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TACKLING OPIOID AND SUBSTANCE ABUSE DISORDERS IN MEDICARE, MEDICAID, AND HUMAN SERVICES PROGRAMS

HEARING

BEFORE THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED FIFTEENTH CONGRESS

SECOND SESSION

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CONTENTS

OPENING STATEMENTS

	Page
Hatch, Hon. Orrin G., a U.S. Senator from Utah, chairman, Committee on Finance	1
Wyden, Hon. Ron, a U.S. Senator from Oregon	3

ADMINISTRATION WITNESSES

Giroir, Adm. Brett P., M.D., Assistant Secretary for Health and Senior Adviser to the Secretary for Mental Health and Opioid Policy, Department of Health and Human Services, Washington, DC	8
Brandt, Kimberly, Principal Deputy Administrator for Operations, Centers for Medicare and Medicaid Services, Department of Health and Human Services, Washington, DC	9

ALPHABETICAL LISTING AND APPENDIX MATERIAL

Brandt, Kimberly:	
Testimony	9
Prepared statement	45
Responses to questions from committee members	57
Giroir, Adm. Brett P., M.D.:	
Testimony	8
Prepared statement	45
Responses to questions from committee members	57
Hatch, Hon. Orrin G.:	
Opening statement	1
Prepared statement	121
Heller, Hon. Dean:	
Letter from Albertsons Companies et al. to Senators Bennet and Heller, April 19, 2018	122
McCaskill, Hon. Claire:	
Homeland Security and Governmental Affairs Committee minority staff reports	124
Wyden, Hon. Ron:	
Opening statement	3
Prepared statement with attachments	165

COMMUNICATIONS

Alliance for the Treatment of Intractable Pain (ATIP)	189
American College of Osteopathic Family Physicians (ACOFP)	198
Becker, Kristi	201
Bransfield, Robert C., M.D., DLFAPA	202
Center for Fiscal Equity	203
Clark, Kathleen M.	206
Coalition of 50 State Pain Advocacy Groups	209
Efaw, Carol	211
Huber, Sonya	212
Ibsen, Mark, M.D.	213
O'Keefe, Cherri	218
Polson, Elizabeth	219
Smith, Amanda	220
Tyrell, Reese	221

TACKLING OPIOID AND SUBSTANCE ABUSE DISORDERS IN MEDICARE, MEDICAID, AND HUMAN SERVICES PROGRAMS

THURSDAY, APRIL 19, 2018

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

The hearing was convened, pursuant to notice, at 10:04 a.m., in room SD–215, Dirksen Senate Office Building, Hon. Orrin G. Hatch (chairman of the committee) presiding.

Present: Senators Roberts, Cornyn, Thune, Isakson, Portman, Toomey, Heller, Cassidy, Wyden, Stabenow, Cantwell, Nelson, Menendez, Carper, Cardin, Brown, Bennet, Casey, Warner, McCaskill, and Whitehouse.

Also present: Republican staff: Brett Baker, Health Policy Advisor; Jennifer Kuskowski, Chief Health Policy Advisor; Ryan Martin, Senior Human Services Advisor; and Stuart Portman, Health Policy Advisor. Democratic staff: Joshua Sheinkman, Staff Director; Laura Berntsen, Senior Advisor for Health and Human Services; Anne Dwyer, Senior Health-care Counsel; Elizabeth Jurinka, Chief Health Advisor; and Matt Kazan, Health Policy Advisor.

OPENING STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM UTAH, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. The committee will come to order.

I would like to welcome everyone to today's hearing on tackling opioid and substance abuse disorders in Medicare, Medicaid, and human services programs.

I feel compelled to start with news that we all wish was untrue: more than 60,000 Americans died from a drug overdose in 2016—60,000. The majority of these overdoses involved prescription opioids or illicit opioids like heroin or fentanyl. These numbers are more than mere statistics. They represent our constituents, our friends, and our loved ones.

My home State of Utah continues to be hard hit. An alarming number of Utahans have undergone hospital stays and emergency room visits due to opioid overdoses. In 2016 alone, over 450 Utahans died from an opioid overdose.

Americans across the country recognize the challenges posed by the epidemic and are fighting against it. President Trump and Secretary of Health and Human Services Alex Azar have made tackling the opioid epidemic a top priority, and I look forward to working with them to advance policy solutions.

Congress continues to support States and communities in their efforts and has a record of working in a bipartisan manner to identify solutions that can have a meaningful impact for struggling individuals and families. I was pleased to work with Ranking Member Wyden and other members of this committee to lead an effort that makes significant strides to address the opioid epidemic: the Family First Prevention Services Act, enacted last February.

This bill will provide States with access to funds to help families with substance abuse disorders and allow more children to stay safely with their families instead of being placed in foster care.

I am also pleased that Congress wisely opted to build on the foundation of the Family First Prevention Services Act in the March omnibus law by providing States with additional funds to ramp up these services immediately. This will allow States to develop more evidence-based services that will make a real difference in the lives of families affected by substance use disorders.

The Federal Government cannot solve this crisis alone, but my hope is that we can work together to ensure that our Federal programs, such as Medicare, Medicaid, and human services programs, are innovative and responsive to the needs of Americans with chronic pain or opioid use disorders.

My ranking member, Senator Wyden, and I have successfully partnered to make numerous recent improvements in health care. And I really appreciate him for this. He has been a great partner, and I have really enjoyed working with him.

We worked together to realize a 10-year extension of the Children's Health Insurance Program. We pushed through a package of policies, known as the CHRONIC Care Act, that improve Medicare for beneficiaries with chronic conditions.

I would be remiss if I did not point out that none of these accomplishments would have been possible without the bipartisan engagement of members on this committee.

Identifying policies to evaluate and improve the Federal response to the opioid epidemic will be no different, and the success of these efforts will depend upon bipartisan, committee-wide support.

Today, members will have an opportunity to speak with two of the administration's leading experts on opioid-related policies about how Medicare, Medicaid, and human services programs can adapt and be improved to address the crisis, and what this administration and Congress can do to save lives together.

It is my hope that members take advantage of this hearing and the expertise of our two witnesses to drill down into policies that are likely to garner bipartisan support to help this committee advance its long record of working together collaboratively. Anything less would be a missed opportunity to help individuals, families, and communities across the Nation.

In fact, through outreach to stakeholders and soliciting input from each member of the committee, we have already identified areas of potential bipartisan support. These include the need to evaluate access to and utilization of non-opioid treatment options for managing pain, enhancing data-sharing to promote appropriate health-care interventions and strengthen program integrity, and ensuring evidence-based care is available for patients to identify and treat opioid use disorders.

In closing, my view is that the committee must do all it can to prevent and relieve opioid-related suffering by implementing effective policies in Medicare, Medicaid, and human services programs. We have a unique opportunity to do so in the near term.

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

The CHAIRMAN. We will hear the ranking member's thoughts on this momentarily, but I do hope that he agrees on the need to work toward bipartisan solutions that would add to the committee's long list of bipartisan health-care accomplishments. And I am sure he does.

The witnesses will get a proper introduction shortly, but I would like to briefly say a few words before I have to attend a Judiciary Committee markup. I apologize.

First, I would like to welcome Dr. Brett P. Giroir. His recent appointment as Secretary Azar's point person on opioid policy speaks highly of his capabilities. I am grateful that the Finance Committee will be the first congressional committee to hear from him in this capacity.

I am also delighted to have CMS's Kim Brandt appear before the committee today.

Ms. Brandt likely needs no introduction to my fellow committee members, as she served as a senior member of my staff for 6 years before assuming the role of Principal Deputy Administrator for Operations at CMS last year. I am very proud of her.

I would like to quickly say that, while I certainly gave my blessing to Ms. Brandt before she moved on to a CMS leadership role, it was really difficult for me to see Kim go. She is the greatest person.

I ask that you all indulge a point of personal privilege to allow me to explain why. I no longer get those uplifting visits from her puppy, Sherlock. [Laughter.]

Senator WYDEN. And the cookies.

The CHAIRMAN. Yes.

Senator WYDEN. Oh, here they come.

The CHAIRMAN. And those incredible cookies and other goodies.

I do not want this to take away from your expertise. [Laughter.]

She frequently provided all these to members and staff. They are much harder to come by now, I have to say. [Laughter.]

But I am glad to know that Kim is helping to steer the ship at CMS. Truly, it could not be in better hands. As we all know, Kim served this committee and all of us members of this committee on both sides of the aisle with great distinction. I am glad to have her here today.

And with that, I would like to recognize my friend—who has worked so well with me and whom I have such great respect for—the ranking member, for his opening statement.

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

Senator WYDEN. Mr. Chairman, thank you. And I know your time is short.

I will just make a couple of points. First, I want to thank you for the comments about the bipartisanship. And we are definitely going to continue that as we tackle this opioid issue.

I have said to friends in town meetings, if somebody had said in January of 2017—in a very polarized Congress—that we would get the Children's Health Insurance Program reauthorized for a decade, we would transform the foster care system in America under Family First, we would begin the transformation of Medicare from being an acute care program to a chronic care program while updating the Medicare guarantee, Mr. Chairman, if somebody had said that was doable in January of 2017, they would have been accused of hallucinating. People would have said there was no way that this could happen.

And it took place under your leadership, under your chairmanship. I very much appreciated that it allowed us——

The CHAIRMAN. With your help.

Senator WYDEN. Well, we incorporated values from both sides. And I want it understood that we are going to work on this issue in a bipartisan way as well.

The CHAIRMAN. Right. That is great.

Senator WYDEN. Let me make a comment on an important point that many Senators have brought to my attention, and that is, I do think it is long past time to get the opioid executives before the committee, have them raise their right hands, and hold them accountable for their role in creating a public health calamity that is killing tens of thousands of Americans each year.

Some years ago, I participated in a House hearing where a panel of tobacco executives said under oath that their products were not addictive. In my view, there is a clear parallel you can draw to the opioid issue today.

Back then, it was tobacco executives who concealed the dangers of their products and denied they were addictive. Now it is the opioid companies—including those that manufacture the drugs and those that distribute the drugs—that have misled the country about the dangers of their products.

The opioid executives, however, have avoided the spotlight that Congress put on the executives of the big tobacco companies.

Colleagues, we have colleagues and friends now from both sides of the aisle who are saying that has got to change. The executives need to be brought before this committee that pays for so much of American health care and be held accountable.

Flooding American communities with these drugs is big, big business. And so-called safer opioid pills have just kept the cash registers running. Congress would be derelict in its responsibilities if it pretends there is no profit motive or corporate scheming behind the addiction crisis.

In 2015, more than 52,000 Americans died of a drug overdose. And I am glad the chairman touched on those statistics, because it increased to 64,000 in 2016, and in 2017 it was 71,000. There is a tragic and well-documented pattern of opioid addiction escalating into abuse of heroin and fentanyl.

Now, an even stronger narcotic called carfentanil is spreading. Carfentanil is supposed to be used, colleagues, as a sedative for elephants. It is so potent and dangerous, first responders apparently

around the country have to run around in hazmat suits when they are around it. That is the horrifying level of danger plaguing our communities as a result of this epidemic.

So on a bipartisan basis, we have already begun the work to find answers. And when you get into this, you deal with the paradox that cutting down the supply of opioids, depending on how you do it, could drive even more people to heroin and other drugs, leading to even more overdose deaths. That is obviously nothing that any member of this committee could possibly want.

With that said, I want to stress, as Chairman Hatch has, that we have a big-time opportunity for bipartisan action. And I am going to touch on just a couple of issues that have been important to me. And at the top of my list is addressing what I have come to call the prescription pendulum.

Doctors used to be criticized for prescribing too conservatively. Now they are criticized, and I believe fairly, for prescribing too much. There has to be a practical approach that really meets the needs of our people and strikes a responsible balance.

For me, this all began back in the days—and Chairman Roberts has heard some of these stories about the Gray Panthers. I ran the legal aid program for the elderly, was director of the Gray Panthers. And I remember a fellow called and said his 92-year-old dad was in pain and could not get a prescription. His father was 92, and the doctor said, "No, no, no, I am not going to prescribe for pain because the risk of addiction is too great." Compare that with the fact that today one in three Medicare patients has a prescription for opioids.

And of course—I see my friend Senator Isakson—this has been part of our effort on chronic care, our bipartisan effort on chronic care.

I have also heard, more recently, agonizing stories from parents at home who have lost kids to the epidemic.

At one of my roundtables, I met Kerry Strickland, who lost her son Jordan to an overdose. Jordan was a star athlete in the tiny Columbia River town of Knappa. When he suffered an injury, he was prescribed opioids, and I guess he may have gone to a party, gotten involved with some of his friends, and he started using heroin. And for years, he struggled in the battle between addiction and recovery.

Colleagues, I know we have a lot of athletes here. I went to school on a basketball scholarship. I was too small, and I made up for it by being slow. [Laughter.]

But nobody, nobody, who threw out their knee—and I think Dr. Cassidy, I am sure, knows more about it—back when I was coming up suddenly became addicted to painkillers. That was unheard of, just unheard of.

And I am sure my colleagues are all hearing these stories.

So as Chairman Hatch noted—and I want to come back to it—we can come up with bipartisan proposals to help make a difference. The chronic care legislation that the chairman mentioned, I have mentioned, which Senator Isakson joined me on—we were kicking off and hardly anybody figured it had a chance—began literally to transform Medicare from being an acute care program to

being a chronic care program, which is where most of the money is now being spent.

And Senator Isakson deserves an enormous amount of credit, as does the chairman, because we made it a bipartisan process. We can do that again.

I am looking at the three colleagues on my side here. Senator Stabenow has worked hard on this. Senator McCaskill—nobody has worked harder on the opioid issue than Senator McCaskill, in terms of investigating the crisis, holding people accountable. So we have colleagues here.

And I do not want to overlook the fact that I see colleagues on the other side of the aisle who have also put in a lot of time on this.

So we can address these issues in a bipartisan way. And I think particularly important for us is the vital role that Medicaid plays in treatment. Four out of 10 working-age Americans suffering from an opioid addiction rely on Medicaid. It is the largest source of funding for treatment in the country, so it is going to have to be a key part of a solution.

As the chairman noted, the Family First legislation provides a real tool to deal with the epidemic. Family First is about keeping the families together wherever you can.

So under this law—and let us just make sure everybody knows what it means for opioids—if a parent is swept up in opioid addiction, a grandparent could, for example, step in to care for the youngsters while mom or dad got the treatment they needed. It would provide support for both the parent's treatment and services for the relatives. The end result: you have a family that can stay together.

And now we are in the period where we will be working with the Department. We have two of their representatives here to help the States to prepare for the major reform.

But Chairman Hatch and I are determined to see this Federal/State partnership through so that Family First gives us a fresh new tool for fighting back against opioid addiction and keeping the families together in the process.

Last point: a warm welcome to our witnesses. All of us have enjoyed Ms. Brandt's cookies. And that has been referenced. But I want it understood that we very much appreciate her professionalism. Virtually everybody on this committee has had a good experience late at night struggling to try to put together the details on an important piece of domestic legislation.

So, Ms. Brandt, Dr. Giroir, we welcome both of you.

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

Senator WYDEN. And I guess the Kansans are in charge of the committee now, huh?

Senator ROBERTS [presiding]. It is a coup. [Laughter.]

