and quality 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 LLP. 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, but the views expressed today are my own.

I am here today to testify on what I think could be the unintended consequences of the draft bill, the "Tableting and Encapsulating Machine Regulation Act of 2018" and to suggest perhaps a more tailored approach. From my prior role as an FDA official, I have a perspective on the overlapping systems of regulation applicable to manufacturers of drugs, dietary supplements, and other products regulated by FDA. As the Director of the Office of Manufacturing Quality at FDA CDER, I supervised the review of FDA drug facility inspections and made decisions within CDER on whether to recommend administrative or civil enforcement actions in cases of significant regulatory violations. Many of the cases reviewed in the Office of Manufacturing Quality involved tableting or encapsulating operations in the United States and abroad. The Office of Manufacturing Quality was also responsible for enforcement decision making under the Food, Drug and Cosmetic Act (FDCA) in connection with manufacturers of approved and lawfully manufactured controlled substances.

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 and opioid analogs from overseas through 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.

The approach proposed in the draft bill is to regulate tableting and encapsulating machines the same as controlled substances. I am concerned that this approach would significantly and unnecessarily increase regulatory burdens on lawful U.S. manufacturers of tableted and encapsulated products. More importantly, it could harm patients and consumers by potentially disrupting the supply of medicines and other products, and at the very least it could increase consumer prices. I believe the Drug Enforcement Administration (DEA) should continue to investigate individuals who manufacture illicit substances using tableting machines and any future expansion of the regulation of tableting and encapsulating machines should be more narrowly tailored than the approach proposed in the draft bill.

Virtually all manufacturers of "solid oral" drugs in the United States use tableting or encapsulating machines in some form. 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. For instance, the majority of vitamins sold in the United States are tableted or encapsulated. One need only to walk down the

health and wellness aisle of a 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. The collective dollar value of these product sales in the United States is enormous and people use them every day.

Tableting and encapsulating machines are essential to manufacture these products. A tableting machine operates by compressing a substance, generally a granulated powder mixture, using great force into the form of a solid tablet. An encapsulating machine is used to fill soft or hard gelatin capsules with a substance, generally granules, semi-solids or liquids. These machines are carefully designed to ensure that tablets and capsules are consistently the same size, shape, and weight. With respect to drugs, one of the jobs of FDA is to ensure through inspections that manufacturers making tablets and capsules are able to consistently deliver the same dose of drug to patients across the millions of unit doses they may manufacture.

The Controlled Substances Act (CSA) and DEA's regulations have been carefully crafted to prevent controlled substances from being diverted for illegal activity while ensuring they remain available for legal medical and scientific uses. These laws designed to govern substances, however, may not be well suited to regulating tableting and encapsulating machines. The CSA requires sensible and careful control over controlled substances themselves throughout the drug manufacturing process, but it is unclear how such controls could sensibly apply to equipment used by countless U.S. manufacturers that supply necessary products to nearly all Americans.

For example, were the draft bill to be enacted as now written, lawful domestic manufacturers using tableting and encapsulating machines to produce legally marketed, non-controlled products (including non-drug products) 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 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, such as electronically monitored safes, steel cages, or vaults that meet certain specifications. Manufacturers hoping to dispose of or replace malfunctioning machines could need to transfer machines to companies specifically registered by DEA to render the machines "non-retrievable." In addition, manufacturers might need to comply with additional recordkeeping and paperwork requirements each time they move a machine from one location to another, even between two company-owned properties within the same state. These requirements could be unworkable for manufacturers operating large industrial tableting and encapsulating machines integrated within production lines.

Such requirements if enacted would greatly increase regulatory burdens for domestic manufacturers and make everyday products less available to consumers. For instance, although manufacturers of drugs and dietary supplements are already used to a high degree of regulation by FDA, additional requirements imposed by the draft bill could be costly and unwieldy. FDA inspects manufacturing facilities to ensure that equipment such as tableting machines are operating within the scope of Current Good Manufacturing Practices under applicable law and regulations. FDA does not, however, require registration of individual pieces of equipment. Drug, dietary supplement, and other manufacturers have a great deal of flexibility in selecting or changing out the equipment they use, which flexibility could disappear if this bill were enacted as drafted.

Regulating this equipment itself as a controlled substance could be a fundamental and expensive change. Domestic manufacturers could incur direct costs of machine registration, recordkeeping, security, and disposal and indirect costs from training, education, and audits to ensure compliance with the CSA. These additional burdens could increase the costs for manufacturers to produce their products in the United States compared to manufacturing their products abroad, where tableting and encapsulating machines would not be subject to the CSA's controlled substance requirements. We live in a time where there is already enormous pressure on drug manufactures to move their operations overseas for cost reasons. In fact, one of FDA's main challenges today is keeping up with the explosion of drugs 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. Existing manufacturers of medicines that are controlled substances should already have systems in place to ensure that the controlled substances themselves are handled in accordance with DEA rules. Companies that have nothing to do with controlled substances now, which constitute the vast majority of companies that use tableting and encapsulating machines, would have to develop CSA-compliant systems from scratch. This could lead to higher costs to consumers and potentially even drug shortages.

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 (CDTA). Under the CSA as amended by the CDTA, DEA already has a role in connection with the distribution, importation, or exportation of a tableting machine or encapsulating machine. Under existing law, each person selling a tableting or encapsulating machine must report the transaction to DEA. Each person must also file a report to DEA before importing or exporting a machine. DEA may deny entry to any unregistered shipment of tableting or encapsulating machines.

The FDA also has broad powers to regulate drug manufacturing facilities using tableting and encapsulating machines under existing provisions of the FDCA. FDA regularly inspects manufacturing facilities to ensure that equipment, including tableting and encapsulating machines, is functioning properly and being used for legal activities. FDA has authority to take action if it encounters drugs being counterfeited, including counterfeited opioids and other controlled substances. From my own experience, I believe that FDA would be poised to take quick action in concert with DEA if it found a manufacturer under its jurisdiction illegally manufacturing a controlled substance.

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 understand better 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, but 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 again for the opportunity to testify and I would be happy to take any questions.

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 American 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:]

Statement by Andrew Kolodny, MD
Director, Physicians for Responsible Opioid Prescribing (PROP)
Co-Director, Opioid Policy Research Collaborative, Brandeis University

on

Combatting the Opioid Crisis

before

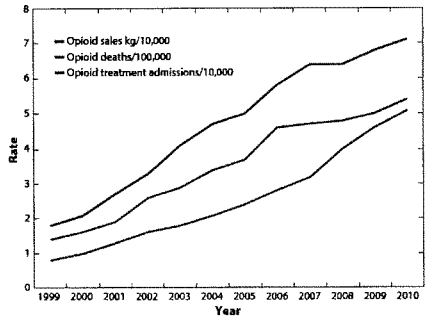
Committee on Energy & Commerce,
Subcommittee on Health
U.S. House of Representatives
February 28, 2018

Chairman Burgess, Ranking Member Green, and Members of the Health Subcommittee, thank you for the opportunity to testify today on measures to address the opioid crisis. The opioid crisis is best understood as an epidemic of opioid addiction. When I use the term "epidemic" I am referring to the very sharp increase in the number of Americans suffering from opioid addiction that occurred over the past 20 years. From 1997 to 2011, there was a 900% increase in the number of Americans seeking treatment for addiction to prescription opioids. It is the increased prevalence of opioid addiction that explains why we are experiencing record high levels of opioid-related overdose deaths. It is the reason we are seeing heroin and fentanyl flood into our communities. It is the reason we have seen a soaring increase in infants born opioid dependent and children entering the foster care system and outbreaks of injection-related infectious diseases and an impact on our workforce.

When the opioid crisis is framed properly, as an epidemic of addiction, the strategies for bringing the epidemic to an end become clear. We must 1) prevent more Americans from becoming opioid addicted and 2) we must ensure easy access to effective addiction treatment. In particular, we must ensure that buprenorphine, the first-line treatment for opioid addiction, is easier to access than painkillers, heroin or fentanyl. At present access to buprenorphine is inadequate. Not enough doctors are able to prescribe it. And of those who do, very few accept commercial insurance or Medicaid. The patient's Medicaid or commercial insurance will pay for their buprenorphine prescription but patients must often pay out of their own pocket for the visit to the doctor. If we want more patients to seek treatment, it needs to cost less than a bag of heroin. Until that happens, I believe opioid overdose deaths will remain at historically high levels.

I would like 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 co-sponsors for introducing this legislation.

The need for this law becomes clear when we look at the cause of our opioid addiction epidemic, a topic the Centers for Disease Control and Prevention (CDC) has been very clear about. The CDC has shown that a sharp increase in prescriptions for opioids resulted in a corresponding rise in addiction and overdose deaths.



This is a CDC graph. The green line represents opioid prescribing, the red line represents opioid deaths, and the blue line represents opioid addiction. As the green line went up, as opioid prescriptions started to soar, it led to parallel increases in addiction and overdose deaths.

The reason the green line began rising, the reason the medical community began prescribing so aggressively, is because we (doctors) were responding to a brilliant, multi-faceted marketing campaign that changed the culture of opioid prescribing. Starting in the 1990s, we began hearing that patients were suffering because we were too stingy with opioids. We began hearing that we should stop worrying about addiction. We began hearing that even with long-term use, the risk that a patient would get addicted was much less than 1%. We began hearing that opioids were safe and effective for chronic pain and that we could improve the quality of life in our patients if we prescribed more liberally. We began hearing that opioids are a gift from mother nature and should be used much more for just about any complaint of pain.

We would have been less gullible if we were only hearing these messages from drug company sales reps. But we were hearing these messages from pain specialists eminent in the field of pain medicine, from the Joint Commission, which accredits our hospitals, and we were hearing these messages from our professional societies—all of whom had financial relationships with opioid manufacturers. More than any other organizations, it was efforts by American Pain Society and the American Academy of Pain Medicine that were most damaging. My greatest concern with H.R. 2063 is that it relies on these organizations and other professional societies with pharmaceutical company ties to provide mandatory prescriber education.

One of the most important lessons from this crisis is the need for strict firewalls between pharmaceutical company marketing and medical education. Had pharmaceutical marketing not been so effectively disguised as education, we might not have an opioid addiction epidemic today. Professional societies with financial ties to pharmaceutical companies should not be offering government-mandated prescriber education.

It may be hard for you to believe that in the midst of our opioid addiction epidemic, doctors are still overprescribing, but they are. The United States continues to prescribe far 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 invested in correcting 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 that do not accept funding from drug companies.

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 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:]

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION
WWW.NCPANET.ORG

United States House of Representatives Energy and Commerce Committee

Subcommittee on Health Hearing

"Combating the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety"

Written Testimony of:

Richard N. Logan, Jr., PharmD, Pharmacist/Owner, Logan + Seiler, Inc.

Drug Diversion Investigator (Retired), Mississippi County Sheriff's Department, Charleston, Missonri

On Behalf of the National Community Pharmacists Association (NCPA)

February 28, 2018

Chairman Burgess, Ranking Member Green and Members of the Subcommittee:

Thank you for conducting this hearing on the opioid crisis and providing me the opportunity to share my views and personal experiences. My name is Richard Logan and I have been a community practice pharmacist since 1975, owning two pharmacies in Southeast Missouri. Additionally, I am a recently retired drug diversion investigator for the Mississippi County, Missouri Sheriff's Department. I have taught officers techniques of drug diversion investigation and have strived to raise awareness of prescription drug abuse in Missouri.

100 Daingerfield Road
Alexandria, VA 22314-2888
(703) 683-8200 PHONE
(703) 683-3619 FAX

I am a member of the National Community Pharmacists Association (NCPA) and have been awarded the NCPA Prescription Drug Safety Award in recognition of my work in educating my community on the beneftis of the correct use of prescription drug products and the hazards associated with their misuse.

NCPA represents America's community pharmacists, including the owners of more than 22,000 independent community pharmacies. Together they represent an $80 billion health care marketplace and employ more than 250,000 individuals on a full or part-time basis. I am here today as a healthcare provider, small business owner and retired drug diversion investigator to present some of my experiences and viewpoints, focusing on viable solutions to prevent drug abuse and diversion while maintaining legitimate patient access.

In this statement, NCPA would like to present thoughts on important issues surrounding the opioid epidemic and appreciates the opportunity to offer recommendations that should be considered to respond to the nation's opioid crisis. Independent community pharmacies play a critical role in ensuring patients have immediate access to medications. Our members have extensive knowledge and experience in caring for patients with chronic pain as well as those in their communities with substance use disorders.

NCPA is committed to working collaboratively with Members of Congress, the Administration, and other stakeholders in adopting viable solutions to prevent drug abuse and diversion. Pharmacists ensure proper medication use and abide by the rules contained in the Controlled Substances Act. Pharmacists perform their due diligence each time they fill a prescription and have a corresponding duty of care as does the prescriber.

As the final check-point in the system of checks and balances, pharmacists play a vital role in ensuring all medications, including controlled substances, are appropriate for their patients. Community pharmacists play an increasingly important role in monitoring for signs of prescription drug abuse and criminal activity, and must separate prescription drug use, misuse, abuse, and criminal behavior. Most importantly, pharmacists must monitor all their patients and work in collaboration with other health care providers, keeping the best interest of the patient at the center of all decisions.

Professional collaboration is key to ensure controlled substances are being prescribed and dispensed and used correctly. It may be the case where a prescriber is unaware of other controlled substance prescriptions a patient is taking and pharmacists need to communicate any concerns to the prescriber.

NCPA participated several years ago in a coalition of stakeholder organizations representing the medical, pharmacist, and supply chain spectrum highlighting the challenges and "red flag" warning signs related to prescribing and dispensing controlled substance prescriptions. A consensus document was released with the goal of providing health care practitioners with an understanding of their shared responsibility to ensure that all controlled substances are prescribed and dispensed for a legitimate medical purpose, as well as to provide guidance on which red flag warning signs warrant further scrutiny.

The consensus document is a good tool for healthcare providers, but at the end of the day pharmacists are not law enforcement officers. Criminals who engage in drug seeking behavior can be dangerous and it's important that pharmacists develop a relationship with local law enforcement and alert them when appropriate.

NCPA believes there are efforts in the marketplace that are currently making a difference in the battle against opioid abuse and are scalable. Also, there are promising policies that Congress or the Administration could move forward that would have a positive impact on mitigating or preventing abuse, without compromising legitimate patient access to needed pain medications.

One such policy is included in H.R. 4275, *the Empowering Pharmacists in the Fight Against Opioid Abuse Act*, introduced by Representatives Mark DeSaulnier (D-Calif.) and Buddy Carter (R-Ga.), to provide for development and dissemination of programs and materials for training pharmacists, health care providers, and patients on indicators that a prescription is fraudulent, forged, or otherwise indicative of abuse or diversion.

H.R. 4275 requires the Administrator of the Drug Enforcement Administration (DEA) work in consultation with the Secretary of Health and Human Services (HHS), the Commissioner of Food and Drugs (FDA), the Director of the Centers for Disease Control and Prevention (CDC), and the Assistant Secretary for Mental Health and Substance Use (SAMHSA), to develop and disseminate programs and materials for training pharmacists, health care providers and patients. The training programs and materials would discuss circumstances under which a pharmacist may decline to fill a prescription for a controlled substance because the pharmacist suspects the prescription is fraudulent, forged, or otherwise indicative of abuse or diversion. In developing the training programs and materials the DEA Administrator must seek input from relevant national, state, and local associations, boards of pharmacy, medical societies, licensing boards, health care practitioners, and patients.

NCPA supports such an effort to bring greater clarity and education to other health care providers and patients regarding a pharmacist declining to fill a controlled substance. Even though pharmacists currently have the right to decline filling any controlled substance as part of their corresponding responsibility per the Controlled Substances Act, it is important to educate patients and entities such as insurance companies and pharmacy benefit managers on such circumstances.

It is also important for the DEA to provide greater clarity and update its regulations and guidance surrounding laws currently in place, such as Section 702 of the Comprehensive Addiction and Recovery Act (CARA), which amended the Controlled Substances Act to enable patients or physicians to request a "partial fill" of any Schedule II medication. However, it is our understanding that to date DEA has provided no clarity, updated regulations or guidance surrounding this provision.

NCPA's other recommendations for solutions to address the opioid crisis include the following:

Expand Consumer Access to Naloxone: NCPA supports and advocates for pharmacists to participate in wider distribution of naloxone under pathways approved by state regulatory boards. The least restrictive means to increasing access to naloxone is to allow pharmacists to directly prescribe.

Establish Limits on Maximum Day Supply for Certain Controlled Substances: Federal or state based policies to limit initial fills of opioids should be standardized for consistent implementation, taking into consideration certain patient populations, such as hospice patients and those residing in skilled nursing facilities.

Any policy to limit initial fills of opioids should include a list of circumstances in which a prescriber be allowed to deviate from the mandate.

Prohibit Certain Controlled Substances from Being Delivered to Patients via Physician Offices or via Mail: Prohibiting delivery of controlled substances to patients via physician offices or the mail is another policy that can have a positive impact on mitigating or preventing abuse by offering added assurances against diversion. Utilizing the triad of care between a prescriber, pharmacist and patient is vital with opioid therapies.

Expand Electronic Prescribing of Controlled Substances: NCPA also supports expanding electronic prescribing of controlled substances via requiring prescriptions for controlled substances to be electronically prescribed where feasible.

Enhance Prescription Drug Monitoring Programs: We also support enhancing prescription drug monitoring programs by increasing operability of robust electronic databases to track all prescriptions for controlled substances. National standards to provide timely, reliable information at point of prescribing and dispensing should also be leveraged.

Increase Health Care Provider Education: Increasing health care provider education should be a priority. For any required prescriber education program, a verification infrastructure with minimal administrative burden should be considered.

For example, automatic checks related to prescriber status on completion of educational requirements prior to transmission of impacted prescriptions and mechanisms for pharmacists to be informed about the requirements of the program must be considered. We would offer the Transmucosal Immediate Release Fentanyl (TIRF) REMS program as an example. The pharmacist's role is to provide continuity of education and monitoring.

Increase Use and Access to Medication Assisted Treatment: NCPA supports expanding practitioner eligibility for DATA waivers, including pharmacists. Advancement of the pharmacist's role in MAT for opioid use disorders can help improve access and outcomes, while reducing the risk of relapse. Pharmacists are already partnering with physicians to provide MAT. When such relationships form, pharmacists have taken the lead in developing treatment plans, communicating with patients, improving adherence, monitoring patients, identifying treatment options and performing tasks to alleviate the physician' burden. Thus, pharmacists have both the knowledge and experience to provide MAT but treatment is limited because of regulatory barriers.

Expand the Ability of Pharmacies to Identify Individuals with Substance Use Disorders: Pharmacists should be allowed to participate in SBIRT or Screening, Brief, Intervention and Referral to Treatment activities. For example, Virginia Medicaid's Addiction Recovery Treatment Services (ARTS) is a transformative new benefit being offered for Medicaid patients. The benefit includes coverage for SBIRT provided by pharmacies. The purpose of SBIRT is to identify individuals who may have alcohol and/or other substanee use problems. Following screening, a brief intervention is provided to educate individuals about their use, alert them to possible consequences and, if needed, begin to motivate them to take steps to change their behavior.

Conclusion

NCPA greatly appreciates the opportunity to share our recommendations on ways to respond to the nation's opioid crisis. NCPA stands ready to work with all stakeholders to stem the growing tide of opioid abuse and overdose.

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.

Mr. WALDEN. 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.

Mr. WALDEN. Which is the most deadly?

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

Mr. WALDEN. 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.

Mr. WALDEN. 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——

Mr. WALDEN. 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.

Mr. WALDEN. What is the youngest age that you have seen either——

Chief FOWLER. Quite young.

Mr. WALDEN. 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.

Mr. WALDEN. 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 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.

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

Mr. NANCE. Sure.

Mr. WALDEN. 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.

Mr. WALDEN. And so, broadly speaking, do you feel like your department has the tools you need when your team comes across illicit synthetic drugs? 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.

Mr. WALDEN. Right.

Chief FOWLER. 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——

Mr. WALDEN. 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——

Mr. WALDEN. Against Spike?

Chief FOWLER. Excuse me?

Mr. WALDEN. Against Spike.

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

Mr. WALDEN. What is the penalty?

Chief FOWLER. It is a violation, so——

Mr. WALDEN. Oh, it is a traffic ticket, in effect.

Chief FOWLER. Basically, sir.

Mr. WALDEN. So it is not a deterrent, to speak of?

Chief FOWLER. Not at all. Not at all.

Mr. WALDEN. 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.

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 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 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, 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 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 side effects 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 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 crush and flush the pills, or in case of liquid opioids, just put them down the sink and turn the faucet on. That is what they did.

In later years, when they said, oh, maybe we shouldn't be doing 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, 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, 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. OK.

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 commu-

nity 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 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 psychiatrists 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. OK. 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. OK.

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. OK. I would defer to her on the answer.

Mr. BUCSHON. All right. OK. I didn't like her answer, but that is OK.

Mr. Nance.

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

Mr. BUCSHON. Yes.

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. Yes, what SAMHSA has done is 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. Yes.

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. OK. Now, HHS would increase the therapy—the number of people. Has that been implemented? I mean from 100 to any practice to 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. OK. That is good to hear. Doctor—yes 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 [continuing]. And taking care of these patients.

Mr. BUCSHON. Yes, I agree. In fact, this next question is for you. For long-acting buprenorphine, are 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. Yes, 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 talking about continuing education for physicians. Is there anything the Federal Government can do to encourage, maybe, what I would call ground-level training, which is not after people who 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 [continuing]. Who had it drilled into them for 15 years that 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 went into practice in 1995. We all understood that.

Dr. Kan, last question real quick. The existing laws in-person medical evaluation as well as allowable exemptions, you explained in your testimony that the in-person evaluation committee excepted 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 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 Controlled Substances Act.

Mr. GREEN. OK.

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. OK. 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 re-

searchers, 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, 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. OK. 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 follow up. 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 Combating 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 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, 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. 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 emphases 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 recognizes 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 appreciate everybody's testimony today. It has been very informative.

Dr. Beardsley, if I might 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. Yes. 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 longer written 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. OK. You referenced a Virginia program, Virginia's Medicaid Addiction Recovering Treatment Services has a new benefit for Medicaid patients which 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. OK. 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 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 up 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—buildings are very close together. And yet I have to have four Schedule I registrations, four Schedule II to V 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. 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 have 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 matriculate 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. Yes, the whole point of my testimony is that, especially in rural and frontier areas——

Mr. CARTER. Absolutely.

Mr. NANCE [continuing]. 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. OK. 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. OK. 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. OK.

Mr. LOGAN. And prescribes blame to over-prescribers.

Mr. CARTER. OK. 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 to 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. OK.

Mr. COSGROVE [continuing]. 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. OK.

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. OK. 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 lines 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 the take-back provisions in which, if they are going to receive these medications, whether for the purpose of 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 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, our hospice operates in a facility. We do not have that same restriction.

Mr. WALBERG. OK. 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 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. OK. Well thank you. I appreciate the entire 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 preventable 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 doctors are 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 preventable 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. Yes, 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 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. 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 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 2 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—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 controlled 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 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 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 is 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. 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—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 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 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. Yes. One thing. I had a constituent 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. 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 appears at the conclusion of the hearing.]

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.]

[Material submitted for inclusion in the record follows:]

UNIVERSITY OF CALIFORNIA, SAN DIEGO UCSD

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO SANTA BARBARA • SANTA CRUZ

ADAM L. HALBERSTADT, Ph.D.
ASSISTANT PROFESSOR

DEPARTMENT OF PSYCHIATRY
UNIVERSITY OF CALIFORNIA, SAN DIEGO
9500 GILMAN DRIVE
LA JOLLA, CALIFORNIA 92093-0804
TELEPHONE: (412) 608-4960
FAX: (619) 543-2493
Email: ahalbers@ucsd.edu

February 27, 2018

RE: Comments on the SITSA Act

Our nation is facing an unprecedented epidemic of opioid abuse. Nevertheless, while I appreciate the attention Congress is giving to this issue, I am concerned that the SITSA Act will have unintended consequences for scientific research and drug discovery.

The SITSA Act allows substance to be controlled based on their structural similarity to controlled substances or their predicted pharmacological properties. Unfortunately, it is not always possible to reliably predict the pharmacological properties of new substances based solely on their structural features. Although structure-activity relationships have been defined for many drug classes, it is often the case that pharmacologists do not fully understand the molecular interactions between drugs and their biological targets, meaning that predictions about the pharmacology of novel substances must be confirmed empirically through experimental testing. Slight changes in the molecular structure of a drug can potentially markedly alter its pharmacological properties, often in unexpected or novel ways.