Senator WYDEN. All right.

Senator STABENOW. Is this the Ag Committee? No?

Senator ROBERTS. It is a coup.

I would like to associate myself with the remarks, the bipartisan remarks and approach we have to this problem, stated by my colleague and friend from Oregon, who did start out in Kansas.

Senator WYDEN. My roots. [Laughter.]

Senator ROBERTS. And I would like to read the statement by the distinguished chairman, Senator Hatch, and to extend a warm welcome to our two witnesses here today.

Our first witness today will be Dr. Brett Giroir, who was confirmed by the Senate by a voice vote—something that rarely happens—just 2 months ago in February and is currently serving as our Assistant Secretary for Health in the Department of Health and Human Services.

Dr. Giroir's confirmation hearing was not in this committee, but we are pleased his appointment as Secretary Azar's opioid policy lead brings him before us today.

Prior to his current position, Dr. Giroir was a physician, a scientist, and also an innovator. He is a former medical school executive, biotech startup CEO, and served in a number of leadership positions in both the Federal Government and also in academia.

The rest of Dr. Giroir's professional career is far too long to describe here. He is quite a gentleman, but let me include just a few highlights.

He chaired the Veterans Choice Act Blue Ribbon Panel in 2014 and 2015. He directed the Texas Task Force on Infectious Disease Preparedness responses during the Ebola emergency. He was CEO of Texas A&M's Health Sciences Center from 2013 to 2015. He directed DARPA from 2006 to 2008.

Dr. Giroir has authored or coauthored almost 100 peer-reviewed scientific publications and holds patents on a number of biomedical inventions.

He holds a bachelor's degree in biology from Harvard and a medical degree from the University of Texas Southwestern Medical Center in Dallas.

I am grateful, and I know all the members of this committee are, that this committee will be the first congressional committee to hear from him in his capacity as Senior Adviser to the Secretary on Mental Health and Opioid Policy.

I am also delighted to have CMS's Kim Brandt appear before the committee. I was going to say that we used to refer to CMS as "it's a mess," but she has certainly done her best to make it "CMS." So we will forget about that remark. [Laughter.]

Kim also has a lengthy list of credentials. She is currently serving as the Principal Deputy Administrator for Operations of the Centers for Medicare and Medicaid Services. Prior to that, she was here with all of us, serving as the Chief Oversight Counsel on the majority staff from 2011 to 2017. Just prior to that work, Kim was a senior counsel at Alston and Bird—so you know Bob Dole—after working for 7 years as the CMS Director of the Medicare Program Integrity Group.

Prior to that, Kim worked for 5 years at the HHS Office of Inspector General as Special Counsel and Director of External Affairs.

Kim holds a bachelor's degree from Valparaiso University, a master's degree in legislative affairs from George Washington University, and a J.D. with a concentration in health law from the DePaul School of Law.

So, talk about two very qualified witnesses.

Without further ado, let us get to the meat of this very important hearing.

Dr. Giroir, would you please get us started?

STATEMENT OF ADM. BRETT P. GIROIR, M.D., ASSISTANT SECRETARY FOR HEALTH AND SENIOR ADVISER TO THE SECRETARY FOR MENTAL HEALTH AND OPIOID POLICY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Dr. GIROIR. Yes, sir, Senator Roberts. Thank you so much for that introduction.

And I want to first thank Chairman Hatch, Ranking Member Wyden, and all the members of the committee for holding this important hearing.

The opioid epidemic is the most pressing public health challenge of our time. The data are staggering. Each year, nearly 12 million Americans misuse opioids. According to the latest CDC statistics, each day 125 Americans die of opioid overdoses, predominantly caused by heroin and illicit synthetic opioids like fentanyl.

Behind these statistics, I always see the individual patients—always—because I am a pediatric critical-care physician by training and fully feel the pain of needless suffering and death.

Last week, I met a remarkable woman named Missy Owen. Four years ago, Missy learned that her precious son Davis had been found dead in his car due to a heroin overdose. Davis was president of his senior class, hall of fame in his high school, an honor student, and a community volunteer. But his journey with addiction began with use of opioids from the family medicine cabinet to address his difficulty sleeping.

Missy's story is just one example of why the Department has made this crisis a priority and is committed to solving it through our five-point strategy: first, strengthen public health data reporting and collection to inform real-time responses; second, advance the practice of pain management to decrease the inappropriate use of opioids; third, improve access to prevention, treatment, and recovery services; fourth, enhance the availability of overdose-reversing medications; and fifth, support cutting-edge research that improves our understanding of pain and addiction, leads to new treatments, and identifies effective public health interventions.

Regarding public health data, the CDC currently provides funding and scientific support to equip States with tools to track and report opioid overdoses and deaths and to implement comprehensive prevention programs. States also utilize CDC funding to enhance their prescription drug monitoring programs, which are an increasingly powerful tool to ensure safe prescribing practices and share information from multiple sectors.

CDC has received an additional $350 million in 2018 to enhance these initiatives.

Improving the practice of pain management is also critical because, as the chairman pointed out, three of four people who used heroin this past year misused prescription drugs first.

The CDC issued prescribing guidelines recommending no greater than 7 days of opioids for use in acute pain and the use of non-opioid alternatives whenever possible. This guideline and recent

educational efforts to raise awareness among providers and health systems have resulted in significant reductions in opioid prescribing nationwide already.

To improve access to prevention, treatment, and recovery support services, the Substance Abuse and Mental Health Services Administration, or SAMHSA, administers the State Targeted Response to the Opioid Crisis grants, which enable States to focus on areas of their greatest need.

This program provided $485 million to States and U.S. territories in fiscal year 2017. And just last evening, we released funding for the 2018 allocation of another $485 million to States.

And, because of the unprecedented funding requested by the President and appropriated by Congress, SAMHSA will provide an additional $1 billion to States this year. And this additional billion will likely be awarded to States in September.

CMS also has a significant role in prevention, treatment, and recovery, and my colleague Ms. Brandt will speak to their role momentarily.

Regarding overdose-reversing agents, U.S. Surgeon General Vice Admiral Jerome Adams, my colleague, earlier this month issued the first Surgeon General's advisory in 13 years, which urged more Americans to carry overdose-reversing agents like naloxone. In addition, multiple funding streams are now in place to assist States, localities, and first responders to obtain this agent.

Finally, HHS is supporting cutting-edge research. Dr. Francis Collins has recently announced the Helping to End Addiction Long-Term Initiative at the NIH. And as a result of new funding recently provided by Congress, NIH will double its investment in research on pain and addiction.

In closing, the current opioid epidemic is enormously tragic, dauntingly complex, vastly widespread, and scientifically and medically challenging. This epidemic respects no age, no gender, no race, no socioeconomic status. Victims are our sons and daughters, mothers and fathers, brothers and sisters, leaders and colleagues.

Solving this problem will require a whole-of-government approach. I look forward to working with you collaboratively. Thank you very much.

Senator ROBERTS. We thank you, Doctor, for your most comprehensive statement.

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

Senator ROBERTS. Ms. Brandt, please.

STATEMENT OF KIMBERLY BRANDT, PRINCIPAL DEPUTY ADMINISTRATOR FOR OPERATIONS, CENTERS FOR MEDICARE AND MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Ms. BRANDT. Thank you. Chairman Hatch, Ranking Member Wyden, Senator Roberts, and members of the committee, thank you for inviting me to discuss the Centers for Medicare and Medicaid Services' work to address the opioid epidemic.

I am honored to be back in the Finance Committee, though I will say it is a little strange to be on this side of the witness table.

Over 130 million people receive health coverage through CMS programs. And the opioid epidemic affects every single one of them

as a patient, family member, caregiver, or community member. This theme has been repeated throughout the multiple stakeholder listening sessions that CMS has facilitated to discuss best practices and brainstorm solutions.

As a payer, CMS plays an important role by incentivizing providers to provide the right services to the right patients at the right time. Our work at CMS is focused mainly on three areas: prevention, treatment, and data.

Due to the structure of our programs, Medicare Part D plan sponsors and State Medicaid programs are well-positioned to help prevent improper opioid utilization by working with prescribing physicians. Our job at CMS is to oversee these efforts and to make sure that plan sponsors and States have the tools they need to be effective.

Beginning in 2019, CMS expects all Part D sponsors to limit initial opioid prescription fills for acute pain to no more than a 7-day supply, which is consistent with the guidelines issued by the Centers for Disease Control and Prevention.

Additionally, we expect all sponsors to implement a new care coordination safety edit that would create an alert for pharmacists when a beneficiary's daily opioid usage reaches high levels. Pharmacists would then consult with the prescriber to confirm intent.

Thanks to recent action by Congress, CMS now also has the authority to allow Part D plan sponsors to implement lock-in policies that limit certain beneficiaries to specific pharmacies and prescribers. CMS also recently finalized a proposal to integrate lock-in with our Overutilization Monitoring System, or OMS, to improve coordination of care.

The administration also supports legislation which would require plan sponsors to implement lock-in policies.

These new tools will add on to existing innovative efforts in Part D to track high-risk beneficiaries through OMS and to work with plan sponsors to address outlier prescribers and pharmacies.

We have seen a 76-percent decline in the number of beneficiaries meeting the OMS high-risk criteria from 2011 to 2017, even while Part D enrollment has been increasing.

We also support States' efforts to reduce opioid misuse. Medicaid programs can utilize medical management techniques, such as step therapy, prior authorization, and quantity limits for opioids.

In this year's President's budget, CMS proposed establishing minimum standards for the Medicaid Drug Utilization Review program, a tool that we use to oversee State activities in this area.

In addition to prevention measures, ensuring that Medicare and Medicaid beneficiaries with substance use disorders have access to treatment is also a critical component to addressing the epidemic. Our aim is to ensure the right treatment for the right beneficiary in the right setting. And we are working to increase access to medication-assisted treatment, or MAT, as well as naloxone.

The President's budget also includes a proposal to conduct a demonstration to cover comprehensive substance abuse treatment in Medicare through a bundled payment for methadone treatment or a similar MAT. Because current statute limits CMS's ability to pay for methadone, we are focused on ensuring access to other evidence-based MAT.

The administration is committed to increasing treatment access for Medicaid beneficiaries as well through our 1115 waiver authority.

CMS announced a streamlined process last November providing more flexibility for States seeking to expand access to treatment. Already, we have approved five State demonstrations, which include services provided to Medicaid enrollees in residential treatment facilities.

As this committee knows, ordinarily residential treatment services are not eligible for Federal Medicaid reimbursement due to the statutory exclusion to institutions for mental disease, or IMD. Combined with a full spectrum of treatment services, we believe the new residential treatment flexibility is a powerful tool for States. And we look forward to reviewing more requests.

Finally, CMS is utilizing the vast amounts of data at our disposal to better understand and address the opioid crisis, to share with partners, and to ensure program integrity. This includes active monitoring of trends, sharing prescribing patterns through heat maps, and other various efforts to ensure the effectiveness of our prevention and treatment policies.

While CMS has taken numerous steps to address this national epidemic, we know there is more we can do. We appreciate the work that this committee is doing to highlight the importance of addressing this crisis, and we look forward to engaging with you on solutions.

Thank you for your interest in our efforts to protect our beneficiaries. And I look forward to answering your questions.

Senator ROBERTS. Thank you very much, Kim.

[The prepared statement of Ms. Brandt appears in the appendix.]

Senator ROBERTS. Let us see; in the order of arrival and the order of being here, I think Senator Isakson—I beg your pardon, it is Senator Portman.

Senator PORTMAN. Thank you, Mr. Chairman.

And thank you both for being here.

Admiral Giroir, we are fortunate to have your expertise there. We have enjoyed working with you all on a number of issues.

I want to start, if I could, talking about an issue that comes before this committee, which is the STOP Act. Some of you know this is legislation that deals directly with the huge challenge we face with synthetic opioids coming into our country. We know it is coming mostly from China. We know it is coming mostly through the U.S. mail system.

Our Permanent Subcommittee on Investigations did a year-long study of this. In fact, earlier Senator McCaskill was here, who is very involved in that. Senator Carper is the co-chair of that effort and very involved with it.

Senator MCCASKILL. I am still here.

Senator PORTMAN. We reported back in January something shocking, alarming, which is that, if you go online and ask about opioids, people say, fine, we are happy to sell you synthetic opioids, but we will send it through the U.S. mail system, because it is going to get there without any concern because the U.S. mail system, unlike the private carriers, does not require the advanced

electronic data that helps law enforcement to identify these packages.

Sixty percent of the people who died in Ohio of overdoses, in the most recent data we have, died of fentanyl overdoses—carfentanil, fentanyl, other synthetic opioids.

The county that comprises Columbus, OH just came out with their report from last year, showing a 47-percent increase in overdose deaths; two-thirds of those were related to fentanyl. This is a huge crisis.

And it is amazing to me that we are allowing our United States Post Office to be able to continue not to provide law enforcement the data they need to go and find that needle in the haystack.

We introduced this legislation back in February of 2017. It has 32 cosponsors, including a number of members of this committee on both sides of the aisle.

And I just am frustrated, as the chairman knows and as the staff knows. We cannot get it out of this committee. We cannot report it out and get it to the floor for a vote. There is a companion bill in the House; it is common-sense legislation.

Is it the ultimate answer? No. The CARA legislation, which Senator Whitehouse and I coauthored—Senator Whitehouse is here—is working on treatment and recovery and certainly prevention and helping on Narcan, but this is a clear and present danger, and we are not addressing it. We are allowing people to have access to this fentanyl in our communities, the poison is coming in, and at a minimum it would increase the cost if we could do more in terms of stopping it coming in from China through our U.S. mail system.

So I would ask you about that.

And, Admiral, first, are you aware of this issue? And are you supportive of the STOP Act? I will tell you, the Customs and Border Protection people are, the DEA is, law enforcement is. And would you be willing to help us to get this done?

Dr. GIROIR. Thank you for that question. I want to reinforce how critical the limitation of importation of fentanyl and carfentanil and similar drugs is to our fight.

In the hospital setting, to use fentanyl would be in ICU and anesthesia by trained people. And the thought of this being on the street with its deadly potency is absolutely frightening and astounding.

We would be very pleased—we work very closely with Customs and Border Patrol, as you know. The FDA has increased its enforcement capabilities and the number of import investigators that they have in order to stop the importation of fentanyl and carfentanil so it does not enter our supply.

And of course, Senator Portman, we would be very pleased to provide technical assistance and to work with you collaboratively, because any efforts that we can do to minimize fentanyl and carfentanil getting on the streets will greatly aid our fight in prevention and treatment.

Senator PORTMAN. Thank you, Admiral. I hope the staff on this committee and the leadership of this committee hears that. And I just think it is one of those issues that we should be able, on a nonpartisan basis, to address and address quickly.

With regard to prescribing limits, I noticed that CMS recently finalized their Part D call letter which sets a 7-day opioid prescribing limit for Medicare beneficiary patients with acute pain. Not talking about chronic pain, not talking about cancer—we are talking about acute pain.

As you know, in our CARA 2.0 legislation—Senator Whitehouse, again, is here, the coauthor of that bill—we set a 3-day limit. We do that because of the science and because of what CDC has told us, which is that on the fourth day is when there is a much higher chance of someone becoming addicted. And also, with regard to pain, with regard to acute pain, that fourth day is typically not viewed as necessary from a scientific point of view.