There are many controlled substance analogs that have been discovered to have unexpected, therapeutically useful pharmacological properties, demonstrating why it is necessary to confirm pharmacological predictions with biological testing. The following examples are illustrative:

(1) 3-Fluorofentanyl. It was recently reported in the journal *Science* that 3-fluorofentanyl is a potential non-addictive painkiller. Although 3-fluorofentanyl binds to the same primary target as the narcotic fentanyl — a protein known as the mu opioid receptor — it does so in a manner that restricts the interaction to injured tissues. Experimental testing indicates that 3-fluorofentanyl lacks abuse potential in rodents. Nevertheless, in the absence of experimental data, 3-fluorofentanyl and similar substances would likely be scheduled as controlled substance analogs under the regulations promulgated by the SITSA Act.

(2) UWA-101. UWA-101, a close structural analog of the Schedule I substance MDMA (Ecstasy), was recently developed as a potential treatment for Parkinson's disease. Testing has confirmed that UWA-101 does not produce MDMA-like effects in rodents, meaning that it is unlikely to have abuse potential in humans. Nevertheless, UWA-101 has pharmacological properties that are similar to those of MDMA, so the possibility exists that UWA-101 could be controlled as an MDMA analog under the SISTA Act. The case of UWA-101 is another example that shows why biological testing is necessary in order for the government to make accurate and informed scheduling decisions.

(3) Lisuride. Lisuride is a structural analog of LSD and these two drugs have virtually identical pharmacological properties. Nevertheless, lisuride does not produce hallucinogenic effects in humans and has actually been used in some countries as a treatment for Parkinson's disease and migraine. Although lisuride and LSD interact with the same primary target in the brain (the 5-HT_{2A} receptor), evidence indicates that they do so in subtly different ways, potentially explaining why lisuride does not produce hallucinogenic effects. Unfortunately, scientists are just beginning to understand how LSD interacts with the 5-HT_{2A} receptor and not enough is known about these interactions at the molecular level to reliably predict whether a new analog in this structural class will produce hallucinogenic effects or will mimic the effects of lisuride.

(4) BOL-148. Similar to lisuride, an analog of LSD known as BOL-148 (2-bromo-LSD) interacts with the 5-HT_{2A} receptor but does not produce hallucinogenic effects. Case reports published in the journal *Cephalagia* in 2010 indicate that BOL-148 may be an effective treatment for cluster headaches, which is an extremely debilitating medical condition.

(5) DOI. DOI is a structural analog of several hallucinogens regulated as Schedule I substances, including 4-methyl-2,5-dimethoxyamphetamine (DOM). According to recent reports in the scientific literature, DOI has potent anti-inflammatory effects, potentially making it a useful treatment for arthritis and asthma. The anti-inflammatory effects of DOI were discovered serendipitously — DOI happened to be available in the laboratory conducting this research and it was tested based on a hunch. At that time, there was no other evidence that DOI has anti-inflammatory effects and other chemicals in this class do not produce this effect. It is unlikely that this effect of DOI would have been discovered if it had been scheduled as a controlled substance analog.

(6) Loperamide. The anti-diarrheal loperamide, which is marketed over the counter in the USA under the brand name Imodium™, is an analog of diphenoxylate (a Schedule II narcotic) and diphenoxin (a Schedule I narcotic). Loperamide is a potent agonist at the mu opioid receptor but has little abuse potential because it is actively removed from the brain by a transport protein. Loperamide is yet another example that shows how structural features are not always a reliable predictor of abuse potential.

I am concerned about the repercussions of loosening the criteria for scheduling analogs of controlled substances. To date, several substances that have undergone emergency scheduling were later determined to have no abuse potential. Examples include benzylfentanyl and thenylfentanyl, which were emergency scheduled by the DEA in November 1985, and trifluoromethylphenylpiperazine, which was emergency scheduled in September 2002. Although such erroneous emergency scheduling actions have been rare, the changes to the CSA proposed in the SITSA Act will greatly increase the likelihood that substances lacking abuse potential are erroneously scheduled.

Unfortunately, erroneous scheduling actions have detrimental consequences for science and medicine. Scheduling all compounds that are even remotely related to drugs of abuse as controlled substance analogs will hinder promising research efforts to discover new therapeutic agents. Furthermore, many important "tool compounds" that are routinely used by scientific researchers to study drug responses are structurally related to controlled substances. Although these compounds lack abuse potential, I fear that the availability and use of many of these important tools will be restricted under the regulatory regime proposed in the SITSA Act. The SITSA Act does contain a research exemption, but it does not make sense, in my opinion, to place restrictions on research with these substances unless they actually have abuse potential.

Another aspect of the SITSA Act that would likely harm scientific research is the provision requiring researchers to register as manufacturers in order to distribute Schedule A compounds for use by collaborators at other research institutions. Currently, Schedule 1 researchers are not required to register as manufacturers in order to distribute these substances to collaborators who are licensed by the DEA to work with the same substances. Under the CSA, manufacturers have very burdensome security requirements because they often work with substances in bulk quantities; by contrast, it is not practical for researchers to register as manufacturers in order to synthesize and distribute small quantities of scheduled substances to collaborators. This particular regulation would likely limit the availability of Schedule A substances for research. Although some researchers will be able to synthesize the substances themselves or obtain them from colleagues at the same institution, neither of those options will be feasible for most investigators.

In summary, I am concerned that legitimate research will be hindered by scheduling all compounds that are structurally related to drugs of abuse. Furthermore, it is not clear that new legislation is necessary in light of the recent emergency scheduling action by the DEA to control an entire structural class of fentanyl analogs. Thank you for considering my thoughts on this important issue. If you would like to discuss this matter further, please feel free to contact me.

Sincerely,



Adam L. Halberstadt, Ph.D.

THE COLLEGE ON PROBLEMS OF DRUG DEPENDENCE, INC.
3420 N. Broad Street, Room 324, Philadelphia, PA 19140-5104
Telephone: 215-707-3242 • Fax: 215-707-1904 • Website: http://www.cpdd.org

Executive Officer:
Loretta P. Finnegan, MD
E-mail: finnegal337@aol.com

Director, Executive Office:
Ellen B. Geller, MA
215-707-5307
E-mail: gellerellen@gmail.com

Board of Directors:
Alan J Budney, PhD, President
Leonard Howell, PhD, Past-President
Margaret Haney, PhD, President-Elect
Jack Bergman, PhD, Treasurer
Patrick M Beardsley, PhD
Kathleen M Carroll, PhD
Marilyn E Carroll, PhD
Howard D Chilcoat, ScD
Timothy P Condon, PhD
Sarah H Heil, PhD
Amy C Janes, PhD
Geoffrey K Mumford, PhD
Thomas E Prisinzano, PhD
Beatriz Rocha, MD, PhD
Stacey C Sigmon, PhD
Mark A Smith, PhD
William Stoops, PhD
Jennifer W Tidey, PhD
Elise M Weerts, PhD

June 23, 2017

Representatives Robert Goodlatte and John Conyers
House Judiciary Committee
2138 Rayburn House Office Building
Washington, DC 20515

On behalf of the College on Problems of Drug Dependence (CPDD), we are writing to express our views on H.R. 2851, Stop the Importation and Trafficking of Synthetic Analogues (SITSA) Act of 2017. CPDD is the longest standing scholarly society in the United States that is devoted to issues surrounding substance use disorders. The College has over 1000 members, and serves as an interface among governmental, industry, and academic communities maintaining liaisons with regulatory and research agencies as well as educational, treatment, and prevention facilities in the drug abuse field.

We share the concerns of the Committee and sponsors of H.R. 2851 about the opioid epidemic and its devastating consequences for millions of Americans, their families, and their communities. According to a recent *New York Times* article, an estimated 59,000 Americans died in 2016 of drug overdoses, the largest annual jump in deaths ever recorded in the United States. One of the main reasons for that dramatic and disturbing increase is the spread of fentanyl, a synthetic opioid that is inexpensive and potent. The College supports robust, science-based efforts to curb the sale and use of synthetic analogues.

While CPDD agrees with the spirit of H.R. 2851, we believe that legislation to enhance the Justice Department's efforts to temporarily schedule new synthetic compounds must institutionalize a more enhanced role of the Department of Health and Human Services' science-based agencies, specifically the National Institute on Drug Abuse and the Food and Drug Administration. The current version of H.R. 2851 gives the Attorney General blanket authority to temporarily schedule a substance, and the AG is only required to provide a 30-day public notice of pending scheduling action and "take into consideration any comments" from HHS on proposed orders to temporarily schedule a compound. The temporary scheduling process for synthetic analogues bypasses the current process that requires the AG to conduct a three-factor analysis before temporary scheduling can proceed.

Moreover, to permanently schedule a compound, current law requires the AG to obtain an eight-factor analysis by FDA and a recommendation from HHS on a permanent scheduling action. For synthetic analogues, H.R. 2851 enables the Attorney General to bypass the current role of science-based agencies in reviewing what compounds should be scheduled.

We seek to ensure that science-based Federal agencies, including FDA and NIDA, are involved in decisions regarding temporary scheduling of synthetic analogues, rather than the current version of H.R. 2851, which merely requires that HHS be informed of the AG's intent to schedule such compounds.

If the intent of the legislation is to enable the "scientific and research communities to develop information on these newly-invented substances," then the research exemption written into the current version of H.R. 2851 needs to be enhanced significantly. The bill provides that researchers who already have a Schedule I license will not need an additional one, except to review protocols for research on these targeted substances. This exemption applies to only a small subset of potential scientists who could and should research potential treatments to the targeted synthetic compounds but who will be discouraged from doing this research by the burdens and lengthy regulatory burdens and time required to gain approval of a Schedule I license. CPDD encourages the Committee to consider an expanded exemption that would enable researchers with Schedule I, II, III, IV and V licenses to conduct research on those synthetic analogues that will be temporarily scheduled under terms of this legislation.

Respectively



Alan Budney, PhD
President, The College on Problems of Drug Dependence

House Energy and Commerce Committee, Health Subcommittee

Testimony of Congressman Brad Schneider (IL-10)

February 28, 2018

Thank you, Chairman Burgess, Ranking Member Green, and the Health Subcommittee for considering this legislation.

Across the country, American families and our communities are suffering under a crisis of opioid addiction and misuse. This insidious epidemic does not discriminate based on political party, geography, economic status, gender, or age. Every day it claims more than 115 lives.

This is a multi-faceted problem and addressing it will require a multi-faceted approach. I thank my colleagues on the Bipartisan Heroin Task Force for their work across the aisle to find solutions.

One important action we can take is ensuring our doctors are up-to-date with the most current best practices and research for preventing, identifying and treating the disease of addiction.

The **H.R. 2063, the Preventing Opioid Abuse Through Continuing Education (or Opioid PACE) Act** would require providers who treat patients with prescription opioids for pain management to complete 12 hours of continuing medical education (CME) every three years.

The CME would focus on pain management treatment guidelines and best practices (including non-opiate alternatives), early detection of opioid use disorder, and the treatment and management of patients with opioid use disorder.

The bill would link completion of the CME requirements to the renewal of the provider's Drug Enforcement Agency (DEA) license.

Many states already see the value of continuing education for prescribers of opioids. A 2017 study in the Journal of Medical Regulation found 29 of 50 states have pain

management/controlled substance prescribing continuing education requirements for at least some physicians, and 10 have requirements tied to license renewal.

Equipping the prescribers of opioids with the training to better decide when opioid medications are best indicated will help limit these drugs to only patients who will benefit from them, and prevent overprescribing when other, non-opioid treatment methods may be more effective.

Reducing over-prescription will be an important factor in curbing the epidemic. According to the Centers for Disease Control (CDC), sales of prescription opioids in the United States nearly quadrupled from 1999 to 2014, but there has not been an overall change in the amount of pain Americans report. During this time period, prescription opioid overdose deaths increased similarly.

A modified version of this bill addressing only Department of Defense medical professionals passed the House in 2017 as an amendment to the National Defense Authorization Act.

Our men and women in uniform are not immune from the epidemic of opioid addiction and abuse. In fact, the National Institute of Health reports rates of prescription opioid misuse are higher among service members than among civilians due to the use of these drugs to treat the symptoms of PTSD and chronic pain.

I thank my colleagues for their consideration of the Opioid PACE Act and urge them to support this measure to help equip medical professionals with the training and best practices needed to address this epidemic.

December 18, 2017

The Honorable Lamar Alexander
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, DC 20210

The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, D.C. 20210

Dear Chairman Alexander and Senator Murray:

We, the under-signed organizations, write to indicate our continued support for passage of Section 3 of S. 916, the Protecting Patient Access to Emergency Medications Act of 2017, which was approved by your Committee in April of this year. This legislation will greatly benefit patients who wish to use innovative new forms of medication-assisted treatment (MAT) as part of their recovery.

As you are aware, recent advances in medical technology have made development of new medications to treat addiction possible. These products promise to greatly enhance patient compliance to treatment because they are substantially longer acting than previous therapies. As they are administered directly by a provider to a patient, they also greatly reduce the opportunity for illegal diversion, misuse and accidently pediatric exposure.

The Controlled Substances Act is silent on whether such products can be delivered directly to the administering provider, rather than directly to the patient. This is how non-controlled, provider-administered medications are distributed. Section 3 of S. 916, the *Protecting Patient Access to Emergency Medications Act of 2017,* would address this inequity. It clarifies that controlled substances may be delivered to prescribing or administering practitioners, including medications that are administered by implantation, injection, or through the use of an intrathecal pump, for maintenance or detoxification treatment of addiction.

It is important that opioid use disorder patients have the same access to the full range of Food and Drug Administration approved treatment options as any other patient would. The approval last year of an implantable buprenorphine product, and the anticipated approval in the next few months of long-acting injectable formulations, provide much-needed new treatment options for patients and allow health care providers and patients the choice of selecting a treatment that is most appropriate for their needs.

We appreciate your leadership in recognizing the necessity for this small-but-important change to the Controlled Substances Act. This correction will allow the right treatment to get to the right patient at the right time by increasing access to lifesaving treatments for opioid use disorder. Every day, according to the CDC, 91 people die of an opioid overdose. Congress clearly has a vital role to play in combatting the current the opioid crisis, and we strongly support swift passage of this critical piece of legislation so patients and providers will have access to these important, new treatments.

We urge that you act quickly to see that this legislation is approved by the Senate and moved to the House of Representatives for passage. It is a small change in the law, but one which will greatly benefit patients. The opioid overdose epidemic has already affected too many Americans. Now is the time to act – let's give health care professionals on the front line of this crisis the tools they need to save lives. We urge you to pass S. 916.

Sincerely,

Advocates for Opioid Recovery

Breaking Barriers - Hope Is Alive

Community Pharmacies of Indiana

Cover2 Resources

Daniel's Story

Family Advocates Coalition to End Addiction in Maryland (F.A.C.E. Addiction Maryland)

Heroin Action Coalition

Indiana Pharmacists Association

Maryland Heroin Awareness Advocates

Ohio Society of Addiction Medicine

Prevention Action Alliance

Robby's Voice

Savannah Harm Reduction Coalition

Shatterproof

The Addicts Parents United

The Indiana Academy of Physician Assistants

Tyler's Light

Watauga Recovery Center

Young People in Recovery



ASAM American Society of Addiction Medicine

OFFICERS
President
Kelly J. Clark, MD, MBA, DFASAM
President-Elect
Paul H. Earley, MD, DFASAM
Vice President
Margaret Jarvis, MD, DFASAM
Secretary
Yngvild Olsen, MD, MPH, FASAM
Treasurer
Brian Hurley, MD, MBA, FASAM
Immediate Past President
R. Jeffrey Goldsmith, MD, DLFAPA, DFASAM

BOARD OF DIRECTORS
Directors-at-Large
Anthony Albanese, MD, DFASAM
Marc Galanter, MD, DFASAM
William F. Haning, III, MD, DFAPA, DFASAM
Petros Levounis, MD, MA, DFASAM
Edwin A. Salsitz, MD, DFASAM
John C. Tanner, DO, DFASAM

Regional Directors
Region I Director
Jeff Selzer, MD, DFASAM
Region II Director
Murtuza Ghadiali, MD
Region III Director
Ke[illegible] Freedman, MD, MS, MBA, FACP, AGAF, DF[illegible]M
Region IV Director
Michael Shore, MD, DFASAM, DLFAPA
Region V Director
Anika Alvanzo, MD, MS, FACP, FASAM
Region VI Director
Gavin Bart, MD, PhD, DFASAM
Region VII Director
A. Kennison Roy, III, MD, DLFAPA, DFASAM
Region VIII Director
Miriam Komaromy, MD, FACP, FASAM
Region IX Director
Peter Selby, MBBS, CCFP, FCFP, MHSc, DFASAM
Region X Director
Scott Teitelbaum, MD, DFASAM

Ex-Officio
Stuart Gitlow, MD, MPH, MBA, DFAPA, DFASAM
Randolph P. Holmes, MD, FASAM
Todd Kammerzelt, MD, FASAM
Michelle Lofwall, MD, FASAM
Penny S. Mills, MBA
Aleksandra Zgierska, MD, PhD

FOUNDING PRESIDENT
Ruth Fox, MD
1895-1989

September 21, 2017

The Honorable Bill Cassidy
United States Senate
520 Hart Senate Office Building
Washington DC 20510

The Honorable Michael Bennet
United States Senate
261 Russell Senate Office
Building Washington DC 20510

The Honorable Roy Blunt
United States Senate
260 Russell Senate Office Building
Washington DC 20510

The Honorable Al Franken
United States Senate
309 Hart Senate Office Building
Washington DC 20510

Dear Senators Cassidy, Blunt, Bennet, and Franken:

On behalf of the American Society of Addiction Medicine (ASAM), a national medical specialty representing more than 5,000 physicians and allied health professionals who specialize in the treatment of addiction, I am writing to express our support for Section 3 of your bill, S. 916, the *Protecting Patient Access to Emergency Medications Act of 2017*, which would allow pharmacies to deliver controlled substances to prescribing or administering practitioners, including medications that are administered by implantation, injection, or through the use of an intrathecal pump for maintenance or detoxification treatment of addiction.

Foremost to ASAM's mission is a goal to increase access to and improve the quality of addiction treatment. The introduction and use of novel addiction pharmacotherapies supports this goal. Addiction patients, like all patients, should have available to them a robust and varied array of treatment options, as no one treatment modality is appropriate or therapeutic for everyone. The recent approval of an implantable buprenorphine product, and the anticipated approval of two injectable buprenorphine formulations, expands treatment options for patients. No product will be suitable for all patients, and many will still be best-served by oral formulations, other medications, or no medication at all, but they may help improve treatment adherence and reduce diversion among certain patients for whom they are indicated.

11400 Rockville Pike Suite 200 Rockville, MD 20852
Phone: 301-656-3920 | Fax: 301.656.3815
www.ASAM.org

However, these options are only valuable if patients can access them. S. 916 would facilitate access to these new products by allowing them to be delivered to administering practitioners on a patient-by-patient basis rather than requiring the practitioners anticipate demand, buy the medication in advance, store it on site, and hope they estimated the correct number of doses needed to meet demand and avoid waste. This is not a new pathway for medication delivery, but would allow for these controlled substances to be delivered as many non-controlled substances are already.

ASAM appreciates your attention to this technical detail and your leadership in championing legislation that will promote patient access to new addiction treatment options. We look forward to working with you to ensure your bill's passage.

Sincerely,

Kelly J. Clark

Kelly J. Clark, MD, MBA, DFASAM
President, American Society of Addiction Medicine

CC: The Honorable Lamar Alexander
The Honorable Patty Murray



CLAAD Center for Lawful Access and Abuse Deterrence

November 22, 2017

The Honorable Lamar Alexander
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, DC 20210

The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, DC 20210

Dear Chairman Alexander and Senator Murray:

On behalf of the Center for Lawful Access and Abuse Deterrence (CLAAD), I would like to submit this letter to support the passage of Section 3 of S. 916 to allow pharmacies to dispense controlled substances that are administered by a health care practitioner directly to the health care practitioner.

CLAAD is a tax-exempt, not-for-profit organization working to improve health and safety. We recommend consensus-based solutions to the nation's drug overdose epidemic. All such efforts must revolve around individualized health care.

As you are aware, we are facing an opioid overdose epidemic. Ninety-one Americans die every day from an opioid related overdose.[1] With such alarming rates of overdose, regulators and policymakers should be developing policies that encourage access to treatment with effective medications approved by the FDA that enhance adherence to treatment and reduce the likelihood of diversion.

Practitioner-administered buprenorphine products inherently increase treatment adherence and reduce post dispensing diversion. Yet, current law makes it difficult for a practitioner to administer these products. Under current law, a pharmacy cannot dispense these medications directly to a practitioner. Therefore, if a practitioner wants to treat a patient with a practitioner-administered buprenorphine product, the practitioner has to (1) purchase the product and have it shipped directly to his or her office, (2) administer the product to the patient, and then (3) bill the patient or the patient's insurer for payment. This process is known as "buy and bill." Buy and bill can be burdensome for some practitioners because of the upfront cost of the medication and the uncertainty regarding whether they will get paid. These burdens may deter practitioners from prescribing these medications, and therefore, thereby limiting patient access to these medications.

Therefore, we urge Congress to pass Section 3 of S. 916 to enable pharmacies to dispense practitioner-administered controlled substances directly to the practitioner. Passage of this section will improve access to adherence enhancing and diversion resistant medications. We appreciate your consideration of our comments and would be pleased to discuss this matter in greater detail with you.

Sincerely,

Nellie Wild
Senior Policy Advisor

[1] https://www.cdc.gov/drugoverdose/epidemic/index.html

Catalent®

14 Schoolhouse Road
Somerset, NJ 08873
catalent.com

Cornell Stamoran, Ph.D.
Vice President, Corporate Strategy
and Government Affairs
T +1-732-537-6408
E cornell.stamoran@Catalent.com

February 27, 2018

The Honorable Mike Burgess
Chairman
Subcommittee on Health of the
Committee on Energy & Commerce
United States House of Representatives
2336 Rayburn House Office Building
Washington, DC 20510

The Honorable Gene Green
Ranking Member
Subcommittee on Health of the
Committee on Energy & Commerce
United States House of Representatives
2470 Rayburn House Office Building
Washington, DC 20510

Re: H.R. ____, The Tableting and Encapsulating Machine Regulation Act of 2018

Dear Chairman Burgess and Ranking Member Green:

I write you today on behalf of Catalent, Inc., a NYSE-listed advanced dosage form provider and contract development and manufacturing company, with global headquarters in Somerset, New Jersey. We produce more than 72 billion doses of prescription and consumer health products annually across more than 7,000 products on behalf of our customers, and for patients around the world.

We applaud the comprehensive approach to addressing the illicit use of opioids represented by the eight draft bills to be discussed during the **Combating the Opioid Crisis** hearing planned for this Wednesday, February 28, 2018.

We are reaching out to express some concerns regarding provisions of the initial draft of one of those bills, **The Tableting and Encapsulating Machine Regulation Act of 2018** (the "Tableting Regulation Bill" or the "Bill"). We recognize that testimony by the Drug Enforcement Administration (the "DEA") at 2016 hearings of the Committee of Energy & Commerce indicated a growing use of imported tablet presses and encapsulating machines to supply illicit drug markets in the United States. We also note that, in response to this activity, in late 2016, the DEA established expanded reporting requirements for all import, export, and domestic transactions involving such equipment, which were implemented in mid-2017.[1]

The initial draft of the Tableting Regulation Bill would reclassify **every** machine that produces either tablets or capsules in **any** domestic facility as a controlled substance, and thus subject to DEA oversight, recordkeeping, security, and other requirements—the same standards that apply to narcotic bulk drugs and finished doses. These new requirements are imposed without regard to whether any such machine is sited at a facility that is already governed by the Food, Drug & Cosmetic Act (the "FD&C Act"), or is already regulated by the Food & Drug Administration, nor does the legislation recognize the inherent differences between *machinery* and the sorts of controlled *substances* that are already regulated by the Controlled Substances Act.

[1] *See* https://www.deadiversion.usdoj.gov/fed_regs/rules/2016/fr1230.pdf.

Catalent.

While all the implications of the Bill's reclassification are not fully clear, the Bill is likely to impose substantial new regulatory oversight burdens on legitimate, law-abiding manufacturers of both prescription and non-prescription products, most of which **are not producing opioids or other controlled substances**. Further, the bill would drive significant additional costs for reporting, compliance management, and security, directly reducing funds currently used to invest in growth, expand employment, and drive innovation. Finally, we believe that the application of such provisions to production sites already regulated by the FDA will yield limited added enforcement value above that provided by the expanded transaction reporting requirements only recently implemented by the DEA.