How did you choose a 7-day rather than a 3-day limit?

Ms. BRANDT. So thank you for that question, sir. We chose it because it was consistent with the CDC guidelines. The Centers for Disease Control have a guideline that says a 7-day supply limit is what they recommended as the top end. We sought public comment on it, and the commenters supported this. And we were really trying to strike the right balance.

We recognize that oftentimes 3 days or less will be sufficient, and that is certainly something, so we have 7 days as the top end. It does not mean that is what it has to be, but that was what we did, consistent with the CDC guidelines.

Senator PORTMAN. Yes. Ms. Brandt, I would ask you to go back and look at that CDC data and look at what they say about the fact that during that fourth day, remarkably, because it is, you know, based on science—and it might not seem common sense to some people—but during that period of time after 1, 2, 3 days, there is a much less likelihood of an addiction during that fourth day; the sixth day there is. So I hope you will take another look at that and consider a 3-day limit, again, for acute pain.

And by the way, someone can go back and get another prescription, but they have to go back and explain to the physician that is prescribing it why that is necessary. And you know, if you look at what is happening in my State and States around the country, almost everyone who dies of an overdose started with prescription drugs.

And the ranking member, Senator Wyden, has just talked about this issue of just the pain of the families going through this with regard to prescription drugs being usually the gateway to the overdose and the deaths.

Thank you both for your service. And we look forward to continuing to work with you.

Senator ROBERTS. I thank the Senator for his very incisive comments.

Senator Wyden?

Senator WYDEN. Thank you very much, Mr. Chairman.

Let me start with you, if I could, Dr. Giroir.

I think we all understand we have a public health calamity on our hands, thousands of deaths. We have spent something like a trillion dollars since 2000 in terms of trying to pick up the pieces, you know, financially.

And I reviewed your written testimony carefully, and it almost suggests that the opioid epidemic happened by osmosis.

Your written testimony completely omits the role of the pharmaceutical manufacturers that put a greater emphasis on increasing sales rather than protecting the patients. You state in your written testimony, quote, "Well-intentioned health-care providers began to prescribe opioids to treat pain in ways that we now know are high-risk and have been associated with opioid abuse addiction and overdose."

Now, it is hard to believe that trained physicians would just come up with these pervasive over-prescribing practices on their own. In your view, who told the physicians that these doses and these amounts were acceptable?

Dr. GIROIR. So, thank you for that question. What I can tell you is, I was part of the generation where my teachers, my professors told me, taught me that prescribing opioids in the setting of pain would not be addictive to the patients. We did not, within the medical culture at that time, have the appropriate information, nor was it transmitted.

Pain was the fifth vital sign. Opioids were prescribed based on what we knew.

I cannot tell you, sir, how this started and who is responsible for it. That is a question or an issue for the committee or other components.

Senator WYDEN. So you do not think that the fact that the manufacturers bankrolled patient advocacy groups and experts who placed an outside influence on these over-prescribing practices had anything to do with it?

I have accumulated evidence showing conflicts on these boards. One person has actually been removed. Do you believe that that contributed to this problem?

Dr. GIROIR. I am not here to defend or to place blame on any singular group. I will say that there was a confluence of factors that led to this.

Clearly, opioids were over-prescribed. They were over-prescribed by well-intentioned physicians who believed they were doing the best for the patients, by other prescribers. And we now understand that this problem, which led to heroin and fentanyl, really started with prescription over-prescribing.

Senator WYDEN. We are committed here on this Committee—you heard the chairman and I talk about it—to being bipartisan. But we have to make sure we get the roots of the problem right so you can pull them out and get on with the correction.

And I just want to wrap up this round, and then I have one question for you, Ms. Brandt.

To me, opioid manufacturers—through twisted research, deceptive marketing, and bought and paid-for patient advocacy groups—had a significant role in fueling the crisis.

Now, you are going to be the point person for the Trump team. Do you share those kind of concerns that I have mentioned?

Dr. GIROIR. I am doing everything, and the Department is doing everything we can, to limit opioid prescriptions now to only when opioid prescriptions are important to the patient. We are supporting non-opioid uses. We are supporting alternative care.

So absolutely, I agree with you that opioid prescribing needs to be decreased. We need better science, better information. A key pil-

lar of what we are doing is trying to decrease the unnecessary opioids.

And again, I do mean this respectfully: how we got here and who was responsible, I think is a matter for the committee and others to ascertain.

Senator WYDEN. I want you to have the chance to respond in writing.

Dr. GIROIR. Yes, sir.

Senator WYDEN. Because I do not think we got here by just well-meaning people saying, gee, maybe I do not know how much to prescribe. I think there was a strategy with the opioid executives, and I laid it out item by item: twisted research, excessive hype that downplayed the harmfulness, and stacking these advisory committees where they could.

So we will leave the record open.

Mr. Chairman, if I could just get one question in for Ms. Brandt.

Ms. Brandt, Medicaid is the largest payer of substance abuse disorder services in the country, covering four out of 10 who suffer. In the States ravaged by the epidemic, Medicaid pays for nearly half of the treatments.

Medicaid expansion is clearly going to be a major tool on the ground, and yet I am having trouble squaring the administration's commitment to expanding access to treatment with the President's budget proposal to drastically cut the program and roll back the Medicaid expansion.

Now, we are not over here saying money is the sole answer. But I am going to put into the record some programs that dollar-for-dollar are going to make a big difference in Michigan and Ohio and the States where my colleagues—and Oregon—are fighting this epidemic. And I would just like—because I am over my time—for you to tell us how, when you slash a trillion dollars in Medicaid funding for these lifeline programs, we are going to be able to work with the States to address the epidemic.

Ms. BRANDT. Well, as I mentioned in my oral testimony, we are really committed to working with the States to allow them as much flexibility as possible to use their resources to maximum benefit so they can provide the right treatment to the right people in the right setting.

We have additional money that has been appropriated to go towards the opioid epidemic. The Admiral mentioned some of the additional grants that have just gone out. And we are committed to trying to continue to get as many resources to put towards this problem as possible.

Senator WYDEN. Thank you, Mr. Chairman.

Senator ROBERTS. Senator Stabenow?

Senator STABENOW. Thank you, Mr. Chairman.

I am used to saying, "Thank you, Mr. Chairman," in the Agriculture Committee. So it is nice to see you in this role.

Welcome to both of you.

And first, to follow up, Ms. Brandt, we could talk a lot about—you know, we already talked about the budget. It is great that we were able to get the additional dollars for opioid and mental health services.

One bright light consistent in the President's budget as well has been the strong and consistent support for the Excellence in Mental Health and Addiction Treatment Services. And I thank you for your involvement when you were on this side of the table working in a bipartisan way with Senator Blunt and myself.

As part of the opioid crisis, the fiscal year 2019 budget for the administration also explicitly endorses the Excellence Demonstration and proposed funds to expand the program. And you know this is really creating behavioral health center clinics, federally qualified clinics, like we do for health centers, so that we have permanent structures on the ground. And in the eight States where we are doing that now, a lot of what they are doing is opioid treatment. So it is a very important, long-term way to treat this.

So just a question. As we in the Finance Committee contemplate the best approaches for addressing this crisis, would the Secretary agree that the expansion of Certified Community Behavioral Health Clinics to additional States, as the President's budget proposes, is one important way to address this?

Ms. BRANDT. Thank you for the question. As you know, we have been very supportive of doing innovative approaches. And we believe that the Certified Community Behavioral Health Clinics are part of that innovative solution. That is why the budget proposal includes the extra money.

And we think that this is an issue where no amount of resources, in terms of things like this where you can target it, can be ignored. And this is a very valuable tool that we think could help with this crisis.

Senator STABENOW. Thank you. Well, I look forward to working with you on this.

Let me talk specifically about a critical part of the question of treating people right now involved with opioid addiction, with possible overdoses, with what is happening. And this relates to the question of naloxone, and not only availability for police and fire and for others, as has been suggested, but when we talk about root causes, I just want to take a moment to lay out the fact that naloxone was approved by the FDA as an opioid overdose reversal drug in 1971—1971. Generic versions have been available since 1985. And for a while, prices were not an issue.

In 2005, there were two manufacturers producing a generic version of naloxone, and it cost a dollar for a vial—$1 for a vial. But by 2013, both companies were selling the drug for 15 times that amount. As the need went up, the price went up, which is very concerning to me.

And in 2014, Evzio, a naloxone auto-injector, was introduced. They introduced an auto-injector, the first product approved by the FDA for use by people without medical training.

And so what happened then? They came on the market with $690 for a two-pack. And the price of the generic injectable actually went up a little bit that year. So more need, price goes up. Not exactly how it should operate when it relates to health care and something as serious as this.

Then less than a year later, the price of Evzio increased to $4,500—$4,500. In 2015, Narcan, the nasal spray version of the

drug, also approved for use by people without medical training, came on the market for $150 for a two-pack.

I just want to stress the actual drug naloxone was approved 47 years ago. And as recently as 2005, you could get a vial for a dollar—a dollar. And now taxpayers, in order to support police and fire and medical personnel and others, are going to be spending thousands and hundreds of thousands of dollars in order to address what is an extremely concerning price situation and lack of accountability.

So I just want to ask—because this month the U.S. Surgeon General called for more people to carry naloxone. And you can get it without a prescription. And so we go, over and over again, and we have this price now skyrocketing.

So, Dr. Giroir, you are responsible for coordinating HHS efforts across the agency to fight the opioid crisis. The Commission on Combating Drug Addiction and the Opioid Crisis recommended that HHS use its negotiating power to reduce the prices, use the negotiating power of our government on behalf of our people to be able to bring prices down.

And so I think we all want to know, will you use that power to negotiate what is an uncontrollable situation with no accountability where, frankly, I think the drug companies are taking advantage of the pain and suffering and loss of life in this situation?

Dr. GIROIR. So, thank you, Senator Stabenow. And I appreciate the fact that you are helping us highlight the importance of naloxone.

Naloxone does not solve substance abuse disorder.

Senator STABENOW. Correct.

Dr. GIROIR. It does not get to the root cause, but it is an absolutely critical drug that literally brings life back to a person on the brink of death. So we certainly support that.

Let me give you an update of where we are. First of all, the State targeted grants that I talked about, the $485 million and the extra $485 million yesterday, has increased flexibility for the States to use more of that money as needed for naloxone.

Senator STABENOW. And I am only going to interrupt, not to be rude, but because I am out of time.

Dr. GIROIR. Yes. Yes.

Senator STABENOW. My question was bringing the price down. It is great we are using taxpayer money to pay for these outrageous prices. The question is, something that was on the market for a dollar and now we are talking about these huge price increases, are you going to use the authority that the Commission, the President's Commission, asked you to use to negotiate the best prices for Americans and bring the price down?

Dr. GIROIR. So if I could, the nasal Narcan, which is increasingly the choice reversal agent for first responders, is now fairly significantly discounted and is now to the level of the GSA schedule. So all States and localities are now getting that for $75 for the two-pack, which is consistent with the GSA schedule.

Senator STABENOW. I am sorry, the chairman is telling me to stop.

Dr. GIROIR. Okay. Okay.

Senator STABENOW. But I assume your answer is "no," you are not going to be negotiating the best price, because I am not hearing a "yes."

Dr. GIROIR. So we are now getting that at the GSA schedule. The FDA is looking at all aspects to bring naloxone to over-the-counter and also to increase the generic competition. So that is our current strategy right now.

We have seen the price go down by over 40 percent within the last year.

Senator STABENOW. Well, I would hope so. It started at a dollar. It started at a dollar, and look at where we are right now. And I think it is really outrageous what is happening and what people are having to spend and taxpayers are having to spend.

Thank you, Mr. Chairman.

Senator ROBERTS. I would just observe that the Senator would never advise the distinguished chairman emeritus of the Agriculture Committee to stop with regards to her advice and consent on the committee. [Laughter.]

Senator STABENOW. Thank you, Mr. Chairman.

Senator ROBERTS. Senator Cassidy?

Senator CASSIDY. Thank you.

Thank you both for being here.

Mr. Chairman, thank you.

Last week, I was in Lafayette, LA and announced our Safer Families, Healthier Communities initiative. And I just would speak to folks back home. And what I learned from them will be the basis of my questions for you.

I spoke to the father of a 17-year-old, a young man who eventually died, who when he first went into treatment was asked by the insurance company to be released 2 weeks after treatment began. The fact that he died obviously indicates that this was not an effective strategy.

And then I contrast it with my next conversation, which is that, if you are an impaired physician in Louisiana, there is a minimum of 3 months' inpatient therapy then 1 month follow-up before you are allowed to practice once more.

So contrast that, which is apparently effective—3 months' inpatient with a month of follow-up—with that which clearly was not, after 2 weeks they were asked to leave.

And then lastly, I spoke to another physician who told me of the abuse potential of our medication-assisted therapy: first, that there are a certain number of people who die from methadone overdose, and secondly about the diversion of Suboxone.

So I am going to use that and work backwards for my question.

Dr. Giroir, nice to see a Louisiana guy who does well. Good to have you here.

Dr. GIROIR. Thank you, Senator.

Senator CASSIDY. I know how to pronounce your name, even if others do not.

Let me say, as you know, there are some forms of medication-assisted treatment, like buprenorphine injections and implants, coming onto the market. Next-gen products are provider-administered so they never go into the hands of the patient, therefore cannot be diverted as I have learned that Suboxone is being diverted.

Now, the law is unclear whether or not the pharmacies can dispense this medication directly to the provider, because current law says it has to go to the patient.

Makes sense; you do not want the brother picking it up. But DEA has interpreted this as saying that you cannot give it to the provider to then do the implant and therefore avoid the potential for diversion.

Senator Bennet and I have legislation in the HELP Committee that would address this problem. Can you go back to the Department and see if you can get endorsement of our bill?

Dr. GIROIR. Certainly, I will go back to the Department and discuss this with the Secretary.

I want to state, certainly, that medication-assisted treatment is our best route going forward, in combination with behavioral therapy, to treat patients.

And yes, sir, I will go back. I am not familiar with the specific bill, but we will go back and——

Senator CASSIDY. But we agree that there is certainly abuse potential for both the drugs used in MAT.

Dr. GIROIR. There is abuse potential for the drugs used in MAT, part of the drugs, right? So there is not so much abuse potential for naltrexone, which, of course, is an antagonist, but there is potential diversion abuse with drugs, as you pointed out, yes, sir.

Senator CASSIDY. Ms. Brandt, let me ask you—I have noticed in some localities there are less prescription opioids, but there is no decrease in the number of deaths from opioid overdose, suggesting that it is illegal drugs replacing or backfilling the loss of opioid prescriptions. Is that what your data is showing?

Ms. BRANDT. Actually, I am going to defer to the Admiral on that one.

Dr. GIROIR. Yes, the prescription opioids have been a gateway, if you will, in that three of four people who use heroin started that way. But clearly, the deaths now are far overshadowed by heroin and fentanyl.

Senator CASSIDY. In those areas that are using MAT more extensively, are we seeing fewer deaths related to opioids?

Dr. GIROIR. So, the data we have is that MAT is more effective than non-MAT in preventing death and providing long-term recovery.

I do not have geographic data that correlates geographic use of MAT with a lowering of the death rate within that geography. I will go back and——

Senator CASSIDY. Could you get us that?