Despite these significant concerns, we appreciate the enforcement benefits to be realized by applying such a status change to tableting and encapsulating production equipment that is not sited in facilities otherwise regulated by the FDA or subject to the FD&C Act. We believe that there are several possible approaches to modify the draft Bill to mitigate such concerns from regulated industry. In one such example, the application of such a reclassification might specifically exclude equipment in sites regulated by the FDA under existing sections of the FD&C Act, including but not limited to those relevant to producers of clinical and/or commercial supplies of prescription pharmaceuticals, over-the-counter monograph products, dietary supplements, and veterinary drugs. There are alternative approaches that we are discussing with industry trade associations and other companies, which we have agreed to review with the Subcommittee staff in upcoming weeks.

In closing, we reiterate our support for the efforts of the Subcommittee to address the challenges facing our country as a result of the illicit use of opioids. We recognize the difficult task before you and appreciate your consideration of our concerns and ideas to address them. For additional information, please contact either Cornell Stamoran (cornell.stamoran@catalent.com, 732-537-6408) or Steven Fasman (steven.fasman@catalent.com, 732-537-5958).

Sincerely yours,

Cornell Stamoran
Vice President, Corporate Strategy
and Government Affairs

cc: Steven Fasman
Senior Vice President & General Counsel
Catalent, Inc.

PHARMA & BIOPHARMA OUTSOURCING ASSOCIATION

February 26, 2018

The Honorable Michael C. Burgess
Chairman
Subcommittee on Health
House Committee on Energy and Commerce
United States House of Representatives
2336 Rayburn House Office Building
Washington, DC 20515

The Honorable Gene Green
Ranking Member
Subcommittee on Health
House Committee on Energy and Commerce
United States House of Representatives
2470 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Burgess and Ranking Member Green,

I am writing you today on behalf of the **Pharma & Biopharma Outsourcing Association (PBOA)**, a trade association representing Contract Manufacturing Organizations and Contract Development & Manufacturing Organizations (collectively described as CDMOs for purposes of this letter). PBOA members provide the technologies and services that help the pharma and biopharma industry develop and manufacture drugs, biologics, vaccines, and other treatments safely and cost effectively. Our members represent more than 20,000 domestic manufacturing jobs, and overall manufacture more than 220 billion doses annually. CDMOs produce between 30% and 40% of all dosages consumed by patients in the U.S.

We applaud your ongoing commitment to comprehensively addressing the illicit use of opioids and combating this deadly epidemic unfolding in communities across America. With the enactment of the Comprehensive Addiction and Recovery Act in 2016, and through the Energy and Commerce Committee's ongoing consideration of additional policy proposals, you are truly leading the charge and we support your efforts.

We are, however, concerned about one of the proposals being considered at the Health Subcommittee hearing on February 28, 2018: **The Tableting and Encapsulating Machine Regulation Act of 2018.** We recognize from testimony provided to the Subcommittee by the Drug Enforcement Administration ("DEA") in 2016 that there are legitimate concerns about the illicit use of imported tablet presses and encapsulating machines, and we agree that there is an acute need to curb these practices. We also note that, in response to this activity, in late 2016 the DEA established expanded reporting requirements for all import, export, and domestic transactions involving such equipment, which were implemented in mid-2017.[1]

The legislation being considered on February 28 would reclassify **every** machine that produces either tablets or capsules in **any** domestic facility as a controlled substance, and thus subject to DEA oversight, recordkeeping, security, and other requirements – the same standards that apply to narcotic bulk drugs and finished doses. These new requirements

[1] See https://www.deadiversion.usdoj.gov/fed_regs/rules/2016/fr1230.pdf



would be imposed without regard to whether any such machine is sited at a facility that is already regulated by the Food and Drug Administration ("FDA").

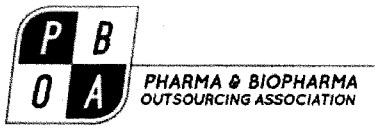
While all the implications of such a reclassification are not fully clear, this legislation, if enacted in its current form, would likely impose substantial new regulatory oversight burdens on manufacturers of both prescription and non-prescription products, most of which are not producing opioids or other controlled substances. Further, the bill would drive significant additional costs for reporting, compliance management, and security, directly reducing funds currently used to invest in growth, expand employment and drive innovation. Finally, we believe that the application of such provisions to production sites already overseen by the FDA will yield limited added enforcement value above that provided by the expanded transaction reporting requirements only recently implemented by the DEA.

We do understand and appreciate the need to more stringently oversee the acquisition and use of such production equipment that is not sited in facilities otherwise regulated by the FDA. We believe that there are several possible approaches to modify the legislation to mitigate our concerns. For example, you could specifically exclude equipment in sites regulated by the FDA under existing sections of the Food, Drug and Cosmetic, including but not limited to those relevant to producers of clinical and/or commercial supplies of prescription pharmaceuticals, over-the-counter monograph products, dietary supplements, and veterinary drugs. There are alternative approaches that we are discussing with industry trade associations and other companies, which we have agreed to review with the Committee staff in upcoming weeks.

In closing, we reiterate our support for the efforts of the Committee to address the challenges facing our country related to the illicit use of opioids. We recognize the difficult task before you, appreciate your consideration of our concerns and ideas, and restate our commitment to working constructively with you to address legitimate concerns about the illicit use of this type of the equipment without imposing inappropriate burdens on legitimate manufacturers.

Sincerely,

Gil Roth
President
Pharma & Biopharma Outsourcing Association



PBOA Member Companies

3M Drug Delivery
Afton Scientific
Alcami
Althea CMO
Avid Bioservices
Avista Pharma Services
Baxter Biopharma Solutions
Berkshire Sterile
Catalent Pharma Solutions
CMIC CMO USA
Coating Place
CPC – Contract Pharmacal Corp.
DPT, a division of Mylan
Emergent BioSolutions
Grand River Aseptic Manufacturing
Groupe PARIMA
Halo Pharma
IDT Biologika
Jubilant HollisterStier
LSNE – Lyo Services of New England
Metrics Contract Services
Mission Pharmacal
Particle Sciences, a Lubrizol Company
Patheon, a part of Thermo Fisher
PCI Pharma Services
Pfizer CentreOne
Pharma Packaging Solutions
Piramal Pharma Solutions
Renaissance Lakewood
Tapemark
Therapure
WellSpring Pharma Services

THE COLLEGE ON PROBLEMS OF DRUG DEPENDENCE, INC.
3420 N. Broad Street, Room 324, Philadelphia, PA 19140-5104
Telephone: 215-707-3242 • Fax: 215-707-1904 • Website: http://www.cpdd.org

Executive Officer:
Loretta P. Finnegan, MD
E-mail: finnegal337@aol.com

Director, Executive Office:
Ellen B. Geller, MA
215-707-5307
E-mail: gellerellen@gmail.com

Board of Directors:
Alan J Budney, PhD, President
Leonard Howell, PhD, Past-President
Margaret Haney, PhD, President-Elect
Jack Bergman, PhD, Treasurer
Patrick M Beardsley, PhD
Kathleen M Carroll, PhD
Marilyn E Carroll, PhD
Howard D Chilcoat, ScD
Timothy P Condon, PhD
Sarah H Heil, PhD
Amy C Janes, PhD
Geoffrey K Mumford, PhD
Thomas E Prisinzano, PhD
Beatriz Rocha, MD, PhD
Stacey C Sigmon, PhD
Mark A Smith, PhD
William Stoops, PhD
Jennifer W Tidey, PhD
Elise M Weerts, PhD

June 23, 2017

Representatives Robert Goodlatte and John Conyers
House Judiciary Committee
2138 Rayburn House Office Building
Washington, DC 20515

On behalf of the College on Problems of Drug Dependence (CPDD), we are writing to express our views on H.R. 2851, Stop the Importation and Trafficking of Synthetic Analogues (SITSA) Act of 2017. CPDD is the longest standing scholarly society in the United States that is devoted to issues surrounding substance use disorders. The College has over 1000 members, and serves as an interface among governmental, industry, and academic communities maintaining liaisons with regulatory and research agencies as well as educational, treatment, and prevention facilities in the drug abuse field.

We share the concerns of the Committee and sponsors of H.R. 2851 about the opioid epidemic and its devastating consequences for millions of Americans, their families, and their communities. According to a recent *New York Times* article, an estimated 59,000 Americans died in 2016 of drug overdoses, the largest annual jump in deaths ever recorded in the United States. One of the main reasons for that dramatic and disturbing increase is the spread of fentanyl, a synthetic opioid that is inexpensive and potent. The College supports robust, science-based efforts to curb the sale and use of synthetic analogues.

While CPDD agrees with the spirit of H.R. 2851, we believe that legislation to enhance the Justice Department's efforts to temporarily schedule new synthetic compounds must institutionalize a more enhanced role of the Department of Health and Human Services' science-based agencies, specifically the National Institute on Drug Abuse and the Food and Drug Administration. The current version of H.R. 2851 gives the Attorney General blanket authority to temporarily schedule a substance, and the AG is only required to provide a 30-day public notice of pending scheduling action and "take into consideration any comments" from HHS on proposed orders to temporarily schedule a compound. The temporary scheduling process for synthetic analogues bypasses the current process that requires the AG to conduct a three-factor analysis before temporary scheduling can proceed.

Moreover, to permanently schedule a compound, current law requires the AG to obtain an eight-factor analysis by FDA and a recommendation from HHS on a permanent scheduling action. For synthetic analogues, H.R. 2851 enables the Attorney General to bypass the current role of science-based agencies in reviewing what compounds should be scheduled.

We seek to ensure that science-based Federal agencies, including FDA and NIDA, are involved in decisions regarding temporary scheduling of synthetic analogues, rather than the current version of H.R. 2851, which merely requires that HHS be informed of the AG's intent to schedule such compounds.

If the intent of the legislation is to enable the "scientific and research communities to develop information on these newly-invented substances," then the research exemption written into the current version of H.R. 2851 needs to be enhanced significantly. The bill provides that researchers who already have a Schedule I license will not need an additional one, except to review protocols for research on these targeted substances. This exemption applies to only a small subset of potential scientists who could and should research potential treatments to the targeted synthetic compounds but who will be discouraged from doing this research by the burdens and lengthy regulatory burdens and time required to gain approval of a Schedule I license. CPDD encourages the Committee to consider an expanded exemption that would enable researchers with Schedule I, II, III, IV and V licenses to conduct research on those synthetic analogues that will be temporarily scheduled under terms of this legislation.

Respectively



Alan Budney, PhD
President, The College on Problems of Drug Dependence

Information on Medicaid Expansion + Opioid Treatment

Center on Budget and Policy Priorities

820 First Street NE, Suite 510
Washington, DC 20002

Tel: 202-408-1080
Fax: 202-408-1056

center@cbpp.org
www.cbpp.org

February 28, 2018

Medicaid Expansion Dramatically Increased Coverage for People with Opioid-Use Disorders, Latest Data Show

By Matt Broaddus, Peggy Bailey, and Aviva Aron-Dine

The latest data from the federal Agency for Healthcare Research and Quality highlight the importance of the Affordable Care Act's (ACA) Medicaid expansion in increasing insurance coverage among people with opioid-use disorders (OUD).[1] Our analysis of these data, which offer a comprehensive picture of opioid-related hospitalizations around the country, finds that the share of hospitalizations in which the patient was uninsured fell dramatically in states that expanded Medicaid: from 13.4 percent in 2013 (the year before expansion took effect) to just 2.9 percent two years later. This steep decline indicates that many uninsured people coping with OUDs have gained coverage through Medicaid expansion. (See Figure 1.)

In addition, the data rebut claims that Medicaid expansion contributed to the opioid crisis. Opioid-related hospitalizations were higher in expansion than non-expansion states as early as 2011, three years before Medicaid expansion took effect, and have been growing at roughly the same rate in expansion and non-expansion states since expansion took effect. Medicaid is part of the solution to the opioid crisis, not a cause.

Medicaid Expansion Increased Coverage and Access to Treatment

The need for substance use disorder (SUD) treatment, particularly as related to OUDs, is acute. A record 63,600 people died of drug overdoses in 2016, with 42,200 due to opioid use. Drug overdose death rates rose by statistically significant amounts in 27 states between 2013 and 2015 and in 34 states between 2013 and 2016, according to the Centers for Disease Control and Prevention.[2]

By itself, having a SUD isn't considered a disabling condition under Medicaid rules, so before the ACA expanded Medicaid, low-income adults with SUDs generally didn't qualify for Medicaid unless they also had a physical or mental health disability. States' recent Medicaid expansions under the

[1] Healthcare Cost and Utilization Project Fast Stats, Agency for Healthcare Research and Quality, December 2017 update, https://www.hcup-us.ahrq.gov/faststats/landing.jsp.

[2] Centers for Disease Control and Prevention, "Drug Overdose Death Data: 2015-2016 Death Increases," https://www.cdc.gov/drugoverdose/data/statedeaths.html.

ACA allow adults with incomes below 138 percent of the poverty line to enroll regardless of disability, opening the door to coverage for far more adults with SUDs.

Recently released data from the Healthcare Cost and Utilization Project (HCUP) at the Agency for Healthcare Research and Quality shed new light on how expansion affects coverage for people with OUDs. For states with available data, the HCUP provides a complete picture of opioid-use-related hospitalizations, including whether the patient was covered by Medicaid, Medicare, or private insurance or was uninsured. We analyzed these data for the states with data available from 2011 through 2015, and which either expanded Medicaid in January 2014 or had not expanded by the end of 2015. (See the methods note for details.)

In Medicaid expansion states, the uninsured rate for opioid-related hospitalizations plummeted by 79 percent, from 13.4 percent in 2013 (the year before expansion implementation) to 2.9 percent in 2015. The decline in non-expansion states was a much more modest 5 percent, from 17.3 percent in 2013 to 16.4 percent in 2015 (see Figure 1). While both expansion and non-expansion states saw sizable declines in their overall uninsured rates during this period, Medicaid expansion appears to have been especially critical for expanding coverage to those with OUDs.[3]

The expansion states with the largest drops in the uninsured rate for opioid-related hospitalizations were Kentucky (90 percent), Oregon (89 percent), West Virginia (86 percent), Arizona (84 percent), and Illinois (83 percent).[4] (See Appendix Table 1 for additional state-level data.)

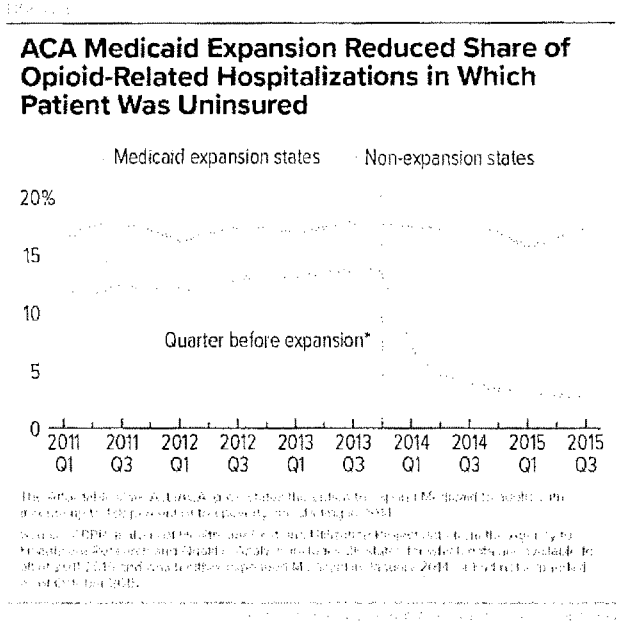
These data are consistent with other evidence that Medicaid expansion is improving access to care for people with opioid use and other substance use disorders. Medicaid makes medications like buprenorphine and naloxone, which are prescribed to combat opioid use disorders, affordable for beneficiaries. Medicaid spending on prescription drug treatment for opioid use disorders more than doubled between 2011 and 2016, from $394 million to $930 million. Five states with particularly high overdose mortality rates — West Virginia, Massachusetts, Ohio, Rhode Island, and Kentucky — have also seen especially rapid growth in Medicaid spending for these drugs; all of these states are Medicaid expansion states.[5] Evidence also suggests that Medicaid expansion improved access to substance use treatment services more broadly. After expanding Medicaid, Kentucky experienced a

[3] Since the full implementation of the ACA's health insurance coverage provisions at the beginning of 2014, overall uninsured rates have declined significantly both in states that adopted the ACA's Medicaid expansion and those that did not, but expansion states have seen a larger decline: from 12.9 percent in 2013 to 6.5 percent in 2016, versus a drop from 17.0 percent to 11.7 percent in non-expansion states. See Matt Broaddus, "Census Data: States Not Expanding Medicaid Lag Further on Health Coverage," Center on Budget and Policy Priorities, September 12, 2017, https://www.cbpp.org/blog/census-data-states-not-expanding-medicaid-lag-further-on-health-coverage.

[4] Some of these newly eligible adults likely enrolled when they were hospitalized. The ACA allows hospitals to provide presumptive eligibility to people likely to be Medicaid eligible. Those found eligible after they complete the eligibility process can receive follow-up treatment (Section 1902(a)(47)(b) of the Social Security Act).

[5] Lisa Clemmons-Cope, Marni Epstein, and Genevieve Kenney, "Rapid Growth in Medicaid Spending on Medications to Treat Opioid Use Disorder and Overdose," Urban Institute, June 28, 2017, https://www.urban.org/research/publication/rapid-growth-medicaid-spending-medications-treat-opioid-use-disorder-and-overdose.

700 percent increase in Medicaid beneficiaries using substance use treatment services.[6] Use of treatment services rose nationally as well; one study found that expanding Medicaid reduced the unmet need for substance use treatment by 18.3 percent.[7]



Moreover, substance use disorders usually don't occur in isolation; people with SUDs also need access to physical and mental health services. Medicaid expansion has been shown to help people get these services, too. For example, an Ohio study found that 59 percent of people with opioid-use disorders who had gained Medicaid coverage under expansion reported improved access to mental health care.[8] Nationwide, the share of people forgoing mental health care due to cost fell by about

[6] "Substance Use and the ACA in Kentucky," Foundation for a Healthy Kentucky, December 2016, https://www.healthy-ky.org/res/images/resources/Full-Substance-Use-Brief-Final_12_16-002-.pdf.

[7] Hefei Wen, Benjamin Druss, and Janet Cummings, "Effect of Medicaid Expansions on Health Insurance Coverage and Access to Care Among Low-Income Adults with Behavioral Health Conditions," *Health Services Research*, December 2015, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4693853/.

[8] "Ohio Medicaid Group VIII Assessment: A Report to the Ohio General Assembly," Ohio Department of Medicaid, December 2016, http://medicaid.ohio.gov/portals/0/resources/reports/annual/group-viii-assessment.pdf.

one-third as the ACA, including Medicaid expansion, took effect.[9] And more generally, studies find that Medicaid expansion has increased access to primary and preventive care, increased the share of people getting regular care for chronic conditions, and reduced the share of people forgoing needed care due to cost.[10]

Research Also Refutes Claims That Expansion Is Driving Opioid Crisis

At a recent hearing of the Senate Homeland Security and Government Reform Committee,[11] Chairman Ron Johnson claimed that Medicaid expansion contributed to the opioid crisis.[12] But the evidence doesn't support this claim; to the contrary, as discussed above, the expansion has increased access to treatment. And the HCUP data show that opioid-related hospitalizations have been growing — since before the expansion took effect — in both expansion and non-expansion states, and at roughly the same rate.

The HCUP data show that opioid-related hospitalizations are increasing across the nation, regardless of Medicaid expansion. They are more prevalent in Medicaid expansion states, reflecting the fact that many of the northeastern and midwestern states at the epicenter of the crisis opted to expand. But these rates were higher as early as 2011 — well before expansion took effect. After expansion, hospitalization rates rose at similar rates in expansion and non-expansion states. Nationally, opioid-related hospitalizations rose by 11 percent between 2013 and 2015, from 208 to 231 per 100,000 people. Medicaid expansion states saw a 12 percent increase, from 241 to 270 per 100,000 people. Non-expansion states saw a 10 percent increase, from 169 to 185 per 100,000 people. (See Figure 2.)

---

[9] Assistant Secretary for Planning and Evaluation, "Continuing Progress on the Opioid Epidemic: the Role of the Affordable Care Act," January 11, 2017, https://aspe.hhs.gov/system/files/pdf/255456/ACAOpioid.pdf.

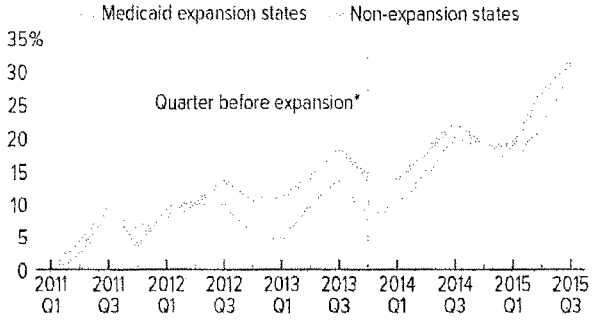
[10] See for example Benjamin D. Sommers *et al.*, "Changes in Utilization and Health Among Low-Income Adults After Medicaid Expansion or Expanded Private Insurance," *Journal of the American Medical Association*, October 2016, http://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2542420. For a review of the literature, see Assistant Secretary for Planning and Evaluation, "Medicaid Expansion Impacts on Insurance Coverage and Access to Care," Department of Health and Human Services, updated January 18, 2017, https://aspe.hhs.gov/system/files/pdf/255516/medicaidexpansion.pdf.

[11] "Unintended Consequences: Medicaid and the Opioid Epidemic," Senate Committee on Homeland Security and Governmental Affairs, January 17, 2018, https://www.hsgac.senate.gov/hearings/unintended-consequences-medicaid-and-the-opioid-epidemic.

[12] Bill Glauber, "Ron Johnson Links Medicaid to Opioid Crisis During Hearing," *Milwaukee Journal Sentinel*, January 27, 2018, https://www.jsonline.com/story/news/politics/2018/01/17/ron-johnson-lead-hearing-explore-if-medicaid-plays-role-opioid-crisis/1038376001/. The committee's Republican staff released a report titled "Drugs for Dollars: How Medicaid Helps Fuel the Opioid Epidemic."

Opioid-Related Hospitalizations Aren't Rising More in ACA Medicaid Expansion States than Other States

Rise in hospitalizations per 100,000 people since first quarter of 2011



These results, which belie claims that Medicaid expansion has caused a disproportionate increase in OUDs, are consistent with other researchers' analysis of drug overdose rates.[13] They are also consistent with new research from the Oregon Health Insurance Experiment. In 2008, prior to the ACA, Oregon undertook its own expansion of Medicaid to low-income adults. But because of limited funding, Oregon assigned Medicaid slots by lottery, which researchers have used as a randomized experiment to evaluate the impact of Medicaid coverage. A new study finds that those enrolled in Oregon's Medicaid expansion program were no more likely to be prescribed opioids — or to be prescribed more opioids — than low-income adults not enrolled in Medicaid. However, Medicaid enrollees were almost twice as likely to be prescribed treatment medications for opioid use disorder as those not enrolled, although this finding falls just short of statistical significance due to a small sample size.

Furthermore, virtually no Medicaid enrollees in Oregon possessed prescription drugs not originally prescribed to them.[14] This is an important finding, given the serious health risks associated

[13] Andrew Goodman-Bacon and Emma Sandoe, "Did Medicaid Expansion Cause the Opioid Epidemic? There's Little Evidence That It Did," *Health Affairs*, August 23, 2017, https://www.healthaffairs.org/do/10.1377/hblog20170823.061640/full/.

[14] Katherine Baicker *et al.*, "The Effect of Medicaid on Medication Use Among Poor Adults: Evidence from Oregon," *Health Affairs*, December 2017, https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2017.0925.

with prescription medication sharing; and it is especially significant in relation to opioids, given the concern that opioid prescription sharing is prevalent.[15]

Of course, some people enrolled in Medicaid have received inappropriate opioid prescriptions. But the problem of people receiving inappropriate opioid prescriptions is not unique to Medicaid. It also exists with private insurers and Medicare, which experience the same challenges in implementing solutions such as improving prescription tracking, identifying providers who overprescribe medications, and researching non-opioid interventions for pain.[16] It is also important to understand that the rise in opioid-related overdose deaths is now largely due to non-prescription drugs like heroin and fentanyl.[17]

States Are Using Medicaid to Help Address Opioid Crisis

Now that more people with SUDs are eligible for Medicaid, states can significantly improve treatment for people with SUDs by improving Medicaid-covered services. Medicaid can be a sustainable funding source for providers, as opposed to capped, short-term grant funding, and states like California, Kentucky, Maryland, Massachusetts, New Hampshire, New Jersey, and West Virginia have new Medicaid initiatives for people with SUDs underway. These states are providing services such as inpatient treatment or short-term residential treatment and innovative evidence-based services like peer supports; they also are providing wraparound supports such as housing and employment to increase the impact of treatment. Other states, including Illinois, North Carolina, and New Mexico, are seeking federal approval for similar proposals.[18]

Among a panel of experts dealing directly with the opioid crisis — public health and law enforcement officials, policymakers, and policy experts — Medicaid expansion was among the policies consistently named as most critical for addressing the crisis.[19] Claims that Medicaid coverage has worsened the epidemic aren't supported by the available evidence and shouldn't deter states that have not yet expanded Medicaid from taking advantage of the opportunity to improve coverage and treatment for people struggling with opioid use and other substance use disorders.

---

[15] Kebede Beyene, Janie Sheridan, and Trudi Aspden, "Prescription Medication Sharing: A Systematic Review of the Literature," *American Journal of Public Health*, April 2014, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4025682/; Alene Kennedy-Hendricks, Andrea Gielen, and Eileen McDonald, "Medication Sharing, Storage, and Disposal Practices for Opioid Medications Among US Adults," *Journal of the American Medical Association*, July 2016, https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2527388.

[16] For example, for an analysis of high rates of opioid use and long-term opioid use among people enrolled in commercial coverage, see Blue Cross Blue Shield Association, "America's opioid epidemic and its effect on the nation's commercially-insured population," June 29, 2017, https://www.bcbs.com/the-health-of-america/reports/americas-opioid-epidemic-and-its-effect-on-the-nations-commercially-insured.

[17] Nadia Kounang, "25% of all overdoses are from heroin," CNN, February 24, 2017, https://www.cnn.com/2017/02/24/health/heroin-overdose-study/.

[18] Peggy Bailey, "Building on ACA's Success Would Help Millions with Substance Use Disorders," Center on Budget and Policy Priorities, April 11, 2017, https://www.cbpp.org/research/health/building-on-acas-success-would-help-millions-with-substance-use-disorders.

[19] Josh Katz, "How a Police Chief, a Governor and a Sociologist Would Spend $100 Billion to Solve the Opioid Crisis," *New York Times*, February 14, 2018, https://www.nytimes.com/interactive/2018/02/14/upshot/opioid-crisis-solutions.html.

Methods Note

The Agency for Healthcare Research and Quality developed the Healthcare Cost and Utilization Project (HCUP) through a collaboration with states and health industry representatives. The result is the nation's most comprehensive source of hospital care data. We use the most recent available HCUP data, released in December 2017, which include consistent quarterly data for 44 states and the District of Columbia (DC) from the first quarter of 2011 through the third quarter of 2015. Revisions to data classification were made in the fourth quarter of 2015, so data after this revision are not comparable to earlier data.

First, we identified states with HCUP data for the entire study period. Data are available for 32 states and DC on the share of total opioid-related hospitalizations by patients without health coverage, and for 40 states and DC on the number of opioid-related hospitalizations per 100,000 people in the state.

Then we classified those states with available data based on their Affordable Care Act Medicaid expansion status. States that expanded in January 2014 compose the "Medicaid expansion group," and states that had not expanded by October 2015 compose the "non-expansion group." For our main analysis, we excluded states that expanded Medicaid either before January 2014 or between January 2014 and October 2015: Alaska, California, Connecticut, DC, Indiana, Minnesota, New Jersey, Pennsylvania, and Washington. (Data for some of these states are included in Appendix Table 1.)

Finally, we aggregated and compared relevant quarterly data over the study period for the expansion and non-expansion groups. Our analysis of insurance coverage status of patients hospitalized for opioid-related conditions included 13 states in each group. Our analysis of opioid-related hospitalizations per 100,000 people included 19 expansion states and 16 non-expansion states. (Because this analysis does not require data disaggregated by payer, data are available for more states.)

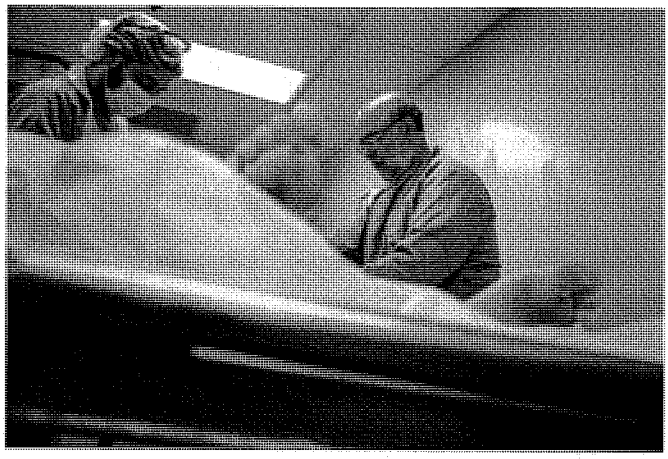
Share of Opioid-Related Hospitalizations by Uninsured Patients, for Medicaid Expansion States

State	2013, % uninsured	2015, % uninsured	% Change
Arizona	16.7%	2.7%	-84%
Arkansas	17.2%	4.2%	-76%
Colorado	13.8%	3.9%	-72%
Illinois	15.6%	2.6%	-83%
Kentucky	27.6%	2.8%	-90%
Maryland	23.0%	5.8%	-75%
Massachusetts	6.0%	1.5%	-75%
Michigan	8.5%	1.7%	-80%
Nevada	20.3%	3.7%	-82%
New York	5.7%	2.7%	-53%
Ohio	20.2%	3.4%	-83%
Oregon	13.2%	1.4%	-89%
West Virginia	21.1%	3.0%	-86%
Expanded in 2015			
Indiana	16.1%	8.6%	-47%
Pennsylvania	7.5%	3.4%	-54%

The New York Times

The Opioid Epidemic: A Crisis Years in the Making

By Maya Salam (https://www.nytimes.com/by/maya-salam) Oct. 26, 2017



Examining the body of a woman who died of an overdose in August.
Todd Heisler/The New York Times

The current opioid epidemic is the deadliest drug crisis in American history. Overdoses, fueled by opioids, are the leading cause of death for Americans under 50 years old — killing roughly 64,000 people last year, more than guns or car accidents, and doing so at a pace faster than the H.I.V. epidemic did at its peak.

President Trump declared the opioid crisis a "public health emergency" (https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html) on Thursday, though he did not release additional funding to address it. Had he declared it a "national emergency," as he promised to do in August, it would have led to the quick allocation of federal funds.

The New York Times has been covering the outbreak — from when it started bubbling up in towns around the United States years ago to now, as it decimates communities and families.

Here is a roundup of our best reporting on the epidemic, including short answers (https://www.nytimes.com/interactive/2017/08/03/upshot/opioid-drug-overdose-epidemic.html) to hard questions about it.

Snapshots of a Public Health Crisis

A team of reporters went inside the epidemic, from New England to "safe injection" areas in the Pacific Northwest, to explore the experiences of addicts and those trying to stem the tide. "I don't know how I'm alive, honestly," one Massachusetts woman said. Here are their stories (https://www.nytimes.com/2017/01/06/us/opioid-crisis-epidemic.html).



Even babies are affected by the crisis, with a surge of newborns dependent on opioids.
Ty Wright for The New York Times

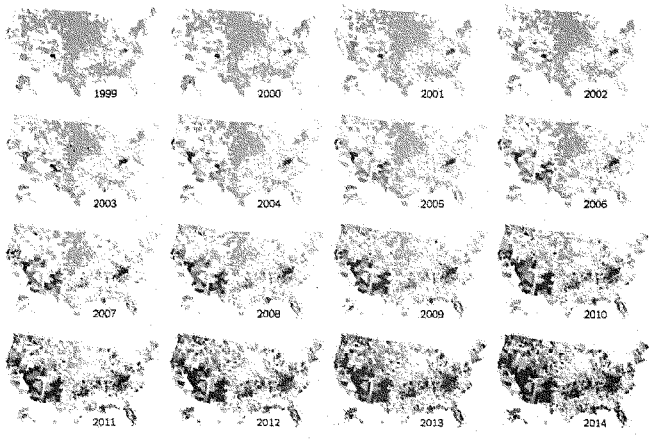
The youngest members of society have not been exempt from the crisis. Toddlers and young children are increasingly being found unconscious or dead (https://www.nytimes.com/2017/09/20/us/opioid-deaths-children.html) after

consuming an adult's drugs, and a surge of opioid-dependent newborns has forced doctors to rethink treatment (https://www.nytimes.com/2017/07/13/health/opioid-addiction-babies.html).

You have 4 free articles remaining.
Subscribe to The Times
(https://www.nytimes.com/subscription/multiproduct/lp8HYKU.html?campaignId=6YH9R&return_url=https%3A%2F%2Fwww.nytimes.com%2F2017%2F10%2F26%2Fus%2Fopioid-crisis-public-health-emergency.html)

The Numbers

Our reporters have been deciphering and providing context to masses of data about the many and varied ways opioids are affecting Americans.



How overdose deaths rippled across the United States.
Haeyoun Park and Matthew Bloch/The New York Times

Illustrated in a series of maps (https://www.nytimes.com/interactive/2016/01/07/us/drug-overdose-deaths-in-the-us.html), here's how overdose deaths rippled across the United States from

1999 to 2014, along with a breakdown of the large concentration of deaths in regions like Appalachia and the Southwest.

This interactive quiz (https://www.nytimes.com/interactive/2017/04/14/upshot/drug-overdose-epidemic-you-draw-it.html?_r=0) aims to provide a deeper understanding of the mounting toll by asking readers to compare drug overdose deaths with other causes of death.



U.S. By Yousur Al-Hlou, Josh Katz a... 2:03

Here are the facts on the deadly ...

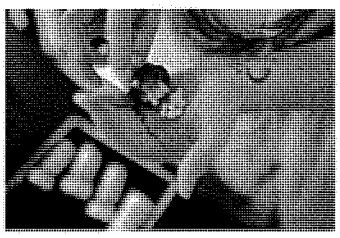
It's the deadliest drug crisis in American history. It kills about 90 Americans every day. Here are answers to some key questions about the crisis.
Oct. 26, 2017 | Image by Michael Bryant/The Philadelphia Inquirer, via Associated Press

The government's account of drug deaths in 2016 was the first national data to break down the growth by drug and by state, which revealed that deaths involving synthetic opioids, mostly fentanyls, had risen 540 percent in just three years (https://www.nytimes.com/interactive/2017/09/02/upshot/fentanyl-drug-overdose-deaths.html).

While Mr. Trump fulfilled his vow to add urgency to the rapidly escalating opioid problem, his declaration falls short of the national emergency declaration he had pledged. These are the 28 currently active national emergencies (https://www.nytimes.com/interactive/2017/08/24/upshot/opioid-crisis-national-emergency.html).

Health Care

Drug companies and doctors have been accused of fueling the opioid crisis, but insurers may also be playing a role by making it easier to get opioids than the drugs that treat addiction to them. Here are the findings of our analysis (https://www.nytimes.com/2017/09/17/health/opioid-painkillers-insurance-companies.html).



A patient had to begin taking a hydrocodone, an opioid, to treat her pain after her insurer changed what it covered.
Kevin D. Liles for The New York Times

With the soaring death toll, routine autopsies are overwhelming medical examiners everywhere. We spoke to Dr. Thomas A. Andrew (https://www.nytimes.com/2017/10/07/us/drug-overdose-medical-examiner.html) of New Hampshire, which had more deaths per capita from synthetic opioids than any other state. Dr. Andrew decided to stop practicing medicine and instead minister to the living about the dangers of drugs. "I'm not an alarmist by nature, but this is not overhyped," he said.

The Upshot reported on prescription drug monitoring programs, a tool that could be more widely used to fight opioid abuse (https://www.nytimes.com/2017/09/11/upshot/a-helpful-tool-to-combat-the-opioid-crisis.html).

Jails and Justice

Heroin users are filling the country's jails, but recovering addicts are almost always cut off from their medication while incarcerated. Connecticut, though, is trying something new: a methadone treatment program to help inmates successfully re-enter society. We looked at the conundrums detention centers are facing (https://www.nytimes.com/2017/08/04/us/heroin-addiction-jails-methadone-suboxone-treatment.html).



U.S. By Kassie Bracken 3:41

Watch: What Happens After Pri...

The Times, in collaboration with the PBS series "Frontline," followed 10 recently released inmates struggling to succeed on the outside. July 16, 2017

On Staten Island, prosecutors are leaping into largely uncharted legal terrain to fight the scourge: charging dealers in overdose deaths (https://www.nytimes.com/2017/07/23/nyregion/new-tactic-in-war-on-opioids-charging-dealers-in-overdose-deaths.html). And a New York Times Magazine writer traveled to a small town in New Hampshire (https://www.nytimes.com/2017/07/12/magazine/a-small-town-police-officers-war-on-drugs.html), where one police officer has been trying to curb the rash of opioid overdoses.

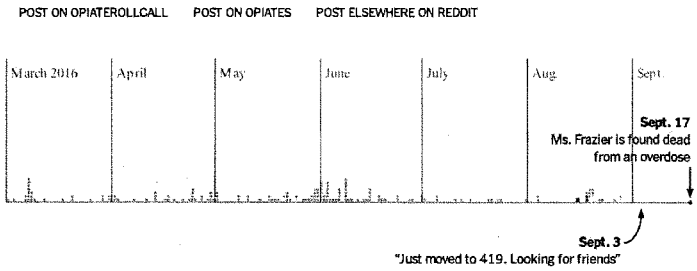
Dealing in the Digital Age

The internet is proving to be a grim tool in the opioid drug trade.

On Reddit, one of the world's largest online communities, opioid forums have offered a place to buy drugs (https://www.nytimes.com/2017/07/20/us/opioid-reddit.html) and find solace for people like Rachel Frazier, who posted on Reddit regularly and dipped into drug-related communities such as "opiates." She died two weeks after seeking drugs in a forum.

Rachel Frazier

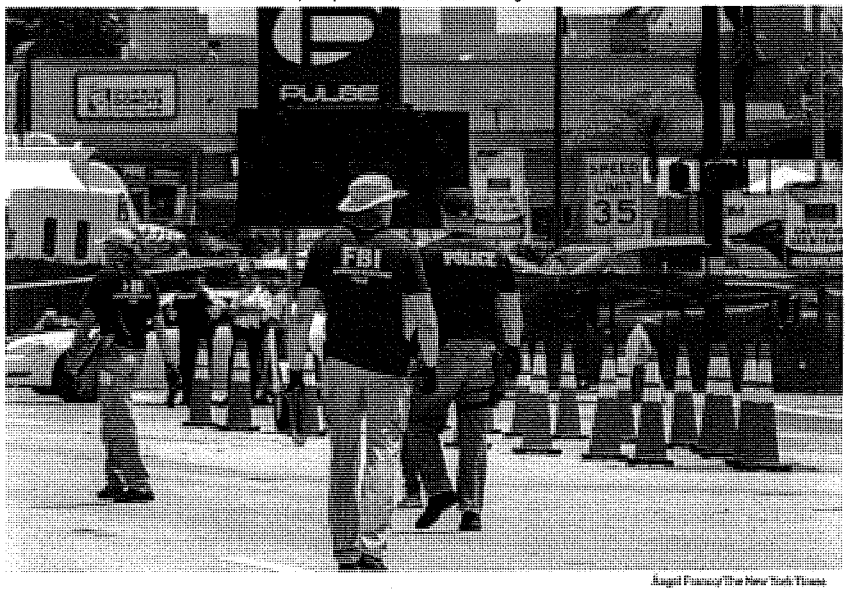
Between 2012 and 2016, Rachel Frazier posted on Reddit regularly as rachell787, occasionally dipping into drug-related communities such as "opiates." Two weeks before she was found dead of an overdose, she posted in "opiaterollcall" for the first time, apparently hoping to obtain drugs using the forum's coded language.



Dealers are embracing the dark web (https://www.nytimes.com/2017/06/10/business/dealbook/opioid-dark-web-drug-overdose.html) to anonymously send powerful synthetic opioids such as fentanyl to nearly every region of the country. Despite dozens of arrests, new merchants — many of them based in Asia — quickly pop up to fill the void.

(https://www.facebook.com/dialog/feed?
app_id=9869919170&link=https%3A%2F%2Fwww.nytimes.com%2F2017%2F10%2F26/
crisis-public-health-emergency.html&smid=fb-
share&name=The%20Opioid%20Epidemic%3A%20A%20Crisis%20Years%20in%20the%
(https://twitter.com/intent/tweet?
url=https%3A%2F%2Fwww.nytimes.com%2F2017%2F10%2F26%2Fus%2Fopioid-
crisis-public-health-
emergency.html&text=The%20Opioid%20Epidemic%3A%20A%20Crisis%20Years%20in%
(mailto:?
subject=NYTimes.com%3A%20The%20Opioid%20Epidemic%3A%20A%20Crisis%20Yea
crisis-public-health-emergency.html)

More in U.S. (https://www.nytimes.com/section/us?action=click&module=MoreInSection&pgtype=Article&region=Footer&contentCollection=U.S.)



Angel Franco/The New York Times

(https://www.nytimes.com/2018/03/01/us/pulse-trial-noor-salman-florida.html?action=click&module=MoreInSection&pgtype=Article&region=Footer&contentCollection=U.S.)

Widow of Pulse Nightclub Killer Goes on Trial, a Challenge for Prosecutors (https://www.nytimes.com/2018/03/01/us/pulse-trial-noor-salman-florida.html?action=click&module=MoreInSection&pgtype=Article&region=Footer&contentCollection=U.S

ago

Lies That Won't Die: 'Outside Agitator' and Paid 'Actor' (https://www.nytimes.com/2018/02/24/us/crisis-actors-florida-shooting.html?action=click&module=MoreInSection&pgtype=Article&region=Footer&contentCollection=U.S



(https://www.nytimes.com/2018/02/24/us/crisis-actors-florida-shooting.html?action=click&module=MoreInSection&pgtype=

24

Her Backpack Has a Bullet Hole in It, but She Went to School (https://www.nytimes.com/2018/02/28/us/stoneman-douglas-parkland-shooting.html?



(https://www.nytimes.com/2018/02/28/us/stoneman-douglas-parkland-shooting.html?action=click&module=MoreInSection&pgtype=Arti

action=click&module=MoreInSection&pgtype=Article&region=Footer&contentCollection=U.S

28

Sign up for California Today

The news and stories that matter to Californians (and anyone else interested in the state), delivered weekday mornings.

SEE SAMPLE (HTTPS://WWW.NYTIMES.COM/NEWSLETTERS/SAMPLE/CALIFORNIA-TODAY)

Enter your email address

☐ You agree to receive occasional updates and special offers for The New York Times products and services.

I'm not a robot

reCAPTCHA
Privacy - Terms

Sign Up

MANAGE EMAIL PREFERENCES (HTTPS://WWW.NYTIMES.COM/MEM/EMAIL.HTML) | OPT OUT OR CONTACT US ANYTIME (HTTPS://WWW.NYTIMES.COM/HELP/INDEX.HTML) | PRIVACY POLICY (HTTPS://WWW.NYTIMES.COM/PRIVACY)

The New York Times

Go to Home Page » (/)

(/)

NEWS

OPINION

ARTS

LIVING

LISTINGS & MORE

© 2018 The New York Times Company (https://www.nytimes.com/content/help/rights/copyright/copyright-notice.html)

Contact Us (https://myaccount.nytimes.com/membercenter/feedback.html) Work with us (http://www.nytco.com/careers)
Advertise (http://nytmediakit.com/) Your Ad Choices (https://www.nytimes.com/content/help/rights/privacy/policy/privacy-policy.html#pp)
Privacy (https://www.nytimes.com/privacy) Terms of Service (https://www.nytimes.com/ref/membercenter/help/agree.html)
Terms of Sale (https://www.nytimes.com/content/help/rights/sale/terms-of-sale.html) Site Map (http://spiderbites.nytimes.com)
Help (https://mobile.nytimes.com/help) Subscriptions (https://www.nytimes.com/subscriptions/Multiproduct/lp5558.html?campaignId=37WXW)

Archaeology U.S. History World History Video Newsletter
Subscribe Shop Travel With Us SmartNews History Science Innovation Arts & Culture Travel At the Smithsonian Photos Videos & Podcasts Games Magazine Newsletters

Smithsonian.com

Contact Privacy Policy Terms of Use

Inside the Story of America's 19th-Century Opiate Addiction

Doctors then, as now, overprescribed the painkiller to patients in need, and then, as now, government policy had a distinct bias

This cartoon from *Harper's Weekly* depicts how opiates were used in the 19th century to help babies cope with teething. (Harpers Weekly)

By Erick Trickey
smithsonian.com
January 4, 2018

The man was bleeding, wounded in a bar fight, half-conscious. Charles Schuppert, a New Orleans surgeon, was summoned to help. It was the late 1870s, and Schuppert, like thousands of American doctors of his era, turned to the most effective drug in his kit. "I gave him an injection of morphine subcutaneously of ½ grain," Schuppert wrote in his casebook. "This acted like a charm, as he came to in a minute from the stupor he was in and rested very easily."

Physicians like Schuppert used morphine as a new-fangled wonder drug. Injected with a hypodermic syringe, the medication relieved pain, asthma, headaches, alcoholics' delirium tremens, gastrointestinal diseases and menstrual cramps. "Doctors were really impressed by the speedy results they got," says David T. Courtwright, author of *Dark Paradise: A History of Opiate Addiction in America*. "It's almost as if someone had handed them a magic wand."

By 1895, morphine and opium powders, like OxyContin and other prescription opioids today, had led to an addiction epidemic that affected roughly 1 in 200 Americans. Before 1900, the typical opiate addict in America was an upper-class or middle-class white woman. Today, doctors are re-learning lessons their predecessors learned more than a lifetime ago.

Opium's history in the United States is as old as the nation itself. During the American Revolution, the Continental and British armies used opium to treat sick and wounded soldiers. Benjamin Franklin took opium late in life to cope with severe pain from a bladder stone. A doctor gave laudanum, a tincture of opium mixed with alcohol, to Alexander Hamilton after his fatal duel with Aaron Burr.

The Civil War helped set off America's opiate epidemic. The Union Army alone issued nearly 10 million opium pills to its soldiers, plus 2.8 million ounces of opium powders and tinctures. An unknown number of soldiers returned home addicted, or with war wounds that opium relieved. "Even if a disabled soldier survived the war without becoming addicted, there was a good chance he would later meet up with a hypodermic-wielding physician," Courtright wrote. The hypodermic syringe, introduced to the United States in 1856 and widely used to deliver morphine by the 1870s, played an even greater role, argued Courtwright in *Dark Paradise*. "Though it could cure little, it could relieve anything," he wrote. "Doctors and patients alike were tempted to overuse."

Opiates made up 15 percent of all prescriptions dispensed in Boston in 1888, according to a survey of the city's drug stores. "In 1890, opiates were sold in an unregulated medical marketplace," wrote Caroline Jean Acker in her 2002 book, *Creating the American Junkie: Addiction Research in the Classic Era of Narcotic Control*. "Physicians prescribed them for a wide range of indications, and pharmacists sold them to individuals medicating themselves for physical and mental discomforts."

Male doctors turned to morphine to relieve many female patients' menstrual cramps, "diseases of a nervous character," and even morning sickness. Overuse led to addiction. By the late 1800s, women made up more than 60 percent of opium addicts. "Uterine and ovarian complications cause more ladies to fall into the [opium] habit, than all other diseases combined," wrote Dr. Frederick Hernan Hubbard in his 1881 book, *The Opium Habit and Alcoholism.*

Throughout the 1870s and 1880s, medical journals filled with warnings about the danger of morphine addiction. But many doctors were slow to heed them, because of inadequate medical education and a shortage of other treatments. "In the 19th century, when a physician decided to recommend or prescribe an opiate for a patient, the physician did not have a lot of alternatives," said Courtwright in a recent interview. Financial pressures mattered too: demand for morphine from well-off patients, competition from other doctors and pharmacies willing to supply narcotics.

Only around 1895, at the peak of the epidemic, did doctors begin to slow and reverse the overuse of opiates. Advances in medicine and public health played a role: acceptance of the germ theory of disease, vaccines, x-rays, and the debut of new pain relievers, such as aspirin in 1899. Better sanitation meant fewer patients contracting dysentery or other gastrointestinal diseases, then turning to opiates for their constipating and pain-relieving effects.

Educating doctors was key to fighting the epidemic. Medical instructors and textbooks from the 1890s regularly delivered strong warnings against overusing opium. "By the late 19th century, [if] you pick up a medical journal about morphine addiction," says Courtwright, "you'll very commonly encounter a sentence like this: 'Doctors who resort too quickly to the needle are lazy, they're incompetent, they're poorly trained, they're behind the times.'" New regulations also helped: state laws passed between 1895 and 1915 restricted the sale of opiates to patients with a valid prescription, ending their availability as over-the-counter drugs.