Dr. GIROIR. Yes, sir, I will go back and see if that data is available. Clearly, MAT is associated with improved outcomes. So, you know, we would tend to believe that that is the case, but we need to verify that those two things go together.

Senator CASSIDY. I keep going back to the 17-year-old boy who was left, who was asked to be discharged and then is now dead. So something is not working.

And, Ms. Brandt, I thought this question might be for you. It may not be; it may be for either of you.

Do we have a way to track which treatment programs have better outcomes versus those which do not?

If empirically I can say a physician with 3 months' inpatient followed up by a year of follow-up as an outpatient works, but being discharged 2 weeks after being admitted and then ultimately dying maybe does not, do we have best practices on this, and are we doing a proactive follow-up to see that, oh, yes, program Acme Rehab is doing really well, but Beta Rehab not so well?

Ms. BRANDT. Well, speaking for the CMS programs, we are starting to accumulate that type of data through our new T–MSIS, our new Medicaid information system, through results of a lot of the demonstration projects we have been doing and through testing a lot of our new innovative models. We are starting to try to collect that.

Senator CASSIDY. Let me interrupt. Is T–MSIS actually getting populated with State data? Because my understanding was that States were not as aggressively populating that as they should be.

Ms. BRANDT. We are actually getting States. We now have 49 States, the District of Columbia, and, as of March 26th, Puerto Rico actively reporting full data into T–MSIS.

Senator CASSIDY. That is great.

I am over time. I yield back. Thank you.

Senator ROBERTS. Okay. Senator Cardin?

Senator CARDIN. Thank you, Mr. Chairman.

First, I want to concur with the comments of Senator Portman on the fentanyl and Senator Wyden on the misuse of the prescription of opioids for the management of pain, and Senator Stabenow's point on the costs of medicines. I think all those are important aspects of dealing with the opioid crisis.

I have been around the entire State of Maryland, and we have opioid addiction problems in every part of our State, from our most rural to our most urban. And they are in desperate need of partnerships with the Federal Government.

So I want to go on. I want to talk about two programs, one that is pretty well established and another that is becoming a popular option or perhaps an option. Both are impeded by our reimbursement structure. We do not have an integrated care system that reimburses for integrated care, so you have to find creative sources in order to deal with a lot of the treatment options.

One of the more successful options in our State has been peer-support services, where those who are recovering from drug addiction help get those who are in need to the appropriate care center.

We have those programs in Maryland, and they are extremely successful, by the way. The programs are very, very popular. The problem is, there is not a reimbursement structure. A lot of this you have to find either third-party sources to fund or creative ways or hospitals coming in to help us because they know this will reduce their emergency room traffic.

So what I am looking for is whether we can find a way to encourage these types of services. So let me start with that first.

What can we do at the national level either in changing our reimbursement structures or providing direct funding? Because when you look at the grant programs that are available from the Federal Government sources, it is really difficult to get support for peer-support services.

Ms. BRANDT. I am actually going to take this one, because this impacts a lot of the Medicare and Medicaid programs.

Senator CARDIN. Sure.

Ms. BRANDT. We agree with you that peer-support services are a key part of the continuum of care. One of the limits—you asked about what can be done—one of the challenges here is that a lot of these types of services are not covered or not considered a provider for purposes of Medicare. So broadening the definition of what is a Medicare provider to be able to encompass these types of services would give us more flexibility, because currently the statute does not recognize them as appropriate Medicare providers.

We have seen some success with this in States. As of 2016, there are a few States that are covering peer-support services for substance use disorder in Medicaid. That is also something that could be encouraged more. It is in a few States right now, but at least on the Medicare side we would need to expand the provider definition to be able to better cover it.

Senator CARDIN. I look forward to working with you on that, because I think that is clearly a very fruitful model.

The States that are changing it, they do not need a waiver, they can just do it under their current authority?

Ms. BRANDT. They can do it under their current authority; that is correct. To the extent that they hit roadblocks, we will work with them on that.

Senator CARDIN. The other area which is relatively new and has some concerns that it is used appropriately is stabilization centers that try to get individuals who are stressed out of the emergency rooms, where sometimes it is affecting access to emergency care, into a facility that can refer them to the proper care that they need in a more appropriate setting.

We have now, I believe, two stabilization centers in the State of Maryland. Again, the reimbursement structure does not provide for this.

Is there some way that we could try to encourage the appropriate placement of those who are in stress so that they can get referred to the appropriate care?

Either one, whoever feels more confident.

Ms. BRANDT. That is something we could work with you on. It is not something that I am familiar with directly, but we could definitely work with you all to sort of find out more about that and see how we could help.

Senator CARDIN. We have had a couple of our communities, through the emergency room, saying that they want to take care of people, everybody who is in stress and in need of care, but there are security issues with people who are coming out of an overdose. That requires security, but it also compromises the ability of emergency rooms to do their intended purpose, and for these individuals, what you really need is follow-up care, not so much—their life is no longer being threatened, but they need follow-up treatment and care.

And yes, we need more community-based centers, but we also need to get the individual, when we have their attention, the appropriate placement.

Admiral, is there hope for an alternative to using the emergency rooms to deal with this?

Dr. GIROIR. We would certainly hope so. The emergency room is great for emergencies, but it is not so great for everything else. So we certainly support community-based programs. The STR grants we have have a large amount of flexibility for States to both institute programs and test programs.

And increasingly, as you suggest, with the numbers that we have, with millions of Americans misusing opioids, probably 2.4 million with substance use disorder, we are going to have to change the way we do things. It is going to have to be outpatient-based primarily, with the inpatient services primarily reserved for people with co-morbidities, severe mental illness as well as opioid issues.

We are going to have to train more behavioral health professionals, not just psychiatrists, but levels all through. And it has to be community-based.

And again, we are all on the same page here and would be delighted to work with you.

Senator CARDIN. Thank you for that. I look forward to removing the roadblocks that we have in the system that prevent communities from pursuing innovative ways, less expensive ways, and more effective ways to deal with those who are stressed.

Dr. GIROIR. And in my new role, if there is a roadblock, I want to hear about it, because part of my job is to make sure that HHS is listening and understanding and can be responsive to those needs. And I would appreciate that direct feedback. I mean that sincerely.

Senator CARDIN. Thank you for that. Thank you.

Senator ROBERTS. Senator Menendez?

Senator MENENDEZ. Well, thank you, Mr. Chairman.

Ms. Brandt, children whose families have been impacted by the opioid epidemic experience trauma when their family structure breaks down. One program that is important to New Jersey in helping these children is the Family First Prevention Services Act, which allows States to draw down funds for evidence-based practices, such as mental health, substance use treatment, parenting programs, as well as kinship navigators to help grandparents.

Given that these programs span multiple HHS agencies, collaboration is critical to them. For instance, New Jersey has a Mommy and Me program that allows mothers in treatment for substance abuse to get inpatient treatment without giving up the custody of their children.

I believe programs like Mommy and Me help avoid the trauma of taking children away from parents and help keep families intact.

The Family First Act allows States to draw down funds starting on October 1st of this year, but we are still awaiting guidance from ACF and CMS on how to make that work.

So my question is, can I count on you to work with ACF to get that guidance out in time for States like mine?

Ms. BRANDT. Certainly. I'm happy to work with ACF and with the Admiral to ensure that we are coordinating to get that guidance out.

Senator MENENDEZ. Okay. In your joint testimony, you talk about the role of Medicaid data. Some States have been able to

take their Medicaid data and analyze it to inform their intervention approach.

Given your statements about the value of Medicaid data to address this epidemic, do you see value in these types of proactive analyses?

Ms. BRANDT. Speaking for CMS, we absolutely do. In fact, as I mentioned in my opening statement, data is one of the three main components of the CMS opioid strategy. We now have 49 States and the District of Columbia and Puerto Rico reporting in to our Medicaid Statistical Information System. And we are using all of our data across CMS and trying to use it to really target how we can better do prevention and treatment and really be able to help give feedback to States and others, working with their data set.

Senator MENENDEZ. That was going to be my second question. How is CMS working with States like mine to support these types of activities?

Ms. BRANDT. So a couple of different ways. We certainly coordinate with States on the data that they report on through their T–MSIS program. And that allows us to take out, for instance, the pharmacy file, which is all of the claims that are related to things like prescription of opioids, and really be able to help tell them where it is that we see patterns and work with their information that they get from their prescription drug monitoring programs, PDMPs, to be able to really see more detail on how we can do interventions.

Senator MENENDEZ. Now, I know you also mentioned the Medicaid Innovation Accelerator Program. Does CMS have plans to provide New Jersey and other States with technical assistance in this space?

Ms. BRANDT. We are certainly continuing to offer ongoing support to the States, and we think that it is something where we want to be able to have more technical assistance and technical support to provide on that program.

Senator MENENDEZ. Do you think additional Federal support would be beneficial to better support these types of activities?

Ms. BRANDT. We really think that we want to really support States' ongoing payment and delivery system reforms. And as I said, we are really looking to see how we continue to look at different program innovations in it and how we can best support them.

Senator MENENDEZ. Well, we would like to follow up with you on that.

And finally, prescription drug monitoring programs have been helpful in curbing the flow of opioids. But according to the *American Journal of Managed Care,* PDMPs are not necessarily associated with a reduction in overdoses. And I think this may be due to the fact that individuals already addicted to opioids will switch to illegal narcotics as their supply of prescription painkillers is cut off.

What opportunities are there to prevent an opioid addiction from becoming a heroin addiction?

Dr. GIROIR. Thank you for that. First of all, I want to say that PDMPs are rapidly developing, and I think they are a very important tool. And the CDC is supporting States to further utilize them.

I think the next level is to not have a PDMP sit on the side of the equation, but be integrated in the workflow of physicians and other providers, which is sort of the next level.

How to prevent people with opioid use disorder from going to heroin? It is a matter of treatment. We have to get people into the appropriate treatment. We have to stage them early. We do not want to wait until they are on heroin and fentanyl and come into the emergency room.

And again, a lot of the State targeted grants and the technical assistance from SAMHSA are really working on that question specifically. But I agree with you 100 percent.

Senator MENENDEZ. Well, I hope what the Congress did in this omnibus is going to help us focus a significant part of that money towards that exact purpose.

Dr. GIROIR. Yes, sir. The omnibus extra billion dollars through SAMHSA, we expect that to be out to the States by September, in addition to the $485 million extra from the original Cures Act that was released yesterday.

Senator MENENDEZ. Thank you, Mr. Chairman.

Senator ROBERTS. Senator Toomey?

Senator TOOMEY. Thank you, Mr. Chairman.

Ms. Brandt, welcome.

You know, we all know Medicare is the largest purchaser of prescription opioids in the country. I was a little shocked to learn that in a typical year, 2016 anyway, one out of three beneficiaries received an opioid prescription.

I am not a doctor, I am not an expert on this, but it is just counterintuitive to me that one out of three people needs to be given a drug that is so powerful and so dangerous, but that is the case.

It is further even more surprising that Medicare actually pays more on a per-patient basis for opioids than either commercial insurance or Medicaid, so over $4 billion on opioids alone in 2016.

So I really, really wonder about the total consumption levels.

I know that Medicare and Medicaid have overutilization monitoring systems, and I know there has been some progress with respect to the people who are being tracked. But I am concerned that the overutilization monitoring systems are in fact monitoring a tiny percentage of the people who maybe should be monitored. And I say that because, in November of last year, the GAO identified 727,000 people, Medicaid beneficiaries, whom they believe are at particularly high risk—727,000.

The OIG determined 500,000 were receiving high dosages of opioids for at least 3 consecutive months, and this excluded cancer and hospice patients. But the overutilization monitoring system, it is my understanding, covers something on the order of 60,000 to 70,000 beneficiaries. And I am wondering if the right number would not be 10 times as high, based on the GAO and the OIG reports.

So what do you think of the number of folks who are being monitored compared to the number of folks who ought to be monitored?

Ms. BRANDT. Well, a couple of things—and I thank you for the question, because this is an area where we have really been work-

ing to improve our oversight and to see how we can address the OIG and GAO concerns.

First of all, the OMS system only covers Part D beneficiaries, which are a subsection of our larger Medicare and Medicaid population.

So, as a result of the OIG and GAO feedback, we have significantly strengthened and significantly improved our ability to do edits and oversight through the OMS system, which, when we reran at last the OIG beneficiaries that they had identified, enabled us to be able to show that we caught over 85 percent of them with our new and improved expansion of the system and with the additional edits that we put in place.

We have been continuing to implement the CDC guidelines, our new safety edits, and a number of other coordination edits to really get at that. But we are looking at how we can expand this to cover the rest of the program.

Senator TOOMEY. Could you send us the backup documentation on that?

Ms. BRANDT. Sure; I would be happy to do that.

Senator TOOMEY. Because, from what I have seen, it looks like we are falling way, way short of the total goal.

Let me go to a specific subset of folks. It is my understanding anyway that people who experience a nonfatal overdose, that that experience alone is not a sufficient criteria for being part of the overutilization monitoring system, that that is not by itself sufficient. But yet, we have had a spike in nonfatal overdoses.

My understanding is, almost half the time there is a nonfatal overdose that preceded a fatal overdose, so it is obviously a very, very dangerous event.

Should a nonfatal overdose in and of itself be sufficient criteria for including someone in the overutilization monitoring?

Ms. BRANDT. Well, I am not a doctor. I cannot speak to whether or not that is an appropriate criterion for us to use, but I think it is something that we want to look at, because we consider the continuum of care to be very important and we want to make sure that there is that coordination.

Senator TOOMEY. So do you have the authority to adopt that as a criterion? What would it take to adopt—for instance, if it turns out that that is an appropriate criterion—what would it take to make it the criterion for inclusion?

Ms. BRANDT. I am happy to go back and get to you exactly what it would take for us to include that.

Senator TOOMEY. Great.

Admiral, did you have any thoughts on this?

Dr. GIROIR. No, sir. I would be happy to go back and look at what authorities would be required. But clearly, a nonfatal overdose is a risk factor moving forward, and in a true sense, a cry for help, and we need to be attentive to that.

Senator TOOMEY. Exactly. But as it stands today, that is not a sufficient criterion for being included in overutilization monitoring. And so I am not a doctor either, but that is extremely counterintuitive.

Dr. GIROIR. We will certainly take that back and provide responses.

Senator TOOMEY. Thanks very much, Mr. Chairman.

Senator ROBERTS. Senator McCaskill?

Senator MCCASKILL. Thank you, Mr. Chairman.

I would, in reference to the ranking member's comments about the contributions by the manufacturers of opioids to the, quote, unquote, "public policy groups," we have been investigating the manufacturers of opioids in the Government Oversight Committee, the minority staff. We have issued a report that shows, for example, the American Academy of Pain Management receiving big money from opioid manufacturers, and then, coincidentally, they actually issued the statement that said that opioids were not significantly addictive.

I would like to enter that report into the record. I think it is important that the work we have done on that committee be added to this hearing record, because it is relevant.

Senator ROBERTS. Without objection.

[The report appears in the appendix on p. 124.]

Senator MCCASKILL. There is another report we issued about a fentanyl manufacturer. Their internal sales slogan—after we got into the documents and started really getting into the weeds—their internal sales slogan was "start them high and hope they don't die."