As doctors led fewer patients to addiction, another kind of user emerged as the new face of the addict. Opium smoking spread across the United States from the 1870s into the 1910s, with Chinese immigrants operating opium dens in most major cities and Western towns. They attracted both indentured Chinese immigrant workers and white Americans, especially "lower-class urban males, often neophyte members of the underworld," according to *Dark Paradise.* "It's a poor town now-a-days that has not a Chinese laundry," a white opium-smoker said in 1883, "and nearly every one of these has its layout" – an opium pipe and accessories.

That shift created a political opening for prohibition. "In the late 19th century, as long as the most common kind of narcotic addict was a sick old lady, a morphine or opium user, people weren't really interested in throwing them in jail," Courtwright says. "That was a bad problem, that was a scandal, but it wasn't a crime."

That changed in the 1910s and 1920s, he says. "When the typical drug user was a young tough on a street corner, hanging out with his friends and snorting heroin, that's a very different and less sympathetic picture of narcotic addiction."

The federal government's efforts to ban opium grew out of its new colonialist ambitions in the Pacific. The Philippines were then a territory under American control, and the opium trade there raised significant concerns. President Theodore Roosevelt called for an international opium commission to meet in Shanghai at the urging of alarmed American missionaries stationed in the region. "U.S. delegates," wrote Acker in *Creating the American Junkie,* "were in a poor position to advocate reform elsewhere when their own country lack national legislation regulating the opium trade." Secretary of State Elihu Root submitted a draft bill to Congress that would ban the import of opium prepared for smoking and punish possession of it with up to two years in prison. "Since smoking opium was identified with Chinese, gamblers, and prostitutes," Courtwright wrote, "little opposition was anticipated."

The law, passed in February 1909, limited supply and drove prices up. One New York City addict interviewed for a study quoted in Acker's book said the price of "a can of hop" jumped from $4 to $50. That pushed addicts toward more potent opiates, especially morphine and heroin.

The subsequent Harrison Narcotic Act of 1914, originally intended as a regulation of medical opium, became a near-prohibition. President Woodrow Wilson's Treasury Department used the act to stamp out many doctors' practice of prescribing opiates to "maintain" an addict's habit. After the U.S. Supreme Court endorsed this interpretation of the law in 1919, cities across the nation opened narcotic clinics for the addicted – a precursor to modern methadone treatment. The clinics were short-lived; the Treasury Department's Narcotic Division succeeded in closing nearly all of them by 1921. But those that focused on long-term maintenance and older, sicker addicts – such as Dr. Willis Butler's clinic in Shreveport, Louisiana – showed good results, says Courtwright. "One

of the lessons of the 20th-century treatment saga," he says, "is that long term maintenance can work, and work very well, for some patients."

Courtwright, a history professor at the University of North Florida, wrote *Dark Paradise* in 1982, then updated it in 2001 to include post-World War II heroin addiction and the Reagan-era war on drugs. Since then, he's been thinking a lot about the similarities and differences between America's two major opiate epidemics, 120 years apart. Modern doctors have a lot more treatment options than their 19th-century counterparts, he says, but they experienced a much more organized commercial campaign that pressed them to prescribe new opioids such as OxyContin. "The wave of medical opiate addiction in the 19th century was more accidental," says Courtwright. "In the late 20th and early 21st centuries, there's more of a sinister commercial element to it."

In 1982, Courtwright wrote, "What we think about addiction very much depends on who is addicted." That holds true today, he says. "You don't see a lot of people advocating a 1980s-style draconian drug policy with mandatory minimum sentences in response to this epidemic," he says.

Class and race play a role in that, he acknowledges. "A lot of new addicts are small-town white Americans: football players who get their knees messed up in high school or college, older people who have a variety of chronic degenerative diseases." Reversing the trend of 100 years ago, drug policy is turning less punitive as addiction spreads among middle-class, white Americans.

Now, Courtwright says, the country may be heading toward a wiser policy that blends drug interdiction with treatment and preventive education. "An effective drug policy is concerned with both supply reduction and demand reduction," he says. "If you can make it more difficult and expensive to get supply, at the same time that you make treatment on demand available to people, then that's a good strategy."

Like this article?
SIGN UP for our newsletter
Email SIGN UP

About Erick Trickey

Erick Trickey is a writer in Boston, covering politics, history, cities, arts, and science. He has written for POLITICO Magazine, Next City, the Boston Globe, Boston Magazine, and Cleveland Magazine

Read more from this author | Follow @ErickTrickey

Tags

American History Illegal Drugs Medicine Prescription Drugs

Around The Web Sponsored By ZergNet

Questions for the Record:
Submitted by Congressman David Kustoff (R-TN)

Energy and Commerce Subcommittee on Health
Hearing: *"Combating the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety"*

Questions to Mr. Thomas Cosgrove, Partner, Covington & Burling, LLP.:

1. In your written testimony, you note that the Drug Enforcement Administration already has a role in connection with the distribution, importation, and exportation of a tableting machine or encapsulating machine." While ultimately, this is true with the legitimate users of these machines, evidence suggests that those engaging in the illicit distribution of narcotics would likely not report their tableting or encapsulating machines to the DEA. The intent of this draft legislation is not to harm or overregulate those companies using tableting machines or encapsulating machine for legitimate purposes but rather, it is designed to give DEA the ability to prosecute those using the machines to produce illegal narcotics. With that in mind, can you provide specific details as to how you would best tailor this legislation to achieve the goal of reducing illegal pill presses on the street while preserving the ability for legitimate companies to avoid onerous regulations?

2. You mentioned that one possibility would be to amend the Chemical Diversion and Trafficking Act to give DEA broader authority under the provision. How would you amend this provision to effectively limit the illicit use of these machines?

3. In your best estimation, which countries do most of these encapsulating and tableting machines originate prior to being imported to the United States? Can you estimate as to how many of these machines are produced domestically?

4. It is understood that legitimate actors using encapsulating machines and tableting machines would register the device with the Drug Enforcement Administration. With that, it is believed that DEA can maintain a database of these machines, which they can monitor regularly. However, in an effort to prevent these machines from being used to produce illicit narcotics, how would you propose the DEA develop a more robust database to prevent these machines from ending up in the hands of bad actors?

Questions to Ms. Susan Gibson, Deputy Assistant Attorney, Diversion Control, Drug Enforcement Administration:

1. According to the written testimony of Mr. Thomas Cosgrove, the Drug Enforcement Administration currently has a "role in connection with the distribution, importation, and exportation of a tableting machine or encapsulating machine." Could you describe DEA's role in enforcing the distribution, importation, and exportation of a tableting or encapsulating machine?

2. How does DEA currently oversee the use of these machines and how regularly does this oversight occur? Is there any coordination between the DEA and other agencies to ensure that those machines currently registered with the DEA are used for legitimate purposes?

3. Of the number of registrants that DEA monitors allowing for the importation, exportation, and distribution of a tableting or encapsulating machine, is it safe to presume that those engaging in illicit activity through the use of these machines would avoid the registration process with the DEA? If so, what are the current penalties that a person could face if he or she is caught with an encapsulating or tableting machine that was not registered with the Drug Enforcement Administration?

4. From an importation standpoint, can DEA offer specifics to as where most of these devices originate? In your best estimation, what percentage of these tableting or encapsulating machines were registered with DEA?

5. How many legitimate shipments of tableting and encapsulating machines entered the United States? Which countries were the source of these shipments?

PRIME THERAPEUTICS

STATEMENT FOR THE RECORD

House Energy and Commerce, Subcommittee on Health
Hearing

"Combating the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety"
February 28, 2018

On behalf of Prime Therapeutics (Prime), a pharmacy benefit manager serving more than 27 million members across the country and headquartered in Eagan, Minnesota, we would like to thank the Subcommittee for your efforts to address our nation's opioid epidemic and alert you to Prime's efforts to address the crisis.

Prime has been working to reduce controlled substance misuse for more than a decade. Our pharmacists created a controlled substance score – an algorithm to identify people who are at risk for controlled substance abuse. We shared this tool publicly in the hopes that our peer-reviewed tool would be adopted by other health organizations so they, too, could help identify people who may need help in their own populations. This controlled substance score is the foundation to Prime's comprehensive Controlled Substance Management Program (overview attached), a program built on the recommendations of the Centers for Disease Control and Prevention (CDC).

As part of our Controlled Substance Management Program we conduct prescriber outreach, which alerts prescribers to patients who have a high controlled substance score. A point-of-sale alert is then applied which notifies pharmacists of potential concerns with controlled substance prescriptions. They then can intervene directly with members. If appropriate, and to increase safety, we may enroll members who are at risk in a "pharmacy home" or single prescriber for obtaining their controlled substance medicines.

Through these efforts, our program is helping produce positive outcomes. In the past five years, Prime has seen a **71 percent decline** in the number of high-risk opioid users and a 16 percent reduction in opioid claims among its commercial membership.

Furthermore, our pharmacists have served on the Pharmacy Quality Alliance to develop "double threat" guidelines to help physicians prevent prescribing of opioids and benzodiazepines which, when combined, may lead to death. Prime also participated in the Institute for Clinical and Economic Review's (ICER's) evaluation of abuse-deterrent formulations (ADFs) where evidence was not sufficient to show a reduced risk of abuse for patients being prescribed ADF opioids and, at current prices, ADFs would need to undergo significant cost reductions to achieve cost neutrality. We've also collaborated with health organizations to advocate for a nationwide prescription drug monitoring program (PDMPs) to prevent "doctor shopping". We actively work with law enforcement agencies to prevent fraud, waste and abuse.

We are also focused on safe disposal of medicines. According to a public opinion survey Prime commissioned, we found that few Americans safely dispose of unused medicine. We need to do what we can to keep these dangerous medicines from falling into the wrong hands. That is why Prime joined with Walgreens and several other health care organizations to announce an expanded safe medication disposal effort. This program is bringing "take back" kiosks

to an additional 900 Walgreens stores – adding to the 600 kiosks in existence – in areas where the opioid epidemic has challenged communities.

Our public opinion survey results also revealed that many people aren't told about the dangers of opioids. This signals that many tools aimed at combatting the opioid crisis may be underused. That's alarming knowing how many resources are already being put into existing tools that may not be used to their fullest potential. A recent Clinton Foundation/Johns Hopkins Bloomberg School of Public Health report – which included extensive contributions from one of Prime's clinical pharmacists – shared similar information and recommendations for action to address the epidemic. It's this kind of collaborative work that will help move the needle to end the epidemic.

Our work is far from over. Prime is now developing a predictive modeling tool so opioid misuse can be avoided before it ever starts. This tool will enable us to identify individuals who are early in their opioid use and have characteristics matching those who use opioids at unsafe levels. We can then work with prescribers to help educate members on the dangers of controlled substances and prescribe other pain management treatments. Preventing misuse is key to slowing and eventually ending this epidemic.

In the realm of public policy, we believe there are several policies that would help address the opioid epidemic. First, we support requiring prescriber use of interoperable PDMPs. While not all states allow managed care plans and PBMs to access PDMPs, where state laws do permit such access, PBMs like Prime are able to obtain complete claims history for covered members. Such access enables improvements in current controlled substances interventions that have been shown to positively influence controlled substances utilization. The literature supports the benefits of PDMPs. For instance, a 2016 study in *Health Affairs* found that the implementation of a PDMP program was associated with more than a 30 percent reduction in the rate of prescribing of Schedule II opioids. Another 2016 *Health Affairs* study found that implementation of state PDMPs was associated with the prevention of one opioid-related overdose death every two hours on average nationwide.

Second, greater adoption of e-prescribing for controlled substances (EPCS) reduces diversion. For instance, since New York State's EPCS mandate took effect in March 2016, there has been a 70 percent reduction in the loss and theft of prescription forms.

Third, Prime also strongly supports the CDC's guidelines for prescribing opioids for chronic pain and believes that greater adherence to them would help reduce inappropriate prescribing. Further, provisions in the Comprehensive Addiction and Recovery Act (CARA) – to "lock-in" Medicare beneficiaries who may be misusing opioids to a pharmacy home or single prescriber – will help complement similar efforts in the Medicaid population and should reduce the incidence of addiction in seniors.

Prime believes this epidemic deserves action on multiple fronts – from pharmacy benefit managers, as well as pharmacies, providers, pharmaceutical manufacturers, government and law enforcement agencies, and many other organizations. Together we have great influence over finding solutions made for those affected by this alarming public health issue.

Prime is proud of what we have accomplished with our controlled substance programs and partnerships over the last decade. Should you have any questions, please do not hesitate to contact Julie Cantor-Weinberg in Prime's Office of Government Affairs at Julie.Cantor-Weinberg@primetherapeutics.com.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Statement

Of

The National Association of Chain Drug Stores

For

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

On

"Combating the Opioid Crisis:
Helping Communities Balance Enforcement and Patient Safety"

February 28, 2018
10:00 a.m.

2123 Rayburn House Office Building

National Association of Chain Drug Stores (NACDS)
1776 Wilson Blvd., Suite 200
Arlington, VA 22209
703-549-3001
www.nacds.org

Introduction

The National Association of Chain Drug Stores (NACDS) thanks Chairman Burgess, Ranking Member Greene and the members of the Subcommittee on Health for your leadership and commitment to finding and implementing policy changes to address the opioid crisis. NACDS and our members remain committed to partnering with policymakers, law enforcement, and others to work on viable strategies to prevent prescription opioid diversion and abuse. Chain pharmacies engage daily in activities with the goal of preventing the diversion and abuse of all prescription medications, including opioids. We thank you for the opportunity to provide recommendations on policy changes to help curb the opioid crisis.

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS' chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.2 million individuals, including 179,000 pharmacists. They fill over 2.9 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 850 supplier partners and over 60 international members representing 22 countries. For more information, visit www.NACDS.org.

NACDS Key Policy Initiatives to Help Curb Prescription Opioid Abuse

As public health authorities have indicated, face-to-face interactions between pharmacists and patients have made pharmacists keenly aware of the extreme challenges and complexities associated with the opioid abuse epidemic.

Pharmacists and pharmacies fully understand that controlled substances are subject to abuse by a minority of individuals who improperly obtain controlled substance prescriptions from physicians and other prescribers. Pharmacists and pharmacies strive to treat medical conditions and ease patients' pain while simultaneously guarding against the abuse of controlled substances. The key is to guard against abuse without impeding our primary goal of assisting patients who need pharmacy services.

Based on our experiences, NACDS is pursuing four public policy solutions to complement pharmacy's collaboration with other stakeholders including healthcare professionals and law enforcement to address prescription opioid abuse in communities across the country.

I. Require Prescriptions to Be Issued Electronically

Chain pharmacy supports policies that promote the use of electronic prescribing to transmit prescription information between prescribers and pharmacists. For controlled substances in particular, use of this technology adds new dimensions of safety and security in the prescribing process. Data from self-reported drug abusers suggest that between 3% and 9%

of diverted opioid prescriptions are tied to forged prescriptions.[1,2] Electronic controlled substance prescriptions serve to reduce the likelihood of diversion in this manner, as electronic controlled substance prescriptions cannot be altered, cannot be copied, and are electronically trackable. Furthermore, the federal DEA rules for electronic controlled substances prescriptions establish strict security measures, such as two-factor authentication, that reduce the likelihood of fraudulent prescribing. Notably, the state of New York saw a 70% reduction in the rate of lost or stolen prescription forms after implementing its own mandatory electronic prescribing law.[3]

The rate of electronic prescribing has increased significantly in recent years. In 2008, there were about 68 million electronic prescriptions.[4] As of 2016, over 1.6 billion prescriptions were issued electronically, including approximately 45.3 million controlled substance prescriptions.[5] Still, there is room for further improvement, particularly with controlled substances prescriptions which lag behind in overall adoption rates. While 90% of all pharmacies are enabled to receive electronic prescriptions, only 17% of prescribers have systems that can send electronic prescriptions for controlled substances.[6]

To enhance healthcare providers' utilization of this technology and to foster prescriber adoption, chain pharmacy urges the adoption of policies to require that all prescriptions be issued electronically, with limited exceptions for situations in which issuing an electronic prescription may not be feasible. ***We support the Every Prescription Conveyed Securely Act (H.R. 3528), legislation that requires electronic prescribing for controlled substances in Medicare Part D. We thank Representative Mullin as an original cosponsor of this legislation and we ask that the Subcommittee work to pass this necessary legislation.***

II. Nationwide Prescription Drug Monitoring Program

NACDS supports the important role of prescription drug monitoring programs (PDMPs) in helping to prevent drug abuse and diversion. Over the years, PDMPs have been established throughout the country as tools to curb diversion and abuse of controlled substance prescriptions. At this time, nearly every state has implemented their own program designed to assist in the identification and prevention of drug abuse and diversion at the prescriber, pharmacy, and patient levels. However, there are significant variances across state programs, which altogether, impede optimal use of PDMPs to their fullest extent.

NACDS is calling upon stakeholders to work together to develop and implement a nationwide PDMP solution to harmonize state requirements for reporting and accessing PDMP data. Our goal is to establish one system with unified expectations for appropriate use of PDMP data by

[1] Rosenblum, Andrew, et al., "Prescription Opioid Abuse Among Enrollees into Methadone Maintenance Treatment," *Drug and Alcohol Dependence,* 90.1 (2007): 64-71.
[2] Inciardi, James A., et al., "The 'Black Box' of Prescription Drug Diversion," *Journal of Addictive Diseases*, 28.4 (2009): 332-347.
[3] Remarks of Anita Murray, Deputy Director, New York State Department of Health at the Harold Rogers Prescription Drug Monitoring Program National Meeting (September 6, 2017).
[4] Surescripts National Progress Report for 2012.
[5] Surescripts National Progress Report for 2016.
[6] Ibid.

prescribers, pharmacies, law enforcement, and others. Such a system would leverage electronic prescribing systems to provide timely, in-workflow analyses of real-time data with actionable point-of-care guidance for prescribers and dispensers. We urge the participation of policymakers, like the Office of the National Coordinator, other healthcare providers, law enforcement, and other stakeholders on this important initiative to create a national PDMP solution.

III. Take Back and Disposal of Consumer's Unused Controlled Substances

Chain pharmacies are committed to creating programs that provide patients with safe and effective ways to dispose of unwanted controlled substances. To this end, NACDS supports policies that accommodate pharmacy participation in a variety of DEA authorized options for controlled substance drug disposal programs. These options include, but are not limited to: take-back kiosks in pharmacies, mail-back envelopes made available by manufacturers or pharmacies, community drug take-back events hosted at pharmacies, in-home disposal products, take-back kiosks at law enforcement locations, and vouchers to patients to obtain mail-back envelopes from manufacturers or pharmacies. Of greatest importance, pharmacies must be offered a variety of program options, so that they can choose which consumer controlled substance drug disposal program best fits their patients' needs and is best suited for the community that they serve.

As highlighted in the above examples of drug disposal options, pharmacies alone are not the solution to the safe and effective disposal of unwanted controlled substances. Combating prescription drug abuse requires collaboration across the supply chain. Chain pharmacy seeks collaborative efforts, including working with manufacturers to help customers safely and effectively dispose of their unwanted opioid drugs. Accordingly, we support programs that require manufacturers to fund and make mail-back envelopes available to pharmacies to distribute to patients, upon request, when those patients fill opioid prescriptions. A program of manufacturer-funded mail-back envelopes for unused opioid drugs recognizes that the entire drug supply chain has a role in drug disposal.

Earlier this month, the FDA provided a policy document to the Energy and Commerce Committee in which FDA called upon manufacturers to establish programs for the return or destruction of unused opioids.[7] NACDS fully supports FDA's policy position and we applaud FDA for recognizing the supply chain team effort required for effective consumer controlled substance disposal. Accordingly, we urge the Subcommittee to also support FDA's policy position, as well.

Beyond the development and implementation of a variety of consumer controlled substance disposal programs, NACDS also supports patient education programs on consumer controlled substance disposal programs. To promote public awareness and use of the available disposal options, we encourage federal and state government and/or pharmaceutical

[7] "FDA Asks E&C For New Authority On Opioid Evaluation, Seizure; Suggests Requirements On Manufacturers;" *Inside Health Policy*, https://insidehealthpolicy.com/daily-news/fda-asks-ec-new-authority-opioid-evaluation-seizure-suggests-requirements-manufacturers, accessed February 9, 2018; Referencing FDA policy document provided to the House Energy and Commerce Committee.

manufacturer stewardship organizations to develop and provide drug disposal educational materials to consumers. Ideally, such materials should focus upon controlled substances, including the dangers of misuse and the potential for addiction to prescription controlled substances, treatment resources available, and the proper way to dispose of unused prescription controlled substances. These educational materials should be posted on government websites and be made available to pharmacies to provide to customers filling controlled substance prescriptions, with each pharmacy determining the best method for making those materials available to its patient population in a written and/or electronic format.

IV. 7-Day Supply Limit for Initial Opioid Prescriptions Issued for Acute Pain

NACDS supports policies establishing a 7-day supply limit for initial opioid prescriptions written for acute pain. This policy aligns with the *Guideline for Prescribing Opioids for Chronic Pain* developed by the Centers for Disease Control and Prevention (CDC) and serves to reduce the incidence of misuse, abuse, and overdose of these drugs.[8]

A clinical evidence review performed by the CDC revealed that a greater amount of early opioid exposure is associated with a greater risk for long-term use and addiction.[9] Notably, the average day supply per opioid prescription has increased in recent years, growing from 13.3 to 18.1 days per prescription between 2006 and 2016.[10] Considering this trend and the risk of early exposure to higher amounts of opioids, it is imperative that lawmakers adopt policies to promote careful prescribing practices for prescription opioids.

So far, over 20 states have adopted laws or other policies limiting the maximum day supply that can be authorized on an initial opioid prescription for acute pain (with appropriate exemptions, such as patients with pain due to cancer, hospice, or other end-of-life care, etc.)

Chain pharmacy encourages Congress to enact legislation that is standardized across the nation to promote consistent patient care and implementation across the country. NACDS would support federal legislation that preempts individual state variations.

- *Limiting Opioid Prescriptions*

  Health plans and their pharmacy benefit managers are also altering health plan designs to cover less than prescribed amounts of opioids. However, existing federal and state standards may complicate efforts by pharmacies to dispense less than prescribed amounts of opioids. Several states have laws or rules that can be read to require pharmacies to dispense medications as prescribed. Section 702 of the Comprehensive Addiction and Recovery Act of 2016 allows pharmacies to dispense less than prescribed amounts of opioids, but only as allowed by DEA rules or when "requested by the patient or the practitioner that wrote the

[8] Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain.* CDC.gov. https://www.cdc.gov/drugoverdose/prescribing/guideline.html.
[9] Ibid.
[10] Centers for Disease Control and Prevention, *Annual Surveillance Report of Drug-Related Risks and Outcomes.* United States, 2017. https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf

prescription." A DEA rule also raises questions regarding the ability of pharmacies to dispense less than prescribed amounts of opioids. The rule provides that a pharmacist may partially fill a prescription for a Schedule II opioid only if the pharmacist is "unable" to dispense the full amount prescribed.[11] NACDS and others have asked DEA to clarify when pharmacies may dispense less than prescribed amounts of opioids.

In the absence of DEA action to clarify these matters, NACDS would support federal legislation to clarify federal policy regarding when pharmacies may dispense less than prescribed amounts of opioids.

Practitioner Education

As the Subcommittee considers H.R. 2063, legislation to amend the Controlled Substances Act to require certain practitioner education as a condition of registration to prescribe or dispense opioids for the treatment of pain or pain management, we ask the Subcommittee to consider expanding this education requirement beyond opioids to include all controlled substances in Schedules II-V.

As currently drafted, H.R. 2063 requires that as a condition of obtaining and maintaining DEA registration, prescribers who prescribe or dispense opioids must complete twelve hours of continuing education on pain management treatment guidelines and best practices, early detection of opioid addiction, and the treatment and management of opioid-dependent patients. However, there are non-opioid controlled substance medications that can be abused individually, by their very nature, and/or concurrently with opioids as potentiators of the desired illicit effect (e.g., the so-called "Holy Trinity" of opioids, benzodiazepines, and carisoprodol).

Given that all controlled substances can potentially be abused as well as the increased risk of overdose with concurrent use of opioids and other controlled substances in particular, prescribers of all controlled substance medications should be educated on pain management treatment guidelines and best practices, early detection of controlled substance medication addiction, and the treatment and management of patients that are addicted to controlled substance medications.

Accordingly, NACDS recommends that H.R. 2063 be amended to ensure that all prescribers of controlled substances complete the required continuing education as a condition of maintaining their DEA registration.

Conclusion

NACDS thanks the Subcommittee for consideration of our comments. We look forward to working with policymakers and stakeholders on these important issues.

[11] 21 CFR §1306.13(a).

UT Health
San Antonio

27 February 2018

To Whom It May Concern:

I am Professor of Pharmacology and Psychiatry and the Robert A Welch Distinguished University Chair in Chemistry at the University of Texas Health Science Center in San Antonio, Texas. I have conducted drug abuse research for more 40 years, and I have held US Drug Enforcement Administration (DEA) Schedule I and Schedule II-V registrations for 28 years, in addition to State of Louisiana and State of Texas registrations.

As a scientist who has dedicated his entire career to studying drug abuse, I am keenly aware of the need to strike a balance between regulatory control of drugs to protect the public and the freedom for researchers to study drugs in order to advance our understanding of drug abuse and develop new treatments. My research program has three major goals: 1) understand the factors that cause drug abuse; 2) evaluate the abuse potential of new chemicals (largely for the pharmaceutical industry and regulatory agencies); and 3) develop new treatments for drug abuse. The success of each of these activities depends upon the availability of a wide variety of drugs – the primary tools that we use to study the brain and addiction – including controlled substances. Scientists need the freedom to pursue lines of research that they, the experts, deem important; for that to occur, they need to have access to drugs.

Current regulatory oversight of scientists working with controlled substances is a significant impediment to research, and further regulatory oversight, as would likely result from the Stop the Importation and Trafficking of Synthetic Analogues Act of 2017 (SITSA), would worsen this situation. Separate storage and record keeping that is currently required of anyone working with Schedule I compounds is a burden for many researchers and institutions that is not clearly reduced with the new Schedule A; moreover, it is unclear whether the new schedule A would facilitate better access to research tools for scientists. Despite having a DEA Schedule I registration for nearly 30 years without incident, when I want to study a Schedule I compound that is not already on my registration, I have to submit volumes of paperwork (much of it redundant with previous requests) as part of a request evaluated by the DEA and others. Decisions on my most recent requests have taken many months; those delays impede research and prevent scientists like me from responding quickly to public health issues (e.g., emergence of a new drug of abuse) that demand systematic study. Increased regulatory oversight of researchers regarding controlled substances would have no obvious impact in protecting public health while significantly decreasing the productivity of scientists.

Rational decisions as to whether a drug should be scheduled or whether it might be a useful medicine can be made only with solid scientific data, and those data can be collected only if scientists have appropriate access to drugs for their experiments. The scheduling of compounds based strictly on chemical structure is a concern since drugs that are nearly identical in structure can have dramatically different effects. For example, some drugs contributing to the current opioid epidemic and overdose crisis (e.g., heroin) are structurally very similar to the drugs used to treat opioid abuse (naltrexone) or rescue patients from opioid overdose (naloxone). Similarly, there is evidence that the toxic effects of some fentanyl derivatives are relatively insensitive to reversal by the only drug (naloxone) that is available for rescue from overdose; however, most researchers do not have a Schedule I registration so they cannot investigate this important question. Schedule A would add another category of registration, but would not improve access to important tools for scientists because under SITSA all Schedule I and Schedule A registrants would be required to submit requests to the Attorney General.

Additional regulatory oversight and scheduling of compounds without solid scientific evidence will not improve public health but will further impede the already difficult job of dedicated addiction researchers.

Respectfully,

Charles P France

Charles P France, PhD | *Robert A Welch Distinguished University Chair in Chemistry*
Department of Pharmacology | Mail Code 7764 | 7703 Floyd Curl Drive | San Antonio, Texas 78229-3900 USA
Voice: 210.567.6969 | Fax: 210.567.0104 | Email: france@uthscsa.edu

Catherine M. Davis, Ph.D.
Assistant Professor

Department of Psychiatry and Behavioral Sciences
Division of Behavioral Biology
Hopkins Bayview Medical Center
5510 Nathan Shock Drive / BBRC 3000
Baltimore, MD 21224-6823
410-550-2775 T
410-550-2780 F
cdavis91@jhmi.edu

Comments of Catherine M. Davis, PhD

Health Subcommittee of the Committee on Energy & Commerce

Wednesday, February 28, 2018

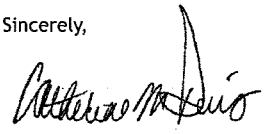
Combating the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety

Performing research with compounds on Schedules I-V creates hurdles for researchers that must be met before state and federal licenses will be issued, including how they store the compounds, in addition to how the compounds are distributed, tracked, and wasted within the laboratory. These are not trivial concerns and require specialized equipment (e.g., certain type of safe) and inspections (from the DEA, but also from each researcher's institution - which can be more variable and restrictive in their requirements than the DEA). A researcher who has completed and received his/her Schedule I and/or II-V licenses has shown the state and federal governments that they have the necessary facilities and personnel in place to safely use this compounds with minimal risk of diversion. Adding another schedule to this structure would increase the burden already placed on these researchers, slow the progress made in researching these substances, and possibly turn away new (and more senior) investigators from researching these substances due to the regulatory and financial burdens of maintaining these various state and federal licenses.

Given that the DEA's emergency scheduling ability, it is not clear exactly what schedule A will do that emergency scheduling to schedule I would be unable to achieve. The creation of Schedule A creates another regulatory burden for researchers, such that they may need to apply for an additional license in the future or have this sub-schedule added to their current licenses, even though they already have both Schedule I and/or II-V licenses and thus have the appropriate facilities in place to receive, store, handle, and dispose of Schedule I-V substances. Further, this bill could limit the research completed on these compounds by making them harder to acquire at a time when it is imperative that we understand the abuse liability of various opioids and their analogues. It is unclear how the creation of this new schedule or sub-schedule will actually decrease abuse of these compounds. As written, this legislation does not differ substantially from Schedule I or II, such that without this legislation, these compounds would go unscheduled.

Finally, this new legislation removes scientific input from the discussion regarding the scheduling associated with a specific compound or class of compounds. With no input from scientists and pubic health officials this legislation would provide the Justice Department a method to put almost any substance in the Schedule A category, even if the scientific evidence for such a classification is limited or lacking. This fact could potentially place many compounds on Schedule A due to their similarities in chemical structure without sufficient evidence from the scientific community to support their possible abuse.

Sincerely,



Catherine M. Davis, Ph.D.

CVSHealth

Statement for the Record
House Energy and Commerce Subcommittee on Health
February 28, 2018

CVS Health's mission is based on the simple premise that health is everything, and we believe our role is to help people on their path to better health. This belief guides every decision we make. Every day, in countless ways, our teams of expert clinicians, pharmacists, and nurses work hard to care for patients.

We share the House Energy and Commerce Committee's concern that across the country, many lives in the communities we serve are being disrupted by the opioid abuse epidemic. The problem is a complex one with many causes and challenges. Defeating the epidemic of opioid abuse requires the active involvement of stakeholders throughout the health care community, as well as law enforcement and regulatory agencies, and CVS Health is committed to being part of the solution.

While CVS Health has developed and implemented numerous programs and initiatives aimed at combating opioid abuse across our company, we understand the Committee is interested in obtaining additional recommendations regarding policy and regulatory changes that could be made to help align and leverage the full range of clinical assets offered across the heath care payor and provider continuum.

As Congress considers new initiatives to address the epidemic, we strongly encourage consideration of the following:

Reducing Quantities of Opioids Prescribed

In 2016, the Centers for Disease Control and Prevention (CDC) released a prescribing guideline to promote medically appropriate use of prescription painkillers. The recommendations in the guideline are intended to assist primary care providers make informed prescribing decisions and improve patient care for those with pain while reducing the number of people who misuse, abuse or overdose from these drugs.

CVS Health has created a program for our clients that incorporates the 2016 CDC recommendations into the utilization management programs for prescriptions adjudicated through CVS Caremark, our pharmacy benefits manager. We have encouraged our clients to adopt this program, and if they do, we limit the quantities of opioids covered to a seven-day supply for most acute conditions. Our initial findings indicate employers, unions, and health plans that implemented our opioid utilization management program in 2017 experienced a 70 percent decrease in the number of patients new to opioid therapy with an acute condition who received more than seven-day supply of an opioid. For those plans, the number of patients new to opioid therapy who now receive a seven-day supply or less is nearly 94 percent.

We believe, however, more can be done at the federal and state level to reduce the risks of inappropriate use and to limit unnecessary supply. The CDC guideline advises there is rarely a need for more than seven days of opioids for acute conditions. Based on this recommendation, at least 18 states have established prescribing limits for acute pain at seven days or less. CVS Health supports these quantity restrictions and believes Congress should take action to amend the Controlled Substances Act to establish similar prescribing limits at the federal level and to expand the circumstances under which a pharmacy could provide a partial fill of a CII opioid medication.

E-Prescribing of Controlled Substances

CVS Health supports electronic prescribing of prescription drugs. Electronic prescribing has proven effective in reducing drug diversion and fraud, as it makes it easier to track prescriptions and more difficult to alter them. We believe Congress should move to require electronic prescribing in Medicare as would be required under H.R. 3528, *The Every Prescription Conveyed Securely Act*, introduced by Congressman Markwayne Mullin (R-OK) and Congresswoman Katherine Clark (D-MA). Enactment of this legislation would be a significant step to improve patient outcomes, increase drug security, and limit the inappropriate use of opioids.

Support for Prescription Drug Take-Back Programs

For several years, CVS Health has supported the *Medication Disposal for Safer Communities Program*, which provides police departments across the United States with an easy way to obtain a drug collection unit for their locations. Through this program, created with the Partnership for Drug-Free Kids, CVS Health has donated more than 860 medication disposal units to local police departments in 43 states, collecting more than 140 metric tons of unwanted medication. Beginning in 2017, CVS Health expanded its total disposal units to 1,550 kiosks, including the phase-in of 750 additional disposal units in CVS Pharmacy locations across the country.

We believe these kinds of programs provide a valuable resource to public health and law enforcement organizations in securing unwanted medications. As Congress considers additional funding to address the opioid abuse epidemic, we encourage members to support financial assistance for community drug take-back programs, which have demonstrated a meaningful impact on reducing drug diversion and abuse across the United States. Additionally, we believe Congress could provide a review of current drug take-back and disposal regulations in an effort to limit costs and to ensure as many providers as possible are able to participate in these important community take-back initiatives.

CVS Health appreciates the opportunity to offer our recommendations to the Committee. We look forward to working with you further as you consider solutions to address this public health crisis.



28 February 2018

Hon. Greg Walden
Chairman
2125 Rayburn HOB
Washington, DC 20515

Hon. Frank Pallone
Ranking Member
2322A Rayburn HOB
Washington, DC 20515

Dear Chairman Walden & Ranking Member Pallone –

braeburn
47 Hulfish St, Suite 441
Princeton, NJ 08542

On behalf of Braeburn, I am writing to thank you for your leadership on the Ensuring Patient Access to Substance Use Disorder Treatments Act of 2018, which will make long overdue updates to federal law to improve the dispensing of implantable and injectable therapies. We share your goal of expanding access to treatments for patients with Opioid Use Disorder, and applaud your efforts to make abuse, misuse and diversion more difficult.

Braeburn is dedicated to developing evidence-based treatments to help stop the opioid epidemic and save American lives. Braeburn provides the healthcare provider with a platform of addiction treatment medications that help promote adherence and are expected to be less prone to abuse and diversion than daily addiction treatments.

The Ensuring Patient Access to Substance Use Disorder Treatments Act will expand access to practitioner-administered treatments, which will help to ensure proper delivery and medication adherence, while potentially minimizing risks of diversion, misuse and accidental pediatric exposure.

The Controlled Substances Act, when originally enacted, did not foresee these innovative new products, and requires that a product must be dispensed to the patient for whom it was written. This requirement creates an unnecessary barrier to next generation treatments.

We thank you again for your leadership on this critical issue.

Best,

Mike Derkacz
President & CEO



800 10th Street, NW
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100 Phone
www.aha.org

February 28, 2018

The Honorable Michael Burgess, M.D.
Chairman
Subcommittee on Health
House Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

The Honorable Gene Green
Ranking Member
Subcommittee on Health
House Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

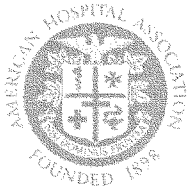
Dear Chairman Burgess and Ranking Member Green:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,00 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) thanks you for your leadership on addressing the opioid crisis.

Every day, hospitals witness the devastating effects of opioids on the patients, families and communities we serve. Prescription opioids can be a safe and necessary element of pain management for those who have experienced trauma or are suffering from cancer, sickle cell disease or other diseases that cause debilitating pain. On the other hand, opioids carry significant risk for misuse, addiction, overdose and death, and must be used judiciously.

To prevent addiction and misuse, hospitals and health systems are working to reduce patients' exposure to opioids by making other types of pain control more readily available. They are implementing standard, evidence-based protocols for prescribing limited amounts of opioids to patients, and they are safeguarding prescription drugs from diversion. Our members are using state prescription drug monitoring programs and working to link them to their electronic health records to ensure that a seamless and accurate flow of information regarding the patient's prescriptions is available.

When patients are diagnosed with substance use disorder, hospitals are offering treatment or referrals, as appropriate, and integrating physical and behavioral health care. They are training first responders to use naloxone and, in some cases, equipping them with this overdose antidote.



We have, along with the Centers for Disease Control and Prevention, developed a resource for patients in hospitals to educate them about the appropriate use of opioids, and we have produced a toolkit for our 5.000 member hospitals to help them provide optimal care to patients. But we are fully aware that the size and scope of this epidemic require collaboration between federal, state, and local governments, and the private sector, and resources that only the federal government is able to provide.

The AHA is gratified to see the Subcommittee on Health begin to receive testimony on specific legislative approaches to solving this crisis. Our membership is evaluating the potential implications of the many bills that have been referred to the Subcommittee this year, and we look forward to working with you and your staff in the coming weeks to shape legislation affecting hospitals and health systems. As you work through the various issues in the Subcommittee's jurisdiction, we ask you to consider the policy priorities in the attached letter, which we submitted to the Senate Committee on Finance earlier this month.

Sincerely,

Thomas P. Nickels
Executive Vice President

Attachment

American Hospital Association.

800 10th Street, NW
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100 Phone
www.aha.org

February 16, 2018

The Honorable Orrin G. Hatch, Chairman
The Honorable Ron Wyden, Ranking Member
Senate Committee on Finance
United States Senate
Washington, DC 20510-6200

Transmitted via email: Opioids@finance.senate.gov

Re: Request for Recommendations for Policy Actions to Address the Opioid Epidemic

Dear Chairman Hatch and Ranking Member Wyden:

As the nation continues to struggle with the devastating public health crisis created by the opioid epidemic, it is encouraging to see the Senate Finance Committee exploring how changes in public policy and the Medicare and Medicaid programs can help in the fight. We appreciate your interest and commitment and welcome this opportunity to continue to work with you. On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,00 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) thanks you for addressing the nation's opioid epidemic.

HOSPITALS AND HEALTH SYSTEMS ARE ALREADY TAKING ACTION

Every day, hospitals witness the devastating effects of the opioid epidemic on the patients, families, and communities we serve. Prescription opioids can be a safe and necessary element of pain management for those who have experienced trauma or are suffering from cancer, sickle cell disease or other diseases that cause debilitating pain. On the other hand, opioids carry significant risk for misuse, addiction, overdose and death, and must be used judiciously.

To prevent addiction and misuse, hospitals and health systems are working to reduce patients' exposure to opioids by making other types of pain control more readily available. They are implementing standard, evidence-based protocols for prescribing limited amounts of opioids to patients, and they are safeguarding prescription drugs from diversion. Our members are using state prescription drug monitoring programs and working to link them to their electronic health

records (EHRs) to ensure that a seamless and accurate flow of information regarding the patient's prescriptions is available.
When patients are diagnosed with substance use disorder (SUD), hospitals are offering treatment or referrals, as appropriate, and integrating physical and behavioral health care. They are training first responders to use naloxone and, in some cases, equipping them with this overdose antidote.

However, hospitals are aware that this epidemic cannot be successfully dealt with by health care providers working independently. They are collaborating with their communities to create coordinated responses. They are forming partnerships with other health care providers, state and local departments of health, law enforcement, schools, community organizations and others. Through these collaborations, we have seen hospitals engage recovery specialists to help patients admitted for drug overdose enter treatment, expand SUD treatment services, join with law enforcement to facilitate access to treatment, fund public education programs, educate community clinicians about prescribing practices, and more. But much remains to be done.

There are five policy issues of paramount importance to enable this work to address opioids to continue.

1) **Preserve and Protect Health Insurance Coverage, Including Medicaid.** We urge the Committee to ensure that coverage through the health insurance exchanges and through Medicaid, which provide a substantial number of Americans with benefits for substance use disorder treatment, be preserved. In addition, the Senate Finance Committee has the opportunity to ensure that Medicaid programs adequately cover SUD treatment, and an essential step in that effort is to eliminate the Institutions for Mental Disease (IMD) exclusion. This exclusion prohibits Medicaid from paying for care for patients between ages 21 and 64 who are hospitalized in inpatient psychiatric hospitals, thus making it extremely challenging for those of limited means to receive effective treatment for substance use disorders. Prohibiting payment for SUD treatment in freestanding psychiatric facilities seems to further stigmatize and blame victims for their illness.

IMDs could expand access to services for patients with SUDs if the exclusion were eliminated. Addressing this exclusion would be particularly helpful in improving access to treatment for those with severe or more complex SUDs. It also could reduce wait times, and possibly the occurrence of emergency department boarding, for patients with both substance use and mental health disorders who would benefit from inpatient treatment. **We urge the Committee to report out legislation to end the IMD exclusion.**

2) **Enhance Parity Enforcement.** The Mental Health Parity and Addiction Equity Act (MHPAEA) gave the Department of Labor responsibility for enforcing parity in health coverage. Our members and the patients they serve continue to face obstacles in securing coverage and payment as intended by the parity law. More must be done to enhance parity compliance, including ensuring that parity provisions included in the 21st Century Cures Act are carried out. New guidance for health plans, improved transparency of benefit information, and additional parity compliance analysis tools can all support better adherence to MHPAEA provisions.

Federal agencies, and especially the Department of Labor, must make parity enforcement a priority. **We urge the Committee to clearly communicate this expectation to the Secretary of Labor.**

3) Make Critical Information Readily Available to All Clinicians Treating Patients with SUD. Clinicians treating patients, for any condition, need information on their substance use disorder to ensure their patients' safety. The partitioning of a patient's medical record to keep SUD diagnoses and treatments hidden from most clinicians who will treat the patient is dangerous for the patient, burdensome for providers and contributes to the stigmatization of mental/behavioral health diseases. Too many patients who suffer from an SUD have stories of how a well-intentioned emergency room physician or other clinician working on physical health issues nearly prescribed them an opioid or another drug that would have endangered their life or sobriety. Such incidents happen because the clinician cannot access information on the patient's SUD and treatment plan unless the patient gives consent. The prevalence of SUD in the population requires that hospitals have access to complete information about the patient's medical history, including information about substance use disorders.

Finally, providers go to extraordinary lengths to comply with the requirements of 42CFR Part 2. For example, we have spoken to obstetricians who specialize in treating pregnant women with SUD diagnoses and other clinicians who treat both the physical and SUD diagnoses of patients. To ensure compliance with 42CFR Part 2, as currently written, these clinicians have to have two separate computers and two separate medical records. This adds burden and expense, with no benefit to patients.

Recent revisions made by the Substance Abuse and Mental Health Services Administration to the Part 2 regulations are not a significant improvement over the previous requirements and do little to eliminate the regulation's barriers that impede the robust sharing of patient information necessary for effective clinical integration and quality improvement. Complete alignment of Part 2 with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule will require statutory changes. **We urge the members of the Committee to support S. 1850, the Protecting Jessica Grubb's Legacy Act, introduced by Sens. Joe Manchin (D-WV) and Shelley Moore Capito (R-WV), which would mandate that 42 CFR Part 2 be brought into alignment with HIPAA. This alignment would protect patients from inappropriate disclosure of their health information while enabling clinicians to more safely treat those with SUD.** Further, while that bill is under consideration, we urge the Committee to encourage the Centers for Medicare & Medicaid Services to include information for beneficiaries in the Medicare & You handbook and in public service announcements to alert patients and their families that clinicians other than those caring for behavioral health issues will not be able to access information about their prescriptions or treatment plan for SUD without their express permission, and explain why it is important for the patients' safety that their clinicians know about their diagnoses.

4) Enhance Medication-assisted Treatment (MAT). A recent report from the National Academies of Sciences, Engineering and Medicine underscores the gaps in availability of MAT in the U.S. The AHA has previously supported efforts to increase patient limits for

buprenorphine prescribing. The federal government should continue to incentivize adequate access to MAT. That starts with having enough clinicians with specialized training. Among the key challenges for health systems in offering SUD services is finding trained providers. Medicare should incentivize providers to get this training by providing an increase in payment to those who have completed the training or by recognizing the acquisition of such skills as a quality improvement activity under the Merit-based Incentive Payment System.

5) Promote Interstate Data Sharing Among Prescription Drug Monitoring Programs (PDMPs). The AHA also supports efforts to ensure that PDMP information is shared across state lines. State PDMPs are an important tool in fighting the epidemic, and Congress should seek ways to maximize the capacity of this technology to help clinicians avoid unnecessary or potentially harmful opioid prescriptions. We understand that most PDMPs already engage in some level of information sharing, especially with their neighboring states. To enhance these efforts, certified EHRs can be used to improve knowledge about a patient's medications – active and prior. The best approach would be to ensure the inclusion of PDMP information in the certified EHR in a timely and efficient manner in the course of the clinical workflow, which requires improved interoperability. **We urge the Committee to consider dedicated funding to promote improved interoperability between health care providers and PDMPs, and among PDMPs in different states.**

Thank you for this opportunity to comment. If you have questions or need further information, please feel free to contact me or have a member of the Committee staff reach out to Priscilla Ross, senior associate director of federal relations, at pross@aha.org or 202-626-2677.

Sincerely,

Thomas P. Nickels
Executive Vice President
Government Relations and Public Policy

February 28, 2018

We are the Drug Policy Alliance.

The Honorable Michael Burgess
US House of Representatives
2336 Rayburn HOB
Washington, D.C. 20515

The Honorable Gene Green
US House of Representatives
2470 Rayburn HOB
Washington, D.C. 20515

Dear Chairman Burgess and Ranking Member Green,

The Drug Policy Alliance appreciates the opportunity to submit testimony for consideration of HR 2851, the "Stop Importation and Trafficking of Synthetic Analogues Act of 2017" during today's hearing titled "Combating the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety."

The Drug Policy Alliance (DPA) works to increase the degree to which problematic drug use is treated as a health issue and advances evidence-based drug policy grounded in compassion and human rights. We accordingly oppose policies that predominantly rely on the criminal justice system to address drug use. Congress has recognized the failings of harsh sentences for drugs like heroin and crack and held hearings in recent years to reduce such penalties. DPA believes that we can best protect the public's health, not through relying on punitive approaches to drugs, but by focusing on the underlying reasons for their demand and offering evidence-based strategies for preventing their use, reducing their harm, and treating those who are using them problematically.

In recent years, a bipartisan consensus has emerged in Congress that urgent action is needed to address the opioid overdose crisis. Both parties have come together to pass measures such as the Comprehensive Addiction and Recovery Act and 21st Century CURES Act that treat the opioid overdose crisis as a public health – not enforcement – challenge. Most recently Congress approved six billion dollars in new funding to address this crisis. This Committee has held numerous hearings that have explored evidence-based and health-based solutions to the opioid overdose crisis. Although there is still a tremendous amount of work to be done, Congress has made important progress toward the goal of addressing the opioid overdose crisis. We are very disappointed then to see the Committee take up HR 2851.

SITSA is a counterproductive approach to the opioid overdose crisis that would greatly expand the penalties for drug offenses and enable the Attorney General to ban hundreds of substances and prosecute people with long federal prison terms in violation of the new drug laws. The Attorney General already has authority granted by Congress to use emergency scheduling powers, as well as the ability to concurrently pursue permanent rulemaking authority for substances that have been emergency scheduled. A heavy reliance on law enforcement and the criminal justice system to prevent addiction has failed to reduce rates of opioid use and overdose. HR 2851 will similarly not deter the use or sale of fentanyl and other synthetic analogues.