They had a fraudulent unit within their company that was posing as doctors' offices and actually calling pharmacy managers to try to get approval for fentanyl—this was Subsys, the fentanyl.

I would like that report also to be made a part of the record.

Senator ROBERTS. Without objection.

[The report appears in the appendix on p. 143.]

Senator MCCASKILL. And I am pleased to say that, as a result of a lot of work, but after this report was issued, the CEO of that company was criminally arrested, which is major progress.

We are continuing to look at the manufacturers, at how they have contributed to this problem. The next report we will be issuing is on the distribution of opioids.

Which brings me to opioid misuse and the failure of CMS Part D to actually require the plans to submit to you potential fraud and abuse. Is there some reason why you are not requiring the plans to give you the evidence of fraud and abuse they uncover?

Ms. BRANDT. I really appreciate the question, because that is something that we have been reexamining. And we are now exploring making that mandatory so that there would be mandatory reporting of fraud, waste, and abuse.

Senator MCCASKILL. Well, I just hope that the exploration does not take very long. We have people dropping dead in my State every day. You know, talk about common sense. Why would this be hard to do immediately? I mean, what studies would you need to do?

If a Part D plan that is making money off our program, that the taxpayers support, is not reporting to you the fraud and abuse they find, then what chance do we have of really getting a handle on this?

Ms. BRANDT. We concur it is a very important part of the program integrity. And as I said, we are working to see how we can begin to implement that.

Senator MCCASKILL. I think you implement it by saying, we are going to have a rule that you have to report fraud and abuse. Can you do that sometime in the next 30 days?

Ms. BRANDT. I will get back to you. I am not sure that we can do a rule in 30 days, but I will get back to you.

Senator MCCASKILL. Well, you can certainly announce you are doing a rule in 30 days.

Ms. BRANDT. I am happy to get back to you with our——

Senator MCCASKILL. Yes; this hands-off approach with these pharmaceutical manufacturers and companies—I mean, Senator Stabenow said, really, a drug that has been around 47 years, that is lifesaving, increases from $690 in 2014 to $4,500 at the beginning of 2017, more than 600 percent? Where is the outrage? Where is CMS in this?

This hands-off approach for these incredibly unconscionable price increases that are not driven by R&D, they are driven by greed, unadulterated greed, in an area where people are dying——

So I think it is great, sir, that you got 75 bucks, but what about the family that has a member they know is addicted? How much is it costing them to get naloxone or Narcan? How can they afford it at a price increase of more than 600 percent?

Why are we not being more aggressive and going after these companies that are doing this? What is their excuse for raising these prices? Because they know they can make more money? Is there any other excuse they have given you?

Have you asked them?

Dr. GIROIR. No, I have not asked the companies about their——

Senator MCCASKILL. Would you ask them? So would you ask them why they are raising these prices this high?

Dr. GIROIR. Yes, we will. We want naloxone to be more available and affordable. There is absolutely no question about that.

Senator MCCASKILL. Well, how about——

Dr. GIROIR. And the nasal spray naloxone, the prices are going down, as we talked about before, but we are going to do everything we can to increase generic competition, to potentially have it over-the-counter, to promote competition to lower that even further.

Again, this is the predominant form that is being used by States and first responders; $75 for two doses is where we are. I would love to see that lower and work on mechanisms to do that.

Senator MCCASKILL. The Evzio naloxone product jumped from $690 to $4,500 in 3 years.

Dr. GIROIR. Right.

Senator MCCASKILL. I would really appreciate you either telling me "yes" or "no," will you write them a letter asking them why the price increased by that much? What was their justification for that price increase? Would you do that?

Dr. GIROIR. I will get back to you on whether I can write a letter. I do not know. But let me just tell you, the $4,000 doses are not being used primarily by first responders and by States.

Senator MCCASKILL. I am talking about families that are trying to save their family members' lives. Do you know how many parents I have talked to who walked into the bedroom and their child was overdosing and they had nothing, they cannot afford this drug

to save their life? I mean, they may need it before the first responders get there.

I just want you all—this hands-off deal about pharma is wrong, and I want you to be as mad as I am about it.

Dr. GIROIR. So I am absolutely aware that naloxone needs to be with families. And again, the inhaled naloxone, the nasal spray naloxone, is generally preferred and useful because it is easy to administer; it is a new form. So I agree with you: it needs to be less expensive.

But now we are at $75 for two lifesaving doses.

Senator MCCASKILL. For first responders.

Dr. GIROIR. For first responders, you are right. You are right.

Senator MCCASKILL. Listen, I am going to hold you accountable on this. I want you to write the letter. I want somebody at CMS to begin to express the outrage towards these pharmaceutical companies that I hear from Missourians every single day.

Thank you, Mr. Chairman.

Senator ROBERTS. Coop, you are up.

Senator THUNE. Thank you, Mr. Chairman.

You know, no State is immune from this issue. Our State does not have some of the data that other States have in terms of prevalence of opioid use disorder, fortunately for us.

But we do have lots of substance use disorder issues, which our Governor is trying to address. And obviously, we are very interested in working with the members of this committee and others of our colleagues and doing everything we can to take this issue head on.

But I do want to express my appreciation to the chairman of this committee and the ranking member for their efforts to help ensure that our committee activity addresses not only the opioid epidemic, but substance use disorder broadly. And I hope that our witnesses and the administration will also keep this issue in mind as they continue theirs efforts to coordinate the Department's activities.

In the face of provider shortages, South Dakota's health systems have worked to innovate through telehealth. As you may be aware, several Senators have been working on the Connect for Health Act, which has the broad goal of expanding access to telehealth and remote patient monitoring services in Medicare.

One provision would provide the Secretary of HHS authority to waive certain Medicare restrictions in current law where telehealth would reduce spending or improve quality of care. And we are hopeful that this is something the Department would have an interest in, particularly as a means to expand access to opioid and substance use disorder treatment.

Is this something Secretary Azar would support? And are there other opportunities that you are looking at administratively to expand access via telehealth?

Dr. GIROIR. Yes, sir; thank you for the question. I certainly want to reaffirm that telehealth is part of the solution. We have to get into an outpatient mentality. We have to reach out to where patients are in their community. And I think telehealth is a really critical and important tool.

The one thing I could say that we are exploring and working with our DEA partners on now is to be able to expand not only

telehealth treatment, but telehealth medication-assisted treatment so that that can be given by a qualified provider across telehealth and monitored by a variety of different professionals.

I think that is really the next step that is really important. And again, we are in very active work with DEA now to see about how we can make that come about in a very short term.

Senator THUNE. Good, good.

In your written testimony, you highlighted the important work being done by the NIH and FDA to advance the research and availability of nonaddictive pain medications and devices, which I applaud. And I know the HELP Committee is also working on further proposals in this space.

Ms. Brandt, has CMS put in place procedures to ensure timely Medicare coverage determination of new therapies once they are approved by the FDA?

Ms. BRANDT. Yes; actually, it is a great question. And because we know the importance of this, we have been working on a parallel process with the FDA. So as the FDA is determining whether or not it will be a drug or device that is approved, we are looking at coverage and reimbursement on our side so that, hopefully, once the FDA approves their piece of it, we can then very quickly move in to getting it approved for Medicare.

Senator THUNE. It seems like a big part of the solution to this problem.

Just one last question. Indian Health Service does not fall directly into this committee's jurisdiction, but I am sure you are aware that many South Dakota tribal members are also eligible for Medicaid, which is the single-largest payer for behavioral health services.

Through your efforts to coordinate the Department's response, what recent engagement has taken place with the tribes and other stakeholders, working with them to address substance use disorder in tribal communities?

Has the National Committee on Heroin, Opioids, and Pain Efforts, or HOPE Committee, that was formed last spring made any changes or suggestions for improving access to culturally appropriate treatment?

Dr. GIROIR. I could say in the 2 weeks that I have had this position, I have probably met with the IHS three times, including an 8-hour principals retreat at HHS, where the Director of the NIH, FDA, IHS and deputies, CDC, myself, Secretary, Deputy Secretary, we were all together, working together and focusing specifically on what we can do to support each other throughout this process.

And as you know, because of your passing the $1 billion that is coming through, the omnibus that will be released in September has a specific $50-million allocation to the tribes specifically.

So I think we are highly coordinated and sensitive to that.

In my other-hat job as the Assistant Secretary for Health, our Office of Minority Affairs, which focuses on culturally and linguistically appropriate treatment, has, even in the last week, done visits to IHS and to multiple tribes to make sure, at the grassroots level, that we are reaching them.

Senator THUNE. Very good; thank you. I hope you will continue those efforts. I appreciate that.

Mr. Chairman, thanks.

Senator CORNYN [presiding]. Thank you.

Senator Heller?

Senator HELLER. Mr. Chairman, thank you.

I want to thank you and the committee for putting together this particular hearing. It is important. And it is important for my State; it is important across the country. And I am pleased that we have this opportunity.

For many Nevadans, substance abuse is an issue that hits close to home. It is an issue I read about in constituent letters, and I hear about it in calls to my office.

Like many of my colleagues, I have heard from those who are struggling with addiction or, for that matter, those who have lost loved ones to this epidemic.

And in my home State of Nevada, there were 665 drug overdose deaths in 2016. And in that same year, opioids were involved in over 40,000 American deaths—statistics, I am sure, you are well familiar with. So opioid abuse is a major public health concern, and more steps need to be taken—I am sure we are all in agreement on that—to ensure that our communities are equipped to address this crisis. So I am pleased to have the panel here before us.

Ms. Brandt, I want to welcome you back to the committee.

Ms. BRANDT. Thank you.

Senator HELLER. It is great to see you.

And I want to thank both of our witnesses for taking a few moments of your time to be with us today.

Dr. Giroir, I would like to start with you.

Dr. GIROIR. Yes, sir.

Senator HELLER. I just had a meeting in my office. I met with Boys and Girls Clubs of western Nevada. And obviously, they were discussing their after-school activities and programs that they had that were available to these young adults. And they were talking about some of the programs, in particular when it comes to trying to prevent students from being involved in drugs, and opioids in particular.

I am just curious as to what—since it was timely—the Department has in mind and what the Department of Health and Human Services is doing, any work they are doing on early prevention.

Dr. GIROIR. So you highlight a very important point, because, obviously, prevention is where it is at.

Senator HELLER. Sure.

Dr. GIROIR. Once you are addicted to opioids, it is a long road, even with the best therapy and cognitive behavioral therapy.

A couple of things regarding that. Number one, we are in the middle of assessing what are the best evidence-based practices to reach different communities. And we are going to have to reach them specifically based on age, based on where they interact. And this is an active, ongoing effort with the CDC and other parts of our agency to target information across the board.

Secondly, the State targeted grants that I spoke about have a significant component of prevention that could support States' activities, because, as you stated, every State is a little bit different, has different organizations that need to be supported and reached.

So I absolutely agree with you there is——

Senator HELLER. Who directs those dollars—in other words, once it gets down to the State level? If the needs are at the, you know, at the school levels, education levels, can the dollars or, for that matter, does HHS have a program with the educational system to get those dollars down there? I just want to know who moves the dollars. And if every State is a little bit different, which I know, how do we get those dollars to the places that need them most?

Dr. GIROIR. So you may have programs in this as well, but these specific grants, they are awarded to the States, and the States can subcontract with any variety of organizations they want to fulfill their mission with those dollars. And it is going to be very similar.

It is highly flexible funding. We want to make sure there is actually prevention and treatment that is covered. But aside from that, the States have tremendous flexibility to subcontract with whomever.

Ms. BRANDT. Yes, and I would just jump in from the Medicaid program side. I am sure you are familiar with the Early and Periodic Screening, Diagnostic, and Testing, or EPSDT. It is mandated that they provide prevention and other types of services for children and adolescents up to age 21. So that is another way, through the Medicaid programs and the flexibilities that they have and resources there, that they can do that.

Senator HELLER. Okay, that is helpful.

Dr. GIROIR. And I just want to emphasize, a couple of weeks ago the President issued an executive order on youth sports participation. And I look at this as a great opportunity to provide opportunities, not just for youth sports participation in underserved communities, but to have that as a platform for health in general where we could send many messages about appropriate nutrition and opioids, et cetera.

Senator HELLER. Thank you.

Ms. Brandt, I wanted to ask you a little bit about electronic prescribing. Senator Bennet and I have introduced the Every Prescription Conveyed Securely Act.

Mr. Chairman, I have a letter I would like to submit for the record, from 20 groups and organizations that support this particular piece of legislation that Senator Bennet and I have introduced.

Senator CORNYN. Without objection.

[The letter appears in the appendix on p. 122.]

Senator HELLER. But I guess the question is to you, Ms. Brandt. What impact would electronic prescribing have on addressing the opioid epidemic?

Ms. BRANDT. Well, there are a couple of things. First of all, I would just note we had a number of stakeholder sessions last fall with various stakeholders across the spectrum, and e-prescribing was one of the top four things that came up across all those stakeholder sessions.

So we really think that the data from that is very important. It has a lot of benefits to the plans, pharmacies, prescribers, and the States. Also, our Part D sponsors are required to support electronic prescribing as part of their participation in the Part D program.

So I think it is something that we think has a lot of potential, and we are aware of your legislation and we would be happy to continue to support technical assistance.

Senator HELLER. Ms. Brandt, thank you.

And, Doctor, thank you for taking time.

My time has run out, Mr. Chairman.

Senator CORNYN. Thank you, Senator Heller.

Senator Carper?

Senator CARPER. Welcome. We are happy you are here today and appreciate your appearance.

I have been writing down the number of times that the two of you have said, well, that is a great question or, I am glad you asked that question or, that was an important question, like, over 25 times so far. That is a record. And I was just wondering, do you ever get questions where you want to just say, God, that is a dumb question; why are you asking that question? [Laughter.]

Maybe not here, but maybe some other committees.

Senator CORNYN. Do not answer that question. [Laughter.]

Dr. GIROIR. I yield to the Senator from Texas. [Laughter.]

Senator CARPER. So I want to talk to you about electronic prescribing. I want to talk with you about something that sounds like electronic prescribing, but it is quite different. It is electronic prior authorization.

And generally, patients in Medicaid, their providers oftentimes wrestle with the prior-authorization requirements for medication—this is to treatments for opioid abuse and increasing the odds that these patients will relapse and return to their use of opioids.

Would increasing the use of electronic prior authorization in Medicaid, in Medicare, and in private health insurance plans help improve access to medication-assisted treatment?

And what do you need from us? What do you need from this committee? What do you need from Congress in order to increase the use of electronic prior authorization for medication-assisted treatment?

I think Senator Roberts, if he were here, would have talked about legislation that he and I have actually, I think, collaborated on. But let me just ask you: what do you think?

Ms. BRANDT. Well, from our perspective, we think that there is great potential for prior authorization. It is something that electronic prior authorization——

Senator CARPER. Would you go so far as to say you are glad I asked this question?

Ms. BRANDT. Well, I decided not to say that——

Dr. GIROIR. I am glad you asked the question.

Ms. BRANDT [continuing]. But I am glad you asked that question, yes, sir; thank you. But it is something that we have been looking at and that we think is one of another potential good tools that we have along with, as I mentioned, e-prescribing—anything we can do that helps us to be able to see in real time what is happening and what is being requested, and especially if it helps us to be able to tell who is requesting different types of services. That is very helpful for us from a program management perspective.