We know that synthetic analogues are often manufactured outside the country. This is also the case with fentanyl and fentanyl analogues. In June 2016, the head of the DEA Chuck Rosenberg testified before the Senate Judiciary Committee that, "Illicit fentanyl, fentanyl derivatives, and

Drug Policy Alliance | 1620 I Street NW, Suite 925, Washington, DC 20006
212.683.2030 voice | 202.216.0803 fax | www.drugpolicy.org

their immediate precursors are often produced in China." Buyers and sellers in the United States are often unaware of the composition and potency of the drugs. However, users and sellers would face heightened penalties under the bill regardless of their knowledge of the presence or potency of these substances. Individuals with unmet overdose prevention and treatment needs are not being served or protected by supply-side strategies. Policies formulated to address the opioid crisis must effectively mitigate risks associated with use, dependence and overdose.

We are also very concerned that SITSA would establish a mechanism by which the Attorney General can add synthetic compounds to the new "Schedule A" for analogues without consent from the Department of Health and Human Services, or input from scientific experts in the relevant fields. Most substances that are permanently scheduled must undergo an administrative rulemaking process that has been in place more than 40 years.

This longstanding process under the federal controlled substances law (21 USC 811) requires that the Department of Health and Human Services analyze scientific and medical information about the substance and give the green light to schedule before the Attorney General can proceed with permanent scheduling. Each agency has equal weight when making decisions. Under this proposal, the public health role is circumvented, leaving the Attorney General with unilateral power to decide which drugs are scheduled and thus how the ensuing penalties are applied.

This is true even in cases where the Department of Health and Human Services would otherwise determine a substance should not be scheduled. This potentially means that thousands of synthetic compounds could be scheduled, including substances that pose no known health risk. Individuals could be subjected to long prison terms for possessing substances that have not even been scientifically evaluated for abuse potential. This makes no sense and provides no benefit to public health and safety but only wastes limited resources that should be prioritized toward interventions such as medication-assisted treatment and health services proven to help reduce overdose and problematic substance use.

We are also concerned about provisions in SITSA that mandate that the United States Sentencing Commission follow the Attorney General's guidance when creating drug equivalency tables for synthetic drugs. The U.S. Sentencing Commission is already studying the issue of synthetic drugs and penalties. They have held hearings on the issue and heard testimony from a variety of law enforcement and public health officials as they seek to find solutions to this complex topic. The expertise and information gathered by the Commission is important to review and consider before this Committee moves forward with legislation in this area.

Thank you for considering our views,



Grant Smith
Deputy Director
Office of National Affairs
Drug Policy Alliance

Columbia University
IN THE CITY OF NEW YORK

Department of Chemistry

February 28, 2018

The Honorable Michael Burgess
US House of Representatives
2336 Rayburn HOB
Washington, D.C. 20515

The Honorable Gene Green
US House of Representatives
2470 Rayburn HOB
Washington, D.C. 20515

Dear Chairman Burgess and Ranking Member Green,

I am writing to express my concerns in regard to the "Stop the Importation and Trafficking of Synthetic Analogues Act of 2017" ("SITSA Act"; H.R. 2851) and respectfully offer my recommendations for improving this proposed legislation. I am a medicinal chemist by training and serve as an Associate Research Scientist at Columbia University, where I pursue multiple lines of research in the broad areas of neuroscience and psychoactive drugs, with a specific focus on the design, synthesis, and study of novel opioid receptor modulators. Myself and colleagues pursue the key long-term goal of applying our work in studying such chemical compounds to positively affect human health, including through the development of new therapeutics for treating psychiatric and physical pain disorders.

To achieve this goal, we also collaborate with scientists across the United States and internationally and thus, have broad exposure to the promise and challenges of this exciting research area. I also serve as CEO and co-founder of a small startup company working to translate our discoveries from the laboratory bench to the doctor's toolbox. The nature of our work often requires the study of controlled substances, whether as controls in experiments, starting points for modification and improvement, or potential therapeutics in their own right. Accordingly, I feel I am well qualified to speak on both the promise and importance of my chosen field's work and also the challenges that regulatory controls often place in the path of these pursuits.

Before proceeding with a specific discussion of the SITSA Act and its negative implications for scientific research as currently written, I feel it is important to review the history of these issues and existing problems with the regulatory framework around controlled substances. As the members of the committee are aware, the Controlled Substances Act (CSA) currently regulates a number of psychoactive compounds as Schedule I drugs. This most restrictive schedule of the act places severe compliance burdens on legitimate researchers who seek to study these substances and unlock their medicinal potential.

For example, prospective Schedule I licensees must submit detailed research plans, permit inspections of their facilities, and obtain specialized storage equipment (lockboxes and the like, in some cases with direct alarms to local law enforcement), often at significant cost. Such burdens are often further complicated by state and local licensing requirements. Further, the existing compliance requirements also dramatically curtail scientific collaboration because most laboratories or commercial vendors with which a Schedule I licensee may wish to collaborate, will not hold the necessary licenses, nor will they be willing or able to obtain them. This problem has become particularly acute in the increasingly interdisciplinary world of modern biomedical research, where collaborative teams are essential to major discoveries. These many challenges have historically resulted in very few researchers being able or willing to obtain such Schedule I licensing. The resulting chilling effect on basic and translational research with Schedule I substances has been dramatic and long lasting and cannot be understated.

Further, the current regulatory requirements do not make sense from a practical perspective and do not serve the purpose of the CSA, ostensibly to protect the public from exposure to harmful psychoactive

Columbia University
IN THE CITY OF NEW YORK

Department of Chemistry

substances. The requirements for Schedule I licensing are significantly more stringent than those for substances in Schedules II-V, despite the fact that many substances in these less restrictive schedules have a potential for abuse and diversion as great, or greater than, many substances listed in Schedule I. It should further be noted that although stringent precautions are certainly warranted for commercial facilities manufacturing or distributing large quantities of controlled substances, it is my respectful opinion that they go above and beyond what is necessary in the context of basic research, where the quantities of material required are extremely limited. Research with cells and/or animals typically requires a quantity of material far below that which could be credibly claimed to have a risk for diversion to the illicit market. In fact, the quantity of material required is in many cases too little to have a measurable effect on even a single human being. Considering this extremely limited risk of diversion or exposure to the public via legitimate scientific research channels, it seems unreasonable to impose restrictions which unnecessarily undermine the ability of the scientific community to study Schedule I compounds.

Lastly, we must consider the immense potential benefits that research on Schedule I substances may ultimately have for medicine, particularly in the area of mental health. Simply because a compound is currently found in Schedule I does not mean it can never be found to have medical benefits when used appropriately and with care. Despite the challenges of working with Schedule I substances, some in the research community have persisted and are demonstrating exciting efficacy for Schedule I drugs in treating a number of serious and underserved medical disorders.

For example, MDMA, the active component of "ecstasy", is currently in Phase III clinical trials for the treatment of post-traumatic stress disorder and has been granted Breakthrough Therapy Designation by the Food and Drug Administration (FDA). Likewise, psilocybin, the active component of "magic mushrooms", has demonstrated efficacy in treating cancer-associated depression, and a little-known compound derived from an African plant, ibogaine, has shown great promise in treating drug addiction (in trials outside the US due largely to regulatory challenges). Further, it should be remembered that even heroin is an effective and safe analgesic for severe pain when used under a doctor's care, and in fact has been used in the United Kingdom for this purpose for decades. Accordingly, a substance's inclusion in Schedule I should not immediately dismiss it as a potential therapeutic.

I am hopeful that the members of the committee will agree that scientific research with such substances must be allowed to continue with limited obstruction when at all possible, such that new medicines may one day be delivered to patients. Although progress has been made, it has been dramatically slowed due largely to our existing regulatory framework and the negative stigma automatically associated with compounds placed in Schedule I.

Given these existing challenges with research on Schedule I compounds, the SITSA Act as written is particularly concerning, as it presents new barriers to scientific research with controlled substances and continues the trend of ignoring the input of the scientific community in regulatory decisions.

First, the SITSA Act creates a new drug schedule, Schedule A, to which compounds may be added with no well-defined evidentiary standard. Specifically, the act requires that a substance to be added to Schedule A have (1) a chemical structure that is *substantially similar* to the chemical structure of a controlled substance in any existing schedule and (2) an actual or *predicted* stimulant, depressant, or hallucinogenic effect on the central nervous system (emphasis mine).

From the expert perspective of a chemist or pharmacologist, both of these requirements are excessively ambiguous. It is not clear how much deviation in chemical structure is required before a

Columbia University
IN THE CITY OF NEW YORK

Department of Chemistry

chemical compound is no longer "substantially similar", nor *could* such a requirement be clearly defined and applied generally across all possible cases given the vast structural variability of drug-like compounds. This is well evidenced by the observation that the concept of "structural similarity" is frequently litigated in US courts in the context of pharmaceutical patent disputes, where each case must be carefully considered by experts and decided on its individual merits.

Similarly, the ability to *predict* a psychoactive effect of a given chemical compound based *solely on its chemical structure*, is *extremely limited.* It is well known to a practicing medicinal chemist that even small changes to the structure of a chemical compound, in some cases as small as the addition or removal of a single atom, can change the potency of that compound's effect by 100-fold or more. Accordingly, an unstudied compound, although appearing largely similar in chemical structure to a known psychoactive drug, may in fact be completely inactive. Thus, to place regulatory controls on a substance based merely on predicted effect is unwarranted at best, and at worst, scientifically negligent.

Second, the SITSA Act specifies that the listing of a substance in Schedule A (either temporary *or permanent*) is at the sole discretion of the Attorney General and requires no input from the scientific community at large, nor the leading federal agency dedicated to the study of drug abuse issues, the National Institute on Drug Abuse (NIDA). Further, temporary scheduling orders under this new statute would not be subject to judicial review. It is unsettling that a law enforcement agency (the Department of Justice) would be solely entrusted to make a complex regulatory decision requiring careful and complex scientific analysis, and having far-reaching consequences for not only scientific research, but public health and criminal justice, without the input of all stakeholders.

Further, the proposed definition of Schedule A and procedures for listing in said schedule largely circumvent and render meaningless the existing regulatory framework and controls of the CSA. Because the SITSA Act would allow the Attorney General to unilaterally place new substances into Schedule A with little if any evidentiary standard, including both temporary and permanent scheduling actions, which can be initiated simultaneously, there is no longer any reason to utilize the existing (if imperfect) scheduling procedures of the CSA. Existing procedures at least require presentation of *some* evidence demonstrating abuse liability, extent of abuse, or adverse public health consequences for a proposed controlled substance (e.g. 8-factor analysis) and include clear pathways for input from federal agencies with specialized medicinal and scientific expertise (e.g. the FDA and NIDA). If a new, easier, and unilateral pathway is now available, there will be no incentive for the Attorney General to proceed through the more rigorous scheduling procedures currently codified in the CSA.

Lastly, the SITSA Act imposes substantially the same regulatory requirements upon legitimate use (e.g. scientific research) of Schedule A substances as those currently imposed for Schedule I substances. Thus, placement of a substance into Schedule A is likely to have a chilling effect on scientific research with said substance identical to that of placing it in Schedule I, which I hope the members of the committee will agree, has historically been substantial. This is unreasonable given both 1) the substantially lower standard for placing a new chemical substance into Schedule A as compared to Schedule I and 2) as noted above, the high possibility which exists for substances to be placed into Schedule A without any actual evidence of abuse liability or danger to public health.

The danger to the scientific enterprise is further exacerbated by the observation that given the lower evidentiary standard of Schedule A listing, as discussed above, such procedures are likely to be the most frequently utilized for scheduling of new substances from this point forward, and therefore preclude an ever-growing list of biologically interesting compounds from scientific study. Further, although I note that

Columbia University
IN THE CITY OF NEW YORK

Department of Chemistry

the legislation has admirably precluded individuals merely in possession of Schedule A controlled substances from criminal and civil sanctions, this exemption will not be expected to protect many scientific researchers. Given that most substances to be listed under Schedule A are expected to be novel compounds with little history of use or study, it is likely that they will not be commercially available to researchers for purchase (especially given the new regulatory requirements for commercial manufacturers). Accordingly, chemists will need to synthesize these compounds in the laboratory (in limited quantities) to permit study and thereby, the activities in many research laboratories would by necessity extend beyond simple possession. Thus, a "possession exemption" as written is not enough to protect the scientific enterprise.

Such regulatory policies are unfortunate not only in their long-term negative implications for development of new therapeutics, but also for their immediate negative consequences for our understanding of little-studied chemical entities. If the Attorney General or another regulatory agency genuinely believes that a new substance, which in many cases has never been the subject of rigorous scientific study, poses a danger to the public, then research must be allowed to continue such that the effects and risks of said substance may be understood. As the committee is well aware, legislation is unlikely to entirely remove any controlled substance from the illicit market or completely prevent its exposure to the public. Accordingly, the physiological and behavioral effects of new and emerging drugs of abuse must be studied to provide reliable information to physicians and public health agencies attempting to cope with the real-world consequences of their use.

In light of the above concerns with the SITSA Act as written, I would like to respectfully propose practical solutions that would provide greater scientific rigor in the evaluation of proposed controlled substances and limit the regulatory burden for legitimate scientific researchers intending to study such substances, while concurrently having little or no impact on the effectiveness of the proposed act to serve its intended purpose. It is my understanding that such intent is to improve the ability of law enforcement to respond rapidly to newly identified harmful substances on the illicit market, with a particular emphasis on interdiction of illegally imported substances and disruption of moderate- or large-scale domestic and international drug trafficking operations. Accordingly, the following recommendations should be considered in the context of this goal and it should be recognized that they will present little or no impediment to its achievement.

First, the SITSA Act should require better evidentiary standards to establish that a proposed controlled substance has an *actual, not merely predicted,* psychoactive effect before scheduling can proceed. Such standards might include, at a minimum, 1) radioligand binding studies and functional assays in cells to demonstrate that a given compound has an effect on a central nervous system receptor activated or blocked by known scheduled substances and a potency similar to or higher than compounds having known effects in humans and 2) effects in classical rodent assays of abuse liability like conditioned place preference or self-administration, again with a potency similar to or higher than compounds having established effects in man. Federal scientific agencies (e.g. NIDA) already maintain laboratories or contract with academic institutions capable of quickly and easily performing such studies, so lack of resources should not be an excuse for more rigorous profiling of unknown substances before regulatory action is taken. For example, the Psychoactive Drug Screening Program funded by the National Institute of Mental Health provides *rapid* screening for binding and functional activity of novel compounds at central nervous system receptors.

Second, the SITSA Act should *require* the concurrence of both federal scientific (e.g. NIDA) and medical agencies (e.g. FDA), or an independent scientific body, that a proposed substance meets the standards for Schedule A control (ideally amended as above).

Columbia University
IN THE CITY OF NEW YORK

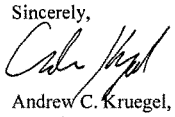
Department of Chemistry

Third, the SITSA Act could greatly minimize the impact on the scientific research community through two mechanisms, 1) making the regulatory requirements for the use and handling of Schedule A substances more consistent with those for substances in Schedules II-V, which are less onerous, and 2) instituting exempt quantities below which regulatory requirements would not apply. Such exemption amounts (the maximum to be possessed/used/manufactured by a given laboratory/individual at any given time) would protect in a clearly defined way not just possession, but also laboratory scale manufacturing, structural modification, or other uses provided that the total quantity at issue was below the exemption amount.

For substances of well-defined potency, an exempt quantity could be set at some small multiple (e.g. 10-fold) of the dose required (or reasonably expected) to elicit an observable psychoactive effect in a human being. For substances where there is no or little information about their pharmacology or potency, a default exempt quantity could apply until such information was obtained. Exempting such limited quantities would permit the vast majority of early stage research in cells and animals to continue unhindered, while presenting extremely limited risk of diversion to illicit markets or risk to public safety. It cannot reasonably be argued that a handful of scientific laboratories across the entire country, each possessing at most a few human-equivalent doses of a Schedule A substance at any given time, could reasonably serve as a viable illicit market for such substances or expose the general public to any appreciable risk of exposure. Further, the existence of such exempt quantities would not interfere with the broader intent of the act whatsoever, especially considering that the act already exempts possession of Schedule A substances from regulatory control, clearly signaling its intent to focus on disruption of moderate- or large-scale drug trafficking operations.

It is my hope that through the above discussion you will understand the challenges the research community has faced both historically and will face in the future, with regard to regulation of controlled substances. I hope you will also agree that careful, legitimate research on controlled psychoactive substances holds great promise for improving human health, particularly in the area of mental health, where improvements to the standard of care are so desperately needed. In light of this, I respectfully ask that you consider my proposals for improving the SITSA Act to limit its detrimental affect on scientific research.

Sincerely,



Andrew C. Kruegel, PhD
Associate Research Scientist
Columbia University
New York, NY 10027

The Honorable Mark DeSaulnier (CA-11)
Committee on Energy and Commerce
Subcommittee on Health
Statement for the Record
February 28, 2018

Deaths from drug overdoses have risen in nearly every county across the United States, with 47,055 lives lost each year due to overdose, the equivalent of about 125 people every day.[1] At the same time, more prescription opioids are being dispensed than ever before. In 2010, prescription opioid use in the U.S. translated into 693 mg of morphine per person, nearly doubled from 2007.[2]

The people on the front lines of the abuse of prescription pain killers are pharmacists.[3] Under current law, pharmacists are required to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription. The responsibility to validate the prescription for a specific set of criteria is done with great care and professionalism by hundreds of thousands of pharmacists every year.

The Empowering Pharmacists in the Fight Against Opioid Abuse Act would require the Department of Health and Human Services, the Drug Enforcement Administration, and other federal agencies responsible for combatting the opioid epidemic to produce and disseminate materials to pharmacists, medical professionals, and patients that provide additional guidance on when and how to refuse to fill a prescription that the pharmacist believes to be fraudulent. It simply clarifies the tools that pharmacists already are empowered with and ensures that information about the rules surrounding denying to fill a prescription are readily available for any professional or patient who may need it.

Pharmacists have a difficult job made even more taxing by the rise of this epidemic. This bipartisan, commonsense legislation will help improve the last line of defense against prescription drug abuse in our communities and could have a meaningful impact in combatting the opioid epidemic.

---

[1] http://blogs.cdc.gov/nchs-data-visualization/drug-poisoning-mortality/
[2] http://www.painpolicy.wisc.edu/opioid-consumption-data
[3] http://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2013/august_2013/prevoznik.pdf

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

April 5, 2018

Ms. Susan Gibson
Deputy Assistant Administrator
Diversion Control Division
Drug Enforcement Administration
700 Army Navy Drive
Arlington, VA 22202

Dear Ms. Gibson:

Thank you for appearing before the Subcommittee on Health on February 28, 2018, to testify at the hearing entitled "Combatting the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on April 19, 2018. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.dareshori@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

AUG 24 2018

The Honorable Michael C. Burgess, M.D.
Chairman
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclosed please find responses to questions for the record arising from the appearance of Susan A. Gibson, Deputy Assistant Administrator for the Office of Diversion Control Regulatory, Diversion Control Division, Drug Enforcement Administration, before the House Energy and Commerce Subcommittee on Health on February 28, 2018, at a hearing entitled "Combating the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety." We hope that this information is of assistance to the Committee.

The Office of Management and Budget has advised us that there is no objection to submission of this letter from the perspective of the Administration's program. Please do not hesitate to contact this office if we can be of additional assistance regarding this or any other matter.

Sincerely,

Prim Escalona

Prim F. Escalona
Principal Deputy Assistant Attorney General

Enclosure

cc: The Honorable Gene Green
Ranking Member

Questions for the Record
Drug Enforcement Administration
Before the Subcommittee on Health
Energy and Commerce Committee
U.S. House of Representatives
For a Hearing Entitled
"Combating the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety"
February 28, 2018

The Honorable Michael C. Burgess, M.D.

1. **Ms. Gibson, in your testimony, you state that manufacturers and distributors will keep one step ahead of government action by introducing and repackaging new synthetic products that are not listed as controlled substances. The distribution and use of these synthetic opioids have wreaked havoc on our nation's public health, and we have convened this hearing to analyze and develop legislation that will prevent further spread of the opioid epidemic.**

    - **In what ways can the Special Operations Division Heroin/Fentanyl Task Force Working Group bridge the gaps between agencies so that there's a united enforcement effort to prohibit crafty manufacturers and distributors from exploiting the cracks in our system?**

RESPONSE: The shared goal of neutralizing criminal networks that threaten our national security as well as our partner nations is what bridges the gaps between agencies. The Drug Enforcement Administration's (DEA) Special Operations Division (SOD) Heroin/Fentanyl Task Force Working Group works in a complementary and comprehensive manner in our approach. This focus, in effect, is about the quality and nature of our relationships that make SOD successful as part of the whole-of-government approach to combat these persistent threats.

Through a "top-down/bottom-up approach," SOD analyzes field inputs and applies its specialized capabilities to identify connections between domestic and foreign networks. This unique approach enables SOD to leverage the authorities, capabilities, and resources of its partners to energize joint operations and satisfy intelligence requirements in support of national coordination strategies. This approach allows SOD to work across Department lines as a powerful resource that coordinates national and international efforts to combat fentanyl, fentanyl related compounds, precursor chemicals, money laundering, and synthetic opioid networks.

HEROIN/FENTANYL TASK FORCE: In 2014, the SOD prioritized operations that targeted major international and domestic heroin/fentanyl distributors and threat streams, and created the SOD Heroin/Fentanyl Task Force (HFTF). The HFTF improved information sharing between U.S. law enforcement agencies, to include DEA, Homeland Security Investigations (HSI), the Federal Bureau of Investigation (FBI), the U.S. Customs and Border Protection (CBP), the U.S. Postal Inspection Service (USPIS), as well as the DEA Special Testing and Research Laboratory (STRL). These agencies collaborate closely by refined information sharing mechanisms established at SOD with the Department of Defense Narcotics and Transnational Crime Support Center, the National Targeting Center, and the Joint Interagency Task Force West to develop actionable lead packages on potential fentanyl/synthetics distributors, which are actioned domestically and internationally in various field offices.

The HFTF collaborates with the STRL regarding large seizures that test positive for fentanyl. The HFTF utilizes the information from the STRL as a pointer system to connect fentanyl networks, regionally and internationally.

EXAMPLE OF SOD-HFTF COORDINATION SUCCESS: Since May 2013, law enforcement agencies, working together under the Attorney General's Organized Crime Drug Enforcement Task Forces (OCDETF) Program, have been investigating the drug trafficking activities of Chinese national Jian Zhang and his criminal organization based in Shandong Province, China. OCDETF used various techniques during the investigation of Zhang, which included judicial wire intercepts of electronic communications by the United States and China, undercover transactions by federal agents, collaboration with the private sector, and debriefing of confidential sources and cooperating defendants. Zhang's criminal organization utilizes the internet to advertise the sale of his controlled substances distributed by various manufacturing laboratories in mainland China. Zhang was responsible in recruiting, teaching and organizing U.S. and Canada based regional distributors to purchase and manufacture his synthetic opioids into counterfeit pills such as 30 mg oxycodone.

SOD-HFTF SUPPORT TO COMBAT CHINESE TCOs: Under these SOD-supported operations, HFTF was able to identify, interdict, and successfully indict Zhang, who was purchasing raw materials from China chemical suppliers for the purpose of synthesizing, producing, and distributing dangerous narcotics through the United States and Canada. The illicit drugs Zhang trafficked into Canada and the United States were linked and directly responsible for multiple overdose deaths and serious injuries across the nation.

RESULTS AND IMPACT: On September 21, 2017, Zhang was indicted in North Dakota on five separate counts to include conspiracy to possess with the intent to distribute the fentanyl resulting in serious bodily injury and death. In addition to the investigation clearly establishing that Zhang was the source of supply for the fentanyl and fentanyl analogues that supplied a Canadian re-distributor, Zhang was also found to be the source of narcotics for eight other federal investigations across the United States. As a result of SOD and OCDETF coordinated enforcement operations, U.S. law enforcement agencies arrested 56 drug traffickers, seized in excess of 1,000 kilograms of drugs of various types, $1 million in currency, and other assets totaling over $450,000 in U.S currency. Each were connected to investigations under SOD Operation Deadly Merchant, Operation Denial, and Operation

Slippery Pete. These actions represent a significant milestone in denying the illicit trafficking of fentanyl in the United States and international markets, as well as sending a clear message of future unified efforts to combat these threats from SOD and its partners. These examples of SOD supported operations are representative of increasing multi-jurisdictional success stories that arise from cooperation and superbly coordinated interagency efforts from dozens of federal, state, and local agencies spanning both regional and international borders.