Senator CARPER. Dr. Giroir, do you agree with what she just said?

Dr. GIROIR. I do.

Senator CARPER. Would you go so far as to say you approve of this message?

Dr. GIROIR. Yes, sir, I do.

Senator CARPER. Oh, good. And I would say, going back to Senator McCaskill's question, I have found that whenever Claire McCaskill is after me to do something, make a phone call, write a letter, I finally just say I will do it, and it saves us all time and trouble. And I think what she is asking is probably the right thing to do.

I have another question. And I am a recovering Governor. And when I was privileged to be Governor of Delaware for 8 years, we established a Family Services Cabinet Council. And it included basically half of my Cabinet Secretaries. We met every month. We developed a strategy that we pursued for 8 years to strengthen families, the basic building block of our society.

We said, rather than just address the symptoms of problems, why don't we go after root causes?

And several people today have mentioned root causes. But as we confront the opioid epidemic, I want to urge you to focus not just on treatment, but also to focus on the root causes for this crisis. And I know there are several.

Our child and family experts tell us that individuals with mental health conditions and adverse childhood experiences are at a greater risk for abusing drugs.

Let me just ask: what are HHS and CMS doing to ensure at-risk children and families have adequate access to early mental health treatments and intervention that could reduce drug abuse and addiction? And how can we make better use of telehealth in Medicaid and the CHIP program in order to improve access to mental health treatment, especially for at-risk children?

Ms. BRANDT. So I think from our perspective, we absolutely agree with you that it is important to get the right services to children. As I mentioned, one of our real mantras with the opioid epidemic is the right services to the right person in the right setting, and making sure, particularly with children—as I mentioned to Senator Heller—through our Medicaid program, we do the EPSDT program, which allows us to do prevention services.

And we have really been looking at ways to expand the use of telehealth, particularly for rural areas and areas where they just do not have as great an access, to be able to really use that as an important tool as part of our efforts to fight this epidemic.

Senator CARPER. Dr. Giroir?

Dr. GIROIR. I agree completely. We are also very actively looking at some demonstrations, particularly for children, that would colocate mental services with physical services and really working with our academic and nonprofit partners to do that, because I think that is, you know, very, very important, and that is one way that we can do that.

Having been in a children's hospital and working there for many years, I understand the importance of that.

The second issue is, there are degrees of susceptibility. And I absolutely agree with you, mental health, adverse childhood experi-

ences always make it much more likely. But I think the point is, everybody in this room is susceptible to addiction.

If you are on prescription opioids for too long, it is like asking yourself not to breathe. After a while, you cannot do it.

So I just want to make it clear that you are absolutely right, we need to target the high risks, we need to work on adverse childhood experiences, we need to co-locate those services. But everybody is at risk.

Senator CARPER. All right; thanks very, very much.

Senator CORNYN. Admiral, it is good to see you again.

Dr. GIROIR. Thank you, sir.

Senator CORNYN. Thank you for being here and for your distinguished service at two great Texas institutions, Texas A&M and the University of Texas, in addition to, of course, the United States military.

Ms. Brandt, it is good to see you.

I would like to talk about the elephant in the room. Is heroin an opioid, Admiral?

Dr. GIROIR. Yes, sir.

Senator CORNYN. When people cannot get prescription drugs for some reason, do addicts frequently resort to heroin?

Dr. GIROIR. Yes, sir.

Senator CORNYN. Because it is cheaper, right?

Dr. GIROIR. Yes, sir.

Senator CORNYN. More readily available?

Dr. GIROIR. Yes, sir.

Senator CORNYN. But the addiction that it produces is just as bad, maybe worse than from prescription drugs. Would you agree with that?

Dr. GIROIR. The addiction is the addiction; the consequences of heroin and fentanyl are much more severe because of their potency. Yes, sir.

Senator CORNYN. And are you aware that one of the major sources of heroin into the United States is across our Southwestern border?

Dr. GIROIR. It is, sir. That is for sure.

Senator CORNYN. And along with tons of heroin come tons of methamphetamine, tons of cocaine. But I know we are talking primarily about opioids.

I heard it described to me recently by the head of Southern Command, the Combatant Commander in charge of that region of the world, he said the criminal organizations that traffic in drugs, poison if you will, into the United States that addict so many Americans, they are commodity-agnostic is the way he put it. They will traffic in drugs, they will traffic in children, they will traffic in whatever will make them a dollar. That is all they really care about. They care nothing for the human misery that they cause as a result of their illegal activity.

Which is why it causes me great pain and disappointment to see that, when Congress has an opportunity to live up to its responsibilities to provide the funds and the means by which to provide greater security along our Southwestern border, even when it is coupled together with a pathway to citizenship for 1.8 million young people, people vote "no," we abdicate our responsibility when

we fail to live up to—I am talking about Congress now—our responsibility to deal with this whole epidemic.

And would you agree with me, Admiral, that if we just dealt with the prescription drug part, but did not deal with the heroin and fentanyl problems, that we would not be able to get our arms around this epidemic?

Dr. GIROIR. We absolutely need a comprehensive solution that includes prescriptions. But I cannot overemphasize the importance of limiting heroin, fentanyl, and carfentanil to the solution set.

Senator CORNYN. Yes. I have heard General Kelly, now the Chief of Staff at the White House, formerly head of Southern Command, bemoan the fact that many of our military or law enforcement who are stationed in places to be able to intercept the movement of illegal drugs into the United States, because they are inadequately resourced in terms of the equipment, airframes and the like, boats, that they have to simply sit there and watch it pour into the United States.

But as we all know, the demand is equally or maybe even more important than the supply. And do you have any suggestions, either one of you, for what Congress might be able to do to deal with the demand side of this terrible problem?

It seems to me we throw up our hands and give up too readily on the demand side. And if we can figure some way to dampen the demand side, that would be an important part of solving this problem. Would you agree?

Dr. GIROIR. Two comments. First, we know that the demand side today, much of that was created by prescription opioids. So three out of four users of heroin started on prescription opioids. So one of our principal strategies to decrease the demand side is to reduce the unnecessary prescribing of prescription opioids across the board.

Senator CORNYN. Absolutely.

Dr. GIROIR. The second comment is, with opioids, the supply does create demand, because once you are on it, you cannot get off of it. It is a disease; it is an addiction. I fully agree. It is like telling someone not to breathe, once you are addicted to these drugs.

So in addition to decreasing the demand, we have to understand that we have to decrease the supply and also that the supply creates demand. Once you are on heroin, fentanyl, or any of these drugs, it is very, very difficult to get off.

Senator CORNYN. Are there strategies that you think that the Federal Government could embrace to try to deal with that demand component?

I hear what you are saying about supply and demand, but if we dealt with the supply and did not do anything on the demand side, I think we would find ourselves pretty much in the same mess we are in right now.

Dr. GIROIR. Yes, sir.

Senator CORNYN. Are there strategies that the Federal Government could embrace to deal with the demand side?

Dr. GIROIR. You know, I think with the unprecedented amount of funding and the programs that we have, we need to evaluate their effectiveness over the next months. But you know, I do believe by decreasing prescription opioids—and we are already seeing

a very significant decrease nationwide, even more in the Medicare population, even more in the VA—that the demand is going down. But it has to be coupled with treatment for those who are already misusing or have substance use disorder.

And again, part of the grant process that we are in supports medication-assisted treatment; it supports comprehensive services.

But I want everybody to understand that, as good as they are, the best MAT and services are still only partially effective. We need a tremendous increase in what we look at to improve the effectiveness of those programs.

And we are actually—one of our major thoughts is to work with Francis Collins and the NIH to really start looking in a way to understand, how do you put all the services together to even be more effective?

Again, most MAT, even with good therapy, is only 50 or 60 percent effective for 6 months. So that is the state of the art, and we need to improve that.

Senator CORNYN. I agree 100 percent. But I would just submit that, unless we come to grips with not just the prescription drug side, but the heroin/opioid component, both supply and demand, we are going to find ourselves——

Dr. GIROIR. There are tons of heroin literally coming over. The problem with fentanyl, among all the problems, is it is very cheap, so the profitability is high. And because it is so potent, you do not have to carry truckloads of it. Only small amounts can have an impact that could kill tens of thousands of individuals.

Senator CORNYN. Senator Cantwell?

Senator CANTWELL. Thank you, Mr. Chairman.

And thank you for your question, because I think it is a good precursor to some of the things that we are interested in.

I do not know if either one of you knows—I am assuming you do—that the Drug Enforcement Administration classified opioids as a dangerous substance with a potential for high abuse and leading to severe psychological and physical dependence.

So because of that, that is why we created a strong network of laws on distribution. We basically said that substances like this needed to be tracked and reported and suspicious orders red-flagged and the distribution of these drugs communicated, so that the Drug Enforcement Administration, DEA, could work through this.

But despite the fact that that law exists, there have been large quantities of opioids flooding our communities, with manufacturers filling excessively large orders in distribution.

In one example, a physician in Everett, WA wrote more than 10,000 prescriptions of the highly addictive OxyContin, and these were 26 times higher than the average for an Everett prescriber.

In another case, an illegal opioid distribution ring in California allowed more than 1 million opioids to be distributed into a community.

So my point is, where is the accountability? Where is the accountability for drug manufacturers not tracking and using that information with the Drug Enforcement Administration to work cost-effectively to try to stop this kind of distribution?

Currently, the fines for manufacturing are a mere $10,000 for neglect in reporting on that distribution. So to me, that is hardly a deterrent. That is why I am asking legislatively for a tenfold increase for not reporting negligent distribution.

And to me, we have to get at this problem of not tracking and seeing the signs of that distribution.

Now, my colleague Senator Harris and I also want to address what my colleague Senator Cornyn just mentioned, which is giving law enforcement the tools to also deal with the heroin epidemic.

The heroin epidemic is also part of the problem, and we want to make sure that they have the resources to deal with heroin traffic. And we think that the front line of that is our law enforcement entities, and they need that help and support.

But the question I have about this, on the distribution, is, does HHS have a system in place to track prescription opioids covered by Medicaid and Medicare and knowing how they might be falling into the wrong hands?

Ms. BRANDT. So, speaking for Medicare and Medicaid, we do, through our Medicare program, particularly the Part D program, have what is called the overutilization monitoring system, which allows us to be able to track—for instance, you were talking about beneficiaries who receive high amounts of opioids. We are able to see if they receive 90 or more morphine milligram equivalents for a sustained period of time, say 6 months, from up to three or more prescribers or three or more pharmacies.

We also have our MEDIC, which is our fraud investigations unit, which looks at prescriber data to really be able to work with the Inspector General to track those prescribers and to really look at pharmacies and prescribers who are high overutilizers and hopefully take action against them.

Senator CANTWELL. So you do not work with the Drug Enforcement Administration on this?

Ms. BRANDT. We do not work directly with them. Our law enforcement partners at the Office of Inspector General and Department of Justice do, but we at CMS do not work directly with DEA.

Senator CANTWELL. Do you think that we need larger controls in place on improper prescribing, billing, and dispensing?

Ms. BRANDT. We are working to try to put as many of those controls in place and agree that we need to really watch these patterns.

Senator CANTWELL. I think we are beyond watching these patterns. I think that is why we are in this problem, because that is all we did and we did not penalize the manufacturer for failing to notify.

We should be able to see some problem on distribution, whether that is a drug ring or an individual physician who has gone awry, whatever the issue is. We should be able to see that. That is what the law requires now.

But there is no penalty severe enough to get people's attention. So I would hope that you would look at this legislation and give us some feedback on it and think about improper prescribing, billing, and dispensing, and what other methods we need for Medicare and Medicaid to be part of that equation.

Ms. BRANDT. We will definitely take a look at the legislation and get back to you.

Senator CANTWELL. And, Admiral, what about giving more resources for an anti-heroin enforcement ring with local law enforcement?

Dr. GIROIR. You know, I can only comment generally. I think we have to be all on the same page to decrease the heroin supply. It is heroin and fentanyl that are now killing much more than prescription drugs. And we absolutely need to support a trans-government approach, including DOJ, local law enforcement, et cetera.

Both of my parents were police officers. I understand how important the front line is to this.

Senator CANTWELL. Well, I see my time is expired.

I would say I hope that we can come together on this because, you know, we have toured our State, we have heard unbelievable stories of what is happening.

People are getting opioids just so they can sell them for the heroin, because they can get that at three times the rate. So we need to combat both. I agree with Senator Cornyn that the heroin part of this is critical, but this is why we need law enforcement, and they need more resources and tools to do that. So I hope you will look at this legislation and give us some feedback.

Thank you, Mr. Chairman.

Senator WYDEN [presiding]. Senator Brown?

Senator BROWN. Thank you, Mr. Chairman.

Ms. Brandt, I know that you, as a native of Ohio, understand how hard this epidemic has hit our State. Eleven people died on Tuesday, 11 people died yesterday, 11 people will die today, and 11 people will die tomorrow, on the average, as you know.

Eleven is not the only number that matters. Let me give you another number: 10,769. According to the American Academy of Pediatrics, that is how many Ohio children were placed in foster care in 2016, many of them—not all—many of them as a direct result of this addiction epidemic.

As you know, the bipartisan Family First Act just signed into law requires the Department to issue guidelines on program criteria and provide a list of preventive services authorized under title IV–E by October 1st of this year.

I understand, since I am way down in the list today because of the Banking Committee, I understand Senator Menendez asked earlier about implementation of Family First. I am pleased to hear you all expect the guidance to States will come out in a timely manner later this year. Thank you to both of you for that. And thanks for your commitment.

Now, I have a few additional questions I will submit for the record on the implementation of Family First, and I encourage you to solicit input and feedback—I know I do not need to admonish you to do that—from the States as you move forward with this guidance.

Before I get to really my only question, Ms. Brandt, I would like to just share some of the things Ohio is doing. We do not do well on infant mortality compared to other States. We do not do well in education. We unfortunately lead the Nation almost in for-profit charter schools abuse.

But we are doing some really innovative things on babies and neonatal abstinence syndrome. I want to talk for a moment about it.

Every 25 minutes, a baby is born suffering from opioid withdrawal in this country. Twenty-one hundred babies, six babies a day, were admitted to a hospital in Ohio for NAS. Just a decade earlier, just 300 cases were reported nationwide, so the explosion of numbers you two are all too familiar with.

Ohio is doing a lot of creative things. Cincinnati Children's established a universal screening program that has helped to identify babies born with NAS and get them to treatment faster.

In previous Finance Committee hearings, Senator Portman and I have talked about our work on the CRIB Act, which would help pediatric recovery centers receive reimbursement through Medicaid.

Secretary Azar made the trip to Kettering, OH—I thank all of you for that—to see firsthand the work happening in our first pediatric recovery center, Brigid's Path. I want to continue our work together to pass the CRIB Act to make sure that these recovery centers have the funding necessary.

Another initiative that our State has been working on is through the Ohio Perinatal Quality Collaborative NAS project, which has developed best practices for treating babies born with NAS. Other States are looking to adopt this successful model.

But our providers are overwhelmed, as you know.

I hosted a conference yesterday for CEOs from a handful of Ohio's smaller and rural hospitals. They spoke about NAS babies, how hard they are for hospitals to treat. Not all of them have NICUs. Some of these smaller hospitals do not have providers who are experienced or specialized enough to care for these babies. As a result, they transfer these high-need infants to other facilities with more resources that are already themselves overwhelmed, but they realize the system is not sustainable.

One of the CEOs of these 100-, 200-bed hospitals, smaller than that even, shared how his hospital is collaborating with another larger system to utilize telehealth technology to keep babies closer to home while they undergo treatment. The larger system will share their resources and expertise through that technology when babies are born with NAS at the smaller hospital.

Their hope is to reduce burden on the regional hospitals that currently are caring for those babies. They anticipate a savings obviously from cutting back on transfer costs.

Now, my request is, Ms. Brandt, talk to me about what CMS is doing to help NAS babies and improve care for moms and babies suffering from the addiction epidemic. What tools do you have to improve care options for these individuals? How does Congress support additional Federal initiatives in that space through multistate demonstrations?

And then if you would answer that and then commit to working, if you would—give us specifically on the record a commitment to work with us on these innovative solutions. So, thank you.

Ms. BRANDT. Well, thank you for the question. And I absolutely recognize the issues back home in my home State of Ohio. The

county I am from back home is one of the hardest hit, and it is a really big issue.

And at CMS, we have been particularly focused on the issues you are talking about in terms of helping mothers and infants struggling with their opioid addiction. We have heard a lot about it.

The Secretary spoke very much about his visit at Brigid's Path and what he learned in Ohio.

So one of the things that we have done is, in February of this year, we approved a State plan amendment for West Virginia, which we hope will be a model for other States to use. It is going to provide additional treatment services for neonatal abstinence syndrome and NAS treatment centers. It basically allows West Virginia to reimburse all medically necessary NAS services through an all-inclusive bundled cost per-diem rate based on a perspective payment methodology.

This is a big shift from how we normally would reimburse for these services and will allow more services to get covered.

Some of the services that they can fund through this would now include nursing salaries, supportive counseling, and case management, which are currently not included.

What it does not include—and this is part of what Congress could potentially take action on—are room and board costs and physician treatment services.

Another thing that we have heard—and that was something that was raised when the Secretary was at Brigid's Path—is the problem with the limitation on 60 days of coverage for mothers who are postpartum and the fact that they do not receive services beyond that. So that is another thing that we have been looking at at CMS, and we have heard a lot of feedback on, and we would love to work with you all, not only on that issue, but on all of these issues, because we think they are critically important.

Senator BROWN. I spoke at the Cleveland City Club the other day about opioids and our government looking at it in a big, comprehensive, public health way. And I used a couple of examples of when government—and you know, a lot of people here do not think there is a role for the Federal Government in a lot of health-care issues, when many of us, on this side at least, believe there is.

But I used the example of tobacco. In 1964, when the U.S. Surgeon General first came out against it, so first recognized tobacco as a public health crisis, 45 percent of American adults smoked; last year, it was down to 15.

You can look at how we treated HIV/AIDS. And at the beginning, I mean, we had a President and a bunch of politicians and many others who would not acknowledge it.

My wife writes a weekly newspaper column that is syndicated, and she wrote about how Barbara Bush, whatever year she did this, when people were so afraid of HIV, you would not even want to touch anybody with it, even though there was no evidence at all that it was transmissible that way, Barbara Bush went into a clinic and held a baby that was HIV-positive. And then once we decided that, what we have been able to do in that public health arena——

So we know how to do this as a country. This one looks more intractable maybe than the other ones; maybe it is, maybe it is not,

but we know how to do these things when we really put our minds to solving a public health crisis.

So you two are really on the front lines of that. And your whole careers have been dedicated to that kind of fight, so thank you both.

Senator WYDEN. Well said, Senator Brown.

Senator Casey?

Senator CASEY. Thanks very much.

I know we are at the end and we are all running for time.

But, Admiral, good to be with you. Thank you for your service.

Dr. GIROIR. Thank you.

Senator CASEY. I do not know which title you like better, Admiral or doctor. We will use them interchangeably.

Dr. GIROIR. Yes, sir.

Senator CASEY. And, Ms. Brandt, we are grateful you are back here. Thanks very much for your service.

I wanted to just highlight what so many others have highlighted and just ask one question, and I will be quick.

This opioid and, frankly, a larger substance use disorder crisis is hitting every State, just as you have heard today.

In my State, the numbers are, as of 2016, I think 4,624 was the number. That number was up 37 percent overall from 2015 to 2016. I do not think I have a 2017 number yet. But in rural areas, it was up more than 37 percent; it was up in the mid-40s, so higher in rural areas.

In one rural county I was in back in August kind of on a tour of the State, the most graphic metric or scenario was the coroner saying we do not have enough places to put the bodies. Literally, they did not have enough slabs or places to put bodies. So it is horrific on every level.

And one question I wanted to ask you is about barriers. I know that we hear a lot about the barriers to accessing treatment being stigma, limited availability of providers, high out-of-pocket costs.

So my only question, because we are all pressed for time, is, do you agree that those barriers exist? And what is the administration doing to confront those?

And it could be either of you. I am directing it to Ms. Brandt, but either or both.

Dr. GIROIR. I certainly agree those barriers exist and particularly for rural populations as well.

Senator CASEY. Yes.

Dr. GIROIR. As I am learning more about this, there is $100 million by HRSA that is going to be targeted specifically to rural areas. The STR funding that we announced yesterday, which was, again, the Cures second tranche and plus the billion dollars, there is great flexibility for the States to use that to support urban or rural, depending on where the needs are.

We talked about it earlier. I am a big believer in telehealth for many issues in distributing health care out of the major centers to where the actual need is. And I think that is part of the answer.

And again, we are exploring, with DEA, sort of the next iteration of that as to, how can we prescribe, have a telehealth prescription of an MAT provider in a rural community where there may not be an MAT provider? There are certain barriers to that, but we are

working on that, because I think that is an important component as well.

I do not want to take up all of your time, so I will stop there and let Ms. Brandt reply, but I would be happy to follow up on that.

Senator CASEY. That is very helpful; thank you.

Ms. BRANDT. And I will just follow up with what the Admiral said.

At CMS, we agree with you: there are a lot of barriers. One of the ways that we are working on those barriers is through demonstration projects. We have 1115 waivers based on some new flexibilities and guidance we issued last November. We have five States that are now using these flexibilities, including allowing them to do things like access residential treatment facilities which, as you are aware, has prior not been allowed under Medicaid reimbursement. So that is something where we are very interested to see the results of those five States and sort of what is happening there and how we can work with other States to provide those flexibilities to help break down those barriers.

Senator CASEY. Great. Thanks very much. And thanks for your help on Wills Eye Hospital. Thank you.

Ms. BRANDT. Oh, happy to help.

Senator WYDEN. Thank you, Senator Casey.

So we are going to wrap up here pretty quickly.

We have a little business left to do, and then I am going to just reiterate a couple of points from 2½ hours ago.

First, I would like to enter into the record Senator Roberts's questions.

[The questions appear in the appendix.]

Senator WYDEN. When we wrap up, we are going to ask that there be a response to questions for the record—and I will do this on behalf of the chairman in a minute—by the close of business on Thursday, April 26th. So we need responses from the administration to Senator Roberts's very good and important questions.

And I am going to—I thought I did it, but perhaps it was not clear—put into the record the various documents that attest to these very serious conflicts of interest that I talked to you about, Dr. Giroir——

Dr. GIROIR. Yes, sir.

Senator WYDEN [continuing]. With respect to these Federal advisory boards.

[The documents appear in the appendix beginning on p. 166.]

Senator WYDEN. In one of these instances already, one of our letters led to the removal of an official where the conflict was so extraordinarily outlandish. But there is a lot of heavy lifting to do here.

All right. Having said that, let me kind of recap where we are.

First, I want to make clear how strongly I feel, and how strongly our side feels, that we tackle this issue in a bipartisan way. We are going to do that under the leadership of the chairman. This is going to be tackled in the same kind of way that we pursued the CHIP bill for 10 years, the historic Family First bill, the potentially transformative Medicare legislation that we have spoken about. We are going to get this bill done, and it is going to be done in a bipartisan way. Period, full stop.

Now, having said that, I want to go back to one of the points that I did make earlier with you, Dr. Giroir, and make sure you understand my expectation.

I continue, as I indicated in my opening statement, to be exceptionally troubled by the role of the opioid executives, the manufacturers, and the distributors. And I do not believe we got into this situation, a public health calamity, by osmosis. And I do not think it was just because some really well-meaning people missed some of the addictiveness.

I think that the opioid manufacturers, through twisted research, deceptive marketing, and bought-and-paid-for advocacy groups, had a significant role to play in creating and fueling the crisis.

So I ask for that answer in writing from you. I expect it within a week because, if we are going to get at the roots of this problem, we have to go at some of what led us to get to this political calamity.

Will you get me an answer to my question within a week?

Dr. GIROIR. Yes, sir. And I just want to be clear that I am fully supportive of the Senate looking at the root causes of this and understanding it and for whatever DOJ is doing. I fully support that.

The only point I was trying to make is that we got here in a multifactorial way. We need to understand the roots so it does not happen again. But where we are is going to require the kind of activities we are doing right now. So, yes, sir, I will provide you that within the time frame.

Senator WYDEN. No one disagrees with the theory that there are a variety of factors here. What I was concerned about in your written statement is it just completely overlooked—completely—the role of the manufacturers and the distributors. And I think that is a significant part of it.

I appreciate your cooperation on this. We will look forward to your answer.

As you could hear, there are differences of opinion on this committee. And I happen to share the views with respect to the role of cost containment. We have to use every effective tool to drive down the costs, because you can have really transformational health products, but people have to be able to afford them.

And also, as Ms. Brandt knows, it is a taxpayer issue as well as an individual issue.

So the question of costs, the question of urgency, as you heard colleagues talk about, is all fundamental.

But we are going to get a bipartisan bill from the Finance Committee, because Chairman Hatch and I have been talking about this for some time. There are colleagues with very good ideas on both sides of the aisle. That is the way we do it.

And with that, we will thank you both.

Always good to see you, Ms. Brandt. You have had a lot of good ideas over the years with respect to the other bipartisan legislation. That is really principled bipartisanship.

And with that, the Finance Committee is adjourned.

[Whereupon, at 12:19 p.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF ADM. BRETT P. GIROIR, M.D., ASSISTANT SECRETARY FOR HEALTH AND SENIOR ADVISER TO THE SECRETARY FOR MENTAL HEALTH AND OPIOID POLICY; AND KIMBERLY BRANDT, PRINCIPAL DEPUTY ADMINISTRATOR FOR OPERATIONS, CENTERS FOR MEDICARE AND MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Chairman Hatch, Ranking Member Wyden, and members of the committee, thank you for holding this important hearing. We appreciate the opportunity to communicate and share with the committee the Department's ongoing activities, programs, and research directed toward responding to the opioid crisis in the United States.

From the start of his administration, President Trump has made addressing the opioid epidemic a top priority, and at HHS we share the President's commitment to bringing an end to this crisis, which is exacting a heavy toll on individuals, families, and communities across the country. On October 26, 2017, at the request of President Trump and consistent with the requirements of the Public Health Service Act, the Acting Secretary of HHS declared a nationwide public health emergency regarding the opioid crisis, and on March 19th in New Hampshire the President announced his "Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand." The Department has made the crisis a top clinical priority and is committed to using our full expertise and resources to combat the epidemic. The Fiscal Year 2018 Consolidated Appropriation Act, which provides HHS new funding to address the opioid epidemic, will allow HHS's agencies to continue to invest resources in expanding opportunities for evidence-based prevention, treatment and recovery support services, surveillance and data collection, and research on pain, new non-addictive pain medications, and to enhance our understanding of addiction and overdose.

Over the past 15 years, communities across our Nation have been devastated by increasing prescription and illicit opioid abuse, addiction, and overdose. According to the Substance Abuse and Mental Health Services Administration's (SAMHSA) National Survey on Drug Use and Health (NSDUH), in 2016, over 11 million Americans misused prescription opioids, nearly 1 million used heroin, and 2.1 million had an opioid use disorder due to prescription opioids or heroin. While the number of individuals who misused opioids is down by one million from 2015, opioid overdoses and related deaths remain a major issue and one that requires a much broader understanding of a complicated problem. Over the past decade, the United States has experienced significant increases in rates of neonatal abstinence syndrome (NAS), hepatitis C infections, and opioid-related emergency department visits and hospitalizations. Most alarming are the continued increases in overdose deaths, especially the rapid increase since 2013 in deaths involving illicitly made fentanyl and other highly potent synthetic opioids. Since 2000, more than 300,000 Americans have died of an opioid overdose. Opioids were involved in 42,249 deaths in 2016, five times more than in 1999.

The opioid epidemic in the United States can be attributed to a variety of factors. For example, there was a significant rise in opioid analgesic prescriptions that began in the mid-to-late 1990s. Not only did the volume of opioids prescribed increase, but also well-intentioned healthcare providers began to prescribe opioids to treat pain in ways that we now know are high-risk and have been associated with opioid abuse, addiction, and overdose, such as prescribing at high doses and for long durations. One additional factor is a lack of health system and healthcare provider capacity to identify and engage individuals with opioid use disorders, and to provide

them with high-quality, evidence-based opioid addiction treatment, in particular the full spectrum of medication-assisted treatment (MAT). It is well-documented that the majority of people with opioid addiction in the United States do not receive treatment, and even among those who do, many do not receive evidence-based care. Accounting for these factors is paramount to the development of a successful strategy to combat the opioid crisis. Further, there is a need for more rigorous research to better understand how existing programs or policies might be contributing to or mitigating the opioid epidemic.

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

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

To date, the Department has taken significant steps to advance the goals of our Opioid Strategy. This statement addresses the unique role that the Centers for Medicare and Medicaid Services (CMS) and the Administration for Children and Families (ACF) are taking to address this opioid crisis. In order to provide a more comprehensive overview of the Department's coordinated strategy, it also includes a summary of activities that may fall outside of the committee's jurisdiction by highlighting efforts within the Office of the Assistant Secretary for Health (OASH), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Centers for Diseases Control and Prevention (CDC), the National Institutes of Health (NIH), and the Food and Drug Administration (FDA).

CMS Role in Addressing the Opioid Crisis

As a payer, CMS plays an important part in the HHS efforts by working to make sure providers are providing the right services to the right patients at the right time. Beneficiaries are CMS's top priority across all of our programs, and CMS works hard to protect their safety and put them in the driver's seat of their care. CMS is keenly focused on three areas—preventing and reducing OUDs by promoting CDC guidelines for opioid prescriptions and encouraging non-opioid pain treatments; increasing access to evidence-based treatment for OUD; and leveraging data to target prevention and treatment efforts and to support fraud, waste, and abuse detection efforts.

PREVENTING OVERPRESCRIBING AND MISUSE OF OPIOIDS

CMS is taking a number of steps to reduce overprescribing in order to help prevent the development of new OUDs that originate from opioid prescriptions while balancing the need for continued access to prescription opioids for certain medical conditions and pain management.

Due to the structure of the Medicare Part D program, Medicare Advantage Organizations (MAOs) and Medicare Part D sponsors have a primary role in detecting and preventing potential misuse of opioids. All Medicare Part D sponsors are expected to have a documented, written strategy for addressing overutilization of prescription opioids given the public health crisis. CMS's job is to oversee Medicare Part D plans to ensure that they are in compliance with requirements that protect beneficiaries and can help prevent and address opioid overutilization. Medicare Part

D plans are expected to use multiple tools including better formulary management, case management with beneficiaries' clinicians aimed at coordinated care, and safety edits at the point of dispensing.

CMS recently finalized a series of additional changes for 2019 to further the goal of preventing OUD.[1] To reduce the potential for chronic opioid use or misuse, beginning in 2019, CMS expects all Part D sponsors to limit initial opioid prescription fills for the treatment of acute pain to no more than a 7 day supply. This policy change is consistent with the Centers for CDC Guideline for Prescribing Opioids for Chronic Pain[2] that states that opioids prescribed for acute pain in most cases should be limited to 3 days or fewer, and that more than a 7-day supply is rarely necessary.

Safety edits alert a pharmacist of possible overutilization at the point of sale. In real-time they can flag for a pharmacist that they should conduct additional review and/or consultation with the plan sponsor or prescriber to ensure that a prescription is appropriate. In 2018, all plan sponsors are utilizing these safety edits. Beginning in 2019, we expect all sponsors to implement a new opioid care coordination safety-edit. This new edit would create an alert for pharmacists when a beneficiary's daily opioid usage reaches high levels. When this occurs, plan sponsors are expected to direct pharmacists to consult with the prescriber to confirm their intent. This new policy aims to strike a balance between addressing opioid overuse without a negative impact on the patient-doctor relationship, preserving access to medically necessary drug regimens, and reducing the potential for unintended consequences.

Lock-In Authority

For years, States have been establishing and augmenting effective "lock-in" programs that require Medicaid enrollees who are "at-risk" for misusing or abusing opioids to use only one pharmacy and/or get prescriptions from only one medical office. The Comprehensive Addiction and Recovery Act of 2016 (CARA) provides CMS with the authority to allow Medicare Part D plans to implement similar pharmacy and prescriber lock-in programs. For both Medicaid programs and Medicare Part D plans, lock-in programs are an additional tool to promote better coordination between providers and beneficiaries who meet the guidelines for lock-in.

Under current law,[3] States are able to implement lock-in requirements for enrollees who have utilized Medicaid services at a frequency or amount that is not medically necessary, according to guidelines established by the State. These limitations may be imposed for "a reasonable period of time." Almost all Medicaid agencies have a Lock-In or Patient Review and Restriction Program in which the State identifies potential fraud or misuse of controlled drugs by a beneficiary.

CMS recently implemented the new CARA lock-in requirements in Part D to provide an important additional tool to combat the growing opioid epidemic that is devastating families and communities across the Nation.[4] CARA requires CMS to establish through regulation a framework that allows Part D sponsors to implement drug management programs. The policy incorporated input gathered from various stakeholders, including beneficiary advocates, clinicians, pharmacists, pharmacy benefit managers, and plan sponsors. With a focus on addressing opioid misuse, the proposal would integrate our new "lock-in" authority with current CMS programs aimed at curbing the opioid epidemic. For example, Part D plan sponsors implementing a drug management program could limit an at-risk beneficiary's access to coverage of frequently abused drugs beginning in 2019 through a beneficiary-specific Point of Sale (POS) claim edit and/or by requiring the beneficiary to obtain frequently abused drugs from a selected pharmacy(ies) and/or prescriber(s) after case management and notice to the beneficiary. In addition, the President's FY 2019 budget[5] includes a proposal that would provide the HHS Secretary with the authority to require plan participation in a prescriber and/or pharmacy lock-in program to prevent prescription drug abuse in Medicare Part D; this proposal would save an estimated $100 million over 10 years.

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[1] *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-04-02-2.html.*

[2] *See https://www.cdc.gov/drugoverdose/prescribing/guideline.html.*

[3] 42 CFR 431.54(e).

[4] *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/CY2019-Medicare-Advantage-Part-D-Final-Rule.*

[5] *https://www.whitehouse.gov/wp-content/uploads/2018/02/budget-fy2019.pdf.*

Tools for State Medicaid Agencies

While the Federal Government establishes general guidelines for Medicaid, States design, implement, and administer their own programs. CMS takes this partnership seriously, and because Medicaid is the single largest payer for behavioral health services, and has been working under the current statutory framework to ensure that States have the tools they need and to share best practices to improve care for individuals with mental illnesses or substance use disorders (SUD).

To reduce opioid misuse without restricting access to legitimate services, Medicaid programs can utilize medical management techniques such as step therapy, prior authorization, and quantity limits. For example, Vermont implemented prior authorization criteria which involves step therapy for methadone as a treatment of pain, requiring that patients must have documented side effects, allergies, or treatment failure to a preferred, long-acting opioid before being prescribed methadone for pain. Virginia implemented prior authorization criteria which involves additional documentation by both providers and beneficiaries before long-acting opioids can be approved for managing chronic, nonmalignant pain. As of FY 2016, 37 States have edits in place to limit the quantity of short-acting opioids that will be covered for a beneficiary and 39 States have similar edits in place to limit the quantity of long-acting opioids. Additionally, to increase oversight of certain prescription opioids, States have the option of amending their Preferred Drug Lists and Non-Preferred Drug Lists to require prior authorization for certain opioids.

States are required to report on their providers' prescribing patterns, including prescription opioids, as part of the Medicaid Drug Utilization Review (DUR) program. This is a two-phase process that is conducted by the State Medicaid agencies. During the first phase, (prospective DUR), the State agency's electronic monitoring system screens prescription drug claims to identify problems such as therapeutic duplication, contraindications, incorrect dosage, and clinical misuse or abuse. The second phase (retrospective DUR) involves ongoing and periodic examination of claims to identify patterns of fraud, abuse, gross overuse, or medically unnecessary care.

The President's FY 2019 budget includes a proposal that would establish minimum standards for Medicaid Drug Utilization Review programs. Currently, CMS does not set minimum requirements for these programs, and there is substantial variation in how States approach this issue. Establishing minimum standards would not only help increase oversight of opioid prescriptions and dispensing in Medicaid, but would save the program an estimated $245 million over 10 years.

ENSURING ACCESS TO EVIDENCE-BASED TREATMENT

A critical part of tackling this epidemic is making sure that beneficiaries grappling with OUD have access to the most effective treatment options. Through its networks of health quality experts and clinicians, CMS advocates the sharing of best practices for OUD screening and treatment.

Medicare Parts A and B cover and pay for substance abuse services in multiple ways. Inpatient treatment in a hospital is covered if reasonable and necessary; treatment in a partial hospitalization program, such as an intensive outpatient psychiatric day treatment program, is also covered when the services are furnished through hospital outpatient departments and Medicare-certified community mental health centers. Medicare pays for substance abuse treatment services provided by physicians and other practitioners on a service-by-service basis under the Medicare Physician Fee Schedule, such as counseling services provided by a psychiatrist. Medicare Part B pays for medications used in physician offices or other outpatient settings that require a physician/practitioner to administer, including injections like naltrexone or implants of drugs like buprenorphine used in medication-assisted treatment. In addition, CMS recently made changes to the Medicare Physician Fee Schedule that help support the fight against the opioid epidemic, such as establishing separate coding and payment for the insertion and removal of buprenorphine implants, a key drug used in medication-assisted treatment for opioid addiction, and improving payment for office-based behavioral health services.

Medication-Assisted Treatment (MAT)

Medication-Assisted Treatment (MAT) is the use of medications, in combination with counseling and behavioral therapies, to treat SUDs, including OUDs. MAT is a valuable intervention that has been proven to be the most effective treatment for OUD, particularly because it sustains long-term recovery and has been shown to re-

duce opioid-related morbidity and mortality.[6] To increase access to MAT, CMS requires that Medicare Part D formularies include covered Medicare Part D drugs used for MAT and mandates Medicare Part C coverage of the behavioral health element of MAT services. In addition, CMS issued guidance on best practices in Medicaid for covering MAT in a joint informational bulletin with SAMHSA, the CDC, and the National Institute on Drug Abuse.[7] CMS also released an informational bulletin with SAMHSA on coverage of treatment services for youth with SUD.[8]

While Medicaid programs vary greatly by State, all 50 States currently offer some form of MAT. In addition, the President's FY 2019 budget includes a proposal that would require State Medicaid programs to cover all FDA-approved MAT for OUD, including associated counseling and other costs. These up-front investments in expanded MAT treatment are expected to reduce total Medicaid expenditures over time as more individuals recover from OUD; this provision would result in an estimated $865 million is savings over 10 years.

Under an additional proposal in the President's FY 2019 budget, CMS would conduct a demonstration to test the effectiveness of covering comprehensive substance abuse treatment in Medicare. This demonstration could be expanded nation-wide if successful in key metrics, such as reducing opioid-related deaths among beneficiaries, reducing hospitalization for opioid poisoning, and reducing emergency room utilization for opioid-related issues. Through this proposal, Medicare would provide bundled reimbursement on a per-week-per-patient basis to providers for methadone treatment or similar MAT and would recognize opioid treatment programs and substance abuse treatment facilities as independent provider types; outpatient counseling would be billed separately as clinically necessary. The model would be allowed to target beneficiaries determined to be at-risk, as defined by the Overutilization Monitoring System, to voluntarily receive comprehensive substance abuse treatment, including MAT and SUD counseling.

Increasing the Use of Naloxone to Reverse Opioid Overdose

CMS is also promoting improved access to the opioid overdose reversal drug naloxone by requiring that it appear on all Medicare Part D formularies.[9] CMS recognizes that it is very important for Medicare beneficiaries and those who care for them to understand that these options are available to them under Medicare, so CMS is also working to educate clinicians, health plans, pharmacy benefit managers, and other providers and suppliers on services covered by Medicare to treat beneficiaries with OUD.[10]

In addition, Medicaid programs in a number of States include forms of naloxone on their Medicaid Preferred Drug Lists. CMS has also issued guidance to States on improving access to naloxone.[11] States can offer training in overdose prevention and response for providers and members of the community, including family members and friends of opioid users.

Substance Use Disorder (SUD) Treatment and Demonstrations in Medicaid

Under the demonstration authority granted by section 1115 of the Social Security Act, CMS can waive certain Federal requirements so that States can test new or existing ways to deliver and pay for health-care services in Medicaid. Last November, CMS announced that it was using this authority to provide for a streamlined process for States interested in designing demonstration projects that increase access to treatment for OUDs and other SUDs by permitting services to be covered in an institution for mental diseases (IMD) as part of a State's comprehensive OUD/SUD strategy. Current law prohibits Medicaid from making payments to IMDs for services rendered to Medicaid beneficiaries ages 21 to 64. Previously, States seeking to cover services otherwise subject to the exclusion of coverage for IMD patients had been required to meet rigid CMS standards concerning operational details for implementation before Medicaid demonstration approvals could be granted. The new policy will allow States to begin to provide better treatment options more quickly while improving the continuum of care over time.

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[6] *https://www.ncbi.nlm.nih.gov/pubmed/24500948.*

[7] *https://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-07-11-2014.pdf.*

[8] *https://www.medicaid.gov/federal-policy-guidance/downloads/cib-01-26-2015.pdf.*

[9] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf.*

[10] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1604.pdf.*

[11] *https://www.medicaid.gov/federal-policy-guidance/downloads/cib-02-02-16.pdf* and *https://www.medicaid.gov/federal-policy-guidance/downloads/cib011717.pdf.*

CMS is encouraging States to apply for approval of a 5-year demonstration allowing them to receive Federal financial participation for services to treat addiction to opioids or other substances, including services provided to Medicaid beneficiaries residing in IMDs, as these States work to improve access to treatment in outpatient settings as well. In addition, CMS is working with States that operate these demonstrations to establish strong quality of care standards, particularly for residential treatment settings.

This initiative offers a more flexible, streamlined approach to accelerate States' ability to respond to the national opioid crisis while enhancing States' monitoring and reporting of the impact of any changes implemented through these demonstrations. In addition to being budget neutral, demonstrations must include a rigorous evaluation based on goals and milestones established by CMS. States must also make available on *Medicaid.gov* information on the progress and outcomes of these demonstrations and evaluations so that other States can learn from these programs; this cycle of evaluation and reporting will be critical to informing our evolving response to the national opioid crisis. To date, CMS have approved these waivers for 5 States—Louisiana, New Jersey, Utah, Indiana, and Kentucky.

To further support this initiative, throughout 2018, the Medicaid Innovation Accelerator Program (IAP) will be available to States that would benefit from strategic design support related to improving their treatment delivery systems. The IAP provides States with access to national learning opportunities and technical expert resources, including strategic design support to States planning targeted addiction treatment delivery system reforms and developing 1115 proposals. In addition, CMS is available to provide technical assistance to States on how to meet Federal transparency requirements as well as to preview States' draft 1115 proposals and public notice documentation to help ensure States successfully meet Federal requirements.

Another tool States have to improve access to treatment through their Medicaid programs is the implementation of a health home benefit focused on improving treatment for beneficiaries with opioid use disorder. Health homes are an optional benefit for which States can receive 90 percent Federal match for the first 2 years to improve care coordination and care management for individuals with chronic conditions including substance use disorders.[12]

LEVERAGING DATA TO ENHANCE PREVENTION AND TREATMENT EFFORTS

Data are a powerful tool and CMS is utilizing the vast amounts of data at our disposal to better understand and address the opioid crisis. CMS is working with its partners to ensure that they have the data and information they need to make changes and improvements to help address the crisis.

Utilizing Medicare Data to Address Overutilization

CMS uses the Overutilization Monitoring System (OMS) to help CMS ensure that sponsors have established reasonable and appropriate drug utilization management programs to assist in preventing overutilization of certain prescribed medications, including opioid pain medications. CMS has continued to refine and improve the criteria used in OMS. OMS identifies and reports on beneficiaries with a high risk of misusing opioids and plan sponsors can then use these reports generated by OMS to conduct case management and beneficiary-specific edits. Starting this year, beneficiaries are now identified as at-risk and reported to plans if, in the most recent 6 months, their daily dose of opioids exceeds 90 morphine milligram equivalent (MME); and if they have received opioids from more than three prescribers and more than three pharmacies, or from more than five prescribers, regardless of the number of opioid dispensing pharmacies.[13]

In the 2019 Final Call Letter,[14] CMS finalized additional enhancements to the OMS including revised metrics to track high opioid overuse and to provide additional information to sponsors about high risk beneficiaries who take opioids and "potentiator" drugs, such as benzodiazepines, (which when taken with an opioid increase the risk of an adverse event). To help identify and prevent opioid users from taking duplicate or key "potentiator" drugs, in 2019 CMS also expects sponsors to

[12] Four States currently focus health home benefits on improving treatment for opioid use disorders: VT, MD, RI, and ME.

[13] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf.*

[14] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf.*

implement additional safety edits to alert the pharmacist about duplicative opioid therapy and concurrent use of opioids and benzodiazepines.

CMS utilizes the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC) to conduct data analysis that is shared with plan sponsors to help them identify outlier prescribers or pharmacies. For example, plans receive Quarterly Outlier Prescriber Schedule II Controlled Substances Reports, which provide a peer comparison of prescribers of Schedule II controlled substances. This report now provides a separate analysis of just opioids. Plans also receive quarterly pharmacy risk assessment reports, which