2. **You also state in your testimony that there was an exponential increase in the number of fentanyl reports from 2013 to 2016. This statistic suggests that fentanyl has become more accessible, which implies that trafficking of illegal fentanyl, and other synthetic opioids, has increased.**

    - **Mr. Katko's bill aims to modernize scheduling guidelines so that your agency can keep up with the rapidly changing nature of synthetic drugs. Can you comment on the importance of working with the Food and Drug Administration in your efforts to discover and schedule these new drugs in a timely manner?**

RESPONSE: The Department of Justice (Department) and DEA have worked with the Department of Health and Human Services, and its appropriate components, including the Food and Drug Administration (FDA), to provide extensive technical assistance to both the House and the Senate on H.R. 2851 and S. 1327, the "Stop the Importation and Trafficking of Synthetic Analogues Act of 2017," or the SITSA Act. The rapidity and ease with which dangerous synthetic drugs are manufactured and introduced into the illicit market make control through law enforcement responses extremely challenging. Additional tools are needed to reduce the threat these substances pose, including a more expeditious pathway to schedule such substances under the Controlled Substances Act (CSA). DEA has engaged extensively with FDA and the National Institute on Drug Abuse on ways to streamline the current scheduling framework, without impeding bona fide scientific and medical research.

DEA agrees that it is important for the research community to have access to psychoactive substances for licit research and DEA strongly supports research on controlled substances, including those in Schedule I of the CSA. Recognizing that the process of obtaining a DEA registration may result in significant delays, DEA has taken steps to improve the process. One example is the new electronic system through which applications can be submitted. DEA also understands the significant role FDA plays in both the scheduling and registration process for controlled substances. SITSA would: provide DEA with a critical tool enabling it to be proactive in combating the influx of synthetic drugs that are causing great harm to the public; preserve an appropriate role for the FDA in the scheduling process; and ensure adequate access to analogues of controlled substances for licit research.

3. **Ms. Gibson, in your testimony, you talk about fentanyl and fentanyl analogues coming into the United States from China to be mixed with heroin and cocaine, or pressed into a pill form. You say, and I quote, "In some cases,**

traffickers have industrial pill presses shipped into the United States directly from China and operate illegal fentanyl pill press mills domestically."

- **What is the DEA doing to stop pill presses from being used for criminal activity?**

Response: All regulated persons are required to submit in advance the notification of an import or export of a tableting or an encapsulating machine. The advance notification must contain the information described in 21 CFR 1310.06 (e)(1) and (e)(2). DEA would pursue enforcement action as it receives information from CBP about illegal imports of tableting or encapsulating machines.

4. **I agree that the current pill press proposal – in discussion draft form – needs to be more narrowly tailored. This concept was raised in the President's Commission made this recommendation – it's number 25. The intent of this legislation is to capture criminal practices of pill presses being used to produce counterfeit drugs and not create a burden on legitimate industries.**

   - **Do you have any creative ways we could do this without causing unnecessary harm on legitimate industries, like over-the-counter products or dietary supplements?**

Response: DEA is willing to work with the Committee by providing technical assistance on any legislation that will address the criminal practices of pill presses being imported and used to produce counterfeit drugs, while also allowing legitimate industries to continue to operate within the confines of the law.

The Honorable Susan W. Brooks

5. **One commonly referenced method of reducing opioid overdoses is to reduce opioid prescriptions. As you know, a DEA registration is required for practitioners to be able to prescribe controlled substances. I would like to focus my questions today on the importance of prescriber education in reducing the number of prescriptions. I am working on a bill that will require prescribers to complete continuing medical education (CME) prior to receiving a DEA registration.**

    - **In what ways does DEA monitor prescribing practices? Have there been any changes related to prescribers that DEA has implemented in response to the current opioid epidemic?**

Response: DEA does not have the statutory authority to monitor the prescribing practices of DEA-registered prescribers. As you know, prescription drug monitoring programs (PDMPs) are state-run electronic database systems used by practitioners, pharmacists, medical and pharmacy boards, and, where permitted, law enforcement. Federal law enforcement access to a state's PDMP is limited and access varies according to state law. It is usually only granted when a prescriber is under a federal investigation. These programs are established through state legislation and are tailored to the specific needs of each state. DEA strongly supports robust PDMPs and encourages medical professionals to use this important tool to detect and prevent doctor shopping and other forms of diversion. Currently, 49 states have an operational PDMP. If funded, Missouri would become the 50th, pursuant to the Governor's Executive Order in July 2017.[1] As of January 2018, 40 of these 49 states with operational PDMPs require controlled substance prescribers to use the state's PDMP prior to prescribing a controlled substance in certain circumstances as mandated by each state's legislation.[2] DEA encourages all practitioners and pharmacists to use their state PDMPs.

PDMPs are valuable tools for prescribers, pharmacists, and law enforcement agencies to identify, detect, and prevent nonmedical prescription drug use and diversion. Law enforcement ability to request, view, and utilize PDMP data in support of ongoing investigations in a manner that protects patient privacy is vital. Access to information in support of active state and federal investigations varies widely from state to state, with some states requiring a court order for law enforcement to obtain data. Some requirements can hinder DEA's investigations of those who are operating outside of the CSA and impact DEA's ability to effectively protect the public health and safety.

In May 2018, DEA initiated a nationwide program to offer training to all DEA-registered prescribers. This program is designed to train DEA-registered prescribers on how to detect and guard against diversion activities in response to the current opioid

[1] The Missouri statewide PDMP has not been funded and is not operational. Please note that the county of St. Louis, Missouri, instituted its own operational PDMP in April 2017. This PDMP is open to participation from additional jurisdictions outside of St. Louis County. As of February 2018, there are 58 jurisdictions participating in the PDMP. These 58 jurisdictions cover 79% of the state population and 92% of healthcare providers.

[2] PDMP Center of Excellence, Brandeis University. http://www.pdmpassist.org/pdf/Mandatory_Query_Conditions_20180102.pdf retrieved March 6, 2018.

epidemic. In addition to the training opportunities offered to registrants, DEA has also begun a program to proactively send targeted email messages to various segments of its registrant population on matters of mutual interest. For example, in February 2018, DEA sent correspondence to 1.3 million doctors nationwide alerting them of the Centers for Disease Control and Prevention's (CDC) recommendations for the prescribing of opioids for acute pain and advising practitioners of a free training webinar available from CDC. In the coming months, DEA will send targeted messages to certain practitioners on how they may utilize telemedicine to treat opioid use disorder.

Much like the recommendations of the President's Commission on Combating Drug Addiction and the Opioid Crisis, DEA recognizes the importance of fostering training amongst prescribers about the risks and benefits of opioid therapy. DEA supports the recommendation made by the Commission to require new and existing practitioners to demonstrate that they have received continuing medical education when applying for or renewing their DEA license. In order to better inform the Department on how many prescribers are taking training in this area, on February 7, 2018, DEA began to ask each individual practitioner, at the time of their application or renewal, whether they have received training regarding the prescribing or dispensing of opioids. Since deployment, 83 percent of the respondents have affirmatively stated that they have taken such training.

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225-2927
Minority (202) 225-3641

April 5, 2018

Dr. David Kan
President
California Society of Addiction Medicine
575 Market Street; Suite 2125
San Francisco, CA 94105

Dear Dr. Kan:

Thank you for appearing before the Subcommittee on Health on February 28, 2018, to testify at the hearing entitled "Combatting the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on April 19, 2018. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.dareshori@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment



ASAM American Society *of* Addiction Medicine

OFFICERS
President
Kelly J. Clark, MD, MBA, DFAPA, DFASAM
President-Elect
Paul H. Earley, MD, DFASAM
Vice President
Margaret Jarvis, MD, DFASAM
Secretary
Yngvild Olsen, MD, MPH, DFASAM
Treasurer
Brian Hurley, MD, MBA, FASAM
Immediate Past President
R. Jeffrey Goldsmith, MD, DLFAPA, DFASAM

BOARD OF DIRECTORS
Directors-at-Large
Anthony Albanese, MD, DFASAM
Marc Galanter, MD, DFASAM
William F. Haning, III, MD, DFAPA, DFASAM
Petros Levounis, MD, MA, DFASAM
John C. Tanner, DO, DFASAM

Regional Directors
Region I Director
Jeff Selzer, MD, DFASAM
Region II Director
Murtuza Ghadiali, MD
Region III Director
Kenneth Freedman, MD, MS, MBA, FACP, AGAF, DFASAM
Region IV Director
Michael Shore, MD, DFASAM, DLFAPA
Region V Director
Anika Alvanzo, MD, MS, FACP, FASAM
Region VI Director
Gavin Bart, MD, PhD, DFASAM
Region VII Director
A. Kenison Roy, III, MD, DLFAPA, DFASAM
Region VIII Director
Miriam Komaromy, MD, FACP, DFASAM
Region IX Director
Peter Selby, MBBS, CCFP, FCFP, MHSc, DFASAM
Region X Director
Scott Teitelbaum, MD, DFASAM

Ex-Officio
Stuart Gitlow, MD, MPH, MBA, DFAPA, DFASAM
Randolph P. Holmes, MD, FASAM
Michelle Lofwall, MD, FASAM
Penny S. Mills, MBA
Aleksandra Zgierska, MD, PhD

FOUNDING PRESIDENT
Ruth Fox, MD
1895-1989

April 19, 2018

Zach Dareshori
Legislative Clerk
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Re: Questions for the record of the hearing entitled "Combatting the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety"

Dear Mr. Dareshori,

It was my pleasure to appear before the Subcommittee on Health on February 28, 2018 to testify at the hearing entitled "Combatting the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety." Please find below my responses to the additional questions for the record submitted by Members.

The Honorable Susan W. Brooks

1. Would you say it is uncommon for a primary care physician or the physician prescribing opioids to detect and diagnose addiction?

A: *Yes. Given that most clinicians receive no or minimal training on diagnosing or treating addiction in their clinical training programs, most are not equipped to recognize the signs and symptoms of addiction or diagnose it. Primary care physicians are especially pressed for time with patients, and likely do not have the time to screen or assess patients for addiction during a typical visit.*

Even if a primary care physician has the time and training to detect and diagnose addiction in a patient, too often the patient is not offered or engaged in evidence-based treatment for their disease. Diagnosing without intervening in a positive manner is not useful. A patient with suspected opioid use disorder should receive a comprehensive assessment with a biopsychosocial approach that comports with the ASAM Criteria to determine the type and intensity of treatment that the patient needs. The clinician should then discuss and offer to the patient all therapeutic options, including all FDA-approved medications for

11400 Rockville Pike, Suite 200, Rockville, MD 20852
Phone: 301.656.3920 | Fax: 301.656.3815
www.ASAM.org

opioid use disorder unless clinically contraindicated. The patient and treating clinician should decide together the best treatment options and individualized treatment plan.

2. Aside from Continuing Medical Education, what can be done to better equip physicians who may not be addiction specialists to detect addiction while evaluating their patents?
A: *Prescription drug monitoring programs (PDMPs) are valuable tools that can help inform safe prescribing and alert clinicians to possible substance misuse by a patient. However, the quality and timeliness of PDMP data varies by state, and many PDMP programs are not integrated into normal clinician workflow, making it more difficult far clinicians to check the reports. Additionol federal investments to help stotes improve the quality and timeliness of their PDMP data and better integrate their systems with clinician workflow and electronic medical records could increase their use and usefulness. Additionally, helping states to make their PDMPs interoperable with neighboring states will give clinicians a more complete picture of their patient's prescription history.*

In addition to investments in PDMPs, the federal government should invest in improved healthcare professional curricula to ensure the next generation of healthcare professionals is better equipped to diagnose and treat addiction omong its patients. These investments could come in the form of grants to healthcare professional schools to support the revision or expansion of their curricula to include enhanced training on diagnosing and treating addiction as well as managing patients with chronic pain.

Again, it is important to stress that detecting addiction without intervening to engage the patient in treatment is unproductive. While clinicians needs to be better trained and have better tools at their disposal to detect and diagnase addiction among their patients, they must also be able to engage patients in evidence-based treatment, whether they treat the patient themselves or refer the patient to a qualified specialist.

3. Are there best practices or education techniques that you know of to help communities and local law enforcement combat addiction by teaching individuals to detect addiction in loved ones?
A: *As with any medical condition, addiction should be diagnosed by a trained and licensed medical professional. However, community members and law enforcement officials can play an important role in supporting those with addiction in their treatment and recovery, providing emergency medical help to individuals who have experienced an overdose, and connecting persons with addiction to community-based resources for assessment and treatment. There are best practices for community programs to prevent addiction, training for the use of nalaxone in the event of an overdose, and law enforcement-assisted diversion to redirect persons with addiction fram the criminal justice system into treatment. The Substance Abuse and Mental Health Services Administration (SAMHSA) oversees programs in all three of these areas and would be best suited to discuss further the role of community members and law enforcement officers in responding to the opioid crisis.*

Naloxone access, as recently recommended by the Surgeon General, for people suffering from addiction, their families, and the community are critical to prevent and reverse fatal overdoses. 50% of people who overdose currently do so in their own home. Encouraging co-prescribing of naloxone with high risk opioid regimens would increase access to naloxone. Many states have state standing orders for naloxone that all citizens can access.

Amendment of telemedicine laws consistent with my prior testimony would allow for more rapid access to treatment.

Initiation of Medication for Addiction Treatment such as buprenorphine or long-acting injectable naltrexone in Emergency Departments, inpatient hospitals, and correctional facilities would reduce the high risk of fatal overdose associated with discharge from criminal justice.

Coalition building is critical as there is no one place that can identify all of the patients. Supporting community opioid safety coalitions would be a valuable role.

Spreading a message of universal precautions to patients, their families, and their doctors around opioids is critical in preventing new inappropriate opioid medication starts. Universal precautions like with bodily fluids recognizes that the medication carries risks and the risks should be mitigated. Risk assessment is a great concept; however, we know that even low risk individuals can become physically dependent and/or addicted.

The Honorable Dianna DeGette
Opioids play an important role in pain management, but when they are prescribed in excess quantities they increase the risk for misuse and abuse. This past decade the United States experienced a parallel increase in opioid prescriptions and the incidence of opioid use disorders among pain patients. Reducing opioid prescriptions should be one part of the federal government's response to the drug epidemic. This goal can be partially achieved by educating providers on safe opioid prescribing practices. Congressman Schneider's bill, the Opioid Preventing Abuse through Continuing Education (PACE) Act, would require physicians to complete a yearly four-hour course on the use of opioid therapy in pain management. Do you believe that the training proposed under the PACE Act is a reasonable requirement for physicians who prescribe opioids?

A: *Yes. ASAM has long endorsed mandatory education for prescribers of controlled substances as a condition of obtaining or renewing a registration to prescribe or dispense controlled substances, including opioids. ASAM is pleased to endorse the PACE Act, as we believe it would help reduce unnecessary exposure to cantrolled medicatians by requiring prescribers ta be educated on safe prescribing practices and addiction. Still, ASAM has offered the following recommendations to strengthen the bill, ensure it is streamlined with federal efforts already underway to inform safe prescribing, and minimize its burden on prescribers who are already well-versed on issues related to pain management and addiction:*

- *Make the new training requirement a condition of registration to prescribe or dispense benzodiazepines in additian to opioids for the treatment of pain.*
- *Streamline federal efforts to promote safe opioid prescribing by incorporating the recommendations included in the CDC Guideline for Prescribing Opioids for Chronic Pain. There is no need for duplicative federal recommendations on opioid prescribing; in fact, duplicative efforts may only confuse practitioners and further clutter an already-crawded educational space on this topic.*
- *Offer a "test-out" option that would give practitioners the opportunity to demonstrate their knowledge and "test-out" of this mandatory training requirement.*

Thank you again for the opportunity to provide testimony to the Subcommittee. If ASAM can be of further assistance to the Committee as it considers addiction-related legislation, please don't hesitate to contact ASAM's Director of Advocacy and Government Relations, Kelly Corredor, at kcorredor@asam.org or 301-547-4111.

Sincerely,

David Kan, MD

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

April 5, 2018

Mr. Thomas Cosgrove
Partner
Covington & Burling LLP
860 10th Street, N.W.
Washington, DC 20001

Dear Mr. Cosgrove:

Thank you for appearing before the Subcommittee on Health on February 28, 2018, to testify at the hearing entitled "Combatting the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on April 19, 2018. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.dareshori@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

Attachment — Additional Questions for the Record

The Honorable Michael C. Burgess, M.D.

I agree that the current pill press proposal – in discussion draft form – needs to be more narrowly tailored. This concept was raised in the President's Commission as a recommendation – it's number 25. Here's what it says: "The importation of tableting machines (pill presses) is regulated by DEA. DEA has recently enhanced importation regulations by replacing paper reporting with an electronic process. However, the active use of pill presses remains unregulated."

While DEA currently can inspect a registrant's use of controlled substances in their usable form to verify they are properly stored and used for their stated, registered purposes, the DEA currently cannot inspect pill presses to verify that the equipment is not being used to produce counterfeit drugs.

The intent of the draft legislation (the Tableting and Encapsulating Machine Regulation Act of 2018) is to capture criminal practices of pill presses being used to produce counterfeit drugs and not create a burden on legitimate industries.

1. Do you have any creative ways we could do this without causing unnecessary harm on legitimate industries, like over-the-counter products or dietary supplements?

You point out that under existing law, each person selling a tableting or encapsulating machine must report the transaction to DEA. A quick search on eBay yesterday produced 572 results. Some of these machines can produce 5,000 pills per hour.

2. Is the DEA requiring transaction reports on these products?

3. What is the difference in a pill press bought on eBay to tablet or encapsulate illicit synthetic fentanyl versus one used by a legitimate licensed manufacturer?

You also note that existing manufacturers of controlled substances have systems in place be sure they're in compliance with DEA standards and rules. But this proposal is targeting illicit drugs.

4. Do you have any suggestions on how we can differentiate between the legitimate and counterfeit use of these machines?

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

April 5, 2018

Dr. Andrew Kolodny
Co-Director, Opioid Policy Research Collaborative
The Heller School for Policy and Management
Brandeis University
415 South Street
Waltham, MA 02453

Dear Dr. Kolodny:

Thank you for appearing before the Subcommittee on Health on February 28, 2018, to testify at the hearing entitled "Combatting the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on April 19, 2018. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.dareshori@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

PROP
Physicians for Responsible Opioid Prescribing

Physicians for Responsible Opioid Prescribing
12800 Whitewater Drive, Suite 100
Minnetonka, MN 55343

www.supportprop.org
T 952 943 3937

April 23, 2018

By Email

The Hon. Michael C. Burgess, M.D.
Chair, Subcommittee on Health

The Hon. Susan W. Brooks
Member, Subcommittee on Health

c/o Zack Dareshori, Legislative Clerk
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515
Email: zack.dareshori@mail.house.gov

Re: Additional Questions for the Record

Dear Chairman Burgess:

Thank you for the opportunity to supplement my testimony at the recent hearing entitled "Combatting the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety." Your and Congresswoman Brooks's follow-up questions raise critically important issues that I am pleased to address.

Enclosed please find my additional testimony for the hearing record in response to your questions. As requested, I have sent a Word version of the document to the e-mail address provided in your letter. Please note that because you and Congresswoman Brooks posed the same questions, I am providing a combined response.

Please do not hesitate to contact me with further questions. Your subcommittee's focus on these issues is essential to bringing the country's opioid addiction epidemic under control.

Sincerely,

Andrew Kolodny, M.D.

Director, Opioid Policy Research Collaborative
Co-Founder, Physicians for Responsible Opioid Prescribing

Enclosure

Supplemental Testimony of Dr. Andrew Kolodny

Responding to Additional Questions for the Record From

Congressman Michael C. Burgess and Congresswoman Susan W. Brooks

1. **Could you discuss your insight on how you arrived at your conclusion that requiring physicians additional CME on opioids would contribute to resolving the public health crisis before us today?**

Our opioid addiction epidemic – now the worst drug epidemic in U.S. history – was caused by a significant change in the way the medical community prescribes opioid analgesics.

Specifically, in the mid-1990s, we began prescribing opioids at increasingly higher rates, and we began prescribing these medicines for more conditions. No longer were opioid medications reserved for short-term, painful conditions like pain after major surgery or to ease suffering at the end of life. Physicians began prescribing opioid medications for common moderately painful conditions such as low-back pain, arthritis and fibromyalgia.

Opioid medications are highly addictive. Consequently, as the number of prescriptions for opioid medications skyrocketed, we saw parallel increases in the number of people suffering from opioid addiction, opioid overdoses, and deaths.

I do not blame doctors for overprescribing. We became more aggressive in our use of opioids because we were responding to a multi-faceted marketing campaign. Enlightened medical providers, we were told, should not allow patients to suffer needlessly. We should recognize pain as a "fifth vital sign" and think of opioids as a "gift from mother nature" to deliver compassionate care. The campaign exaggerated the benefits of opioids and minimized the risks of long-term use, especially the risk of addiction.

We might have been less gullible if we had only heard these messages from advertisements or pharmaceutical sales reps. But we also heard these messages from physicians eminent in the field of pain medicine, from the Joint Commission, and even from state medical boards. Only now is the public learning about the role opioid manufacturers played in coopting these authorities in their campaign to increase opioid prescribing.

I firmly agree that doctors are necessary allies. If we want to bring our country's opioid addiction epidemic under control, we need them to prescribe opioids more cautiously. That requires prescribers to better understand the risks and benefits of opioid medications. Indeed, for precisely this reason, I joined with leading experts in field of pain management and addiction in 2010 to create Physicians for Responsible Opioid Prescribing (PROP) – an organization devoted to correcting the widespread misconceptions about opioid medications.

While I firmly believe that the medical community needs better education about the risks and benefits of opioid medications, I share your concerns about the current mandatory Continuing Medical Education (CME) strategies being pursued in several states. I, too, have spoken to physicians who are frustrated with these programs. The problem with these programs, however, can be fixed.

First, prescribers should have the right to opt-out of mandatory CMEs that are not relevant to their practices. Medical professionals are busy, and our priority should be caring for patients. Clinicians who intend to limit their prescribing to 3 days or less should be permitted to opt out.

The vast majority of clinicians only prescribe opioids for acute pain, conditions that typically require 3 days or less of opioid use. Accordingly, the ability of such medical providers to "opt-out" will alleviate complaints that mandatory CMEs impose "undue" burdens. It will also ensure that the education is reaching clinicians who prescribe opioids to patients likely to become physiologically dependent (physiological dependence starts setting in after 5 days of opioid use).

Second, the content of mandatory CMEs should be scrutinized to ensure that medical professionals are receiving accurate, up-to-date information about the risks and benefits of opioid medications. The content of any CMEs should be free of industry bias, and the faculty should be independent as well.

If these modest steps are taken, I am confident that mandatory CMEs will not create a barrier to the compassionate treatment of patients with chronic pain. To the contrary, it will help ensure that physicians are caring for patients with chronic pain responsibly and not putting patients at risk of opioid addiction based upon the outdated and inaccurate information that fueled a public health catastrophe.

2. **Do you think there would be a better way to address your concerns regarding the overprescribing of opioids other than potentially burdening well-intentioned doctors further?**

For the reasons explained above, I believe that mandatory Continuing Medical Education (CME) is a necessary intervention to bring the opioid addiction epidemic under control, and I am confident that mandatory CMEs will not burden doctors unnecessarily – especially if those who intend to prescribe these medications only for 3 days or less are allowed to opt out.

Your concern for well-intentioned doctors, however, raises another issue. It is important to recognize the role that well-intentioned doctors have played in the opioid addiction crisis. The medical community overprescribed opioid medications not because we were indifferent or set out to harm patients. Rather, the manufacturers of opioid medications targeted well-intentioned doctors and persuaded the medical community that we were allowing pain patients to suffer needlessly and opioids were the answer. As a result, millions of pain patients became addicted to opioids – often by using opioid medications exactly as prescribed.

I admire your desire to see that well-intentioned doctors are not unduly burdened, but there is a more pressing target for those concerns: the extensive and unnecessary burdens on the prescription of buprenorphine (Suboxone).

Buprenorphine is the first-line treatment for opioid addiction. With the help of this medication, many people who are addicted to opioids can once again lead fully productive lives. Unfortunately millions of people who could benefit from buprenorphine do not have access to this medication because there are numerous barriers to treatment. For example, a doctor who wants to prescribe buprenophine must take an 8-hour training course, and after completing the course, that doctor is capped in terms of the number of patients he or she can treat.

It makes no sense to require doctors to take a full day of additional training to prescribe a medicine to *treat* opioid addiction when no extra training is required for physicians who want to *prescribe* opioids like OxyContin that are far more addictive and potentially dangerous.. It is similarly incongruous to cap the number of patients that a doctor can treat with Buprenorphine when no limits exist on the number of patients who may be prescribed opioids or the amount or dosage of opioids patients can receive.

Thank you again for the opportunity to testify and for your leadership on this critically important issue.

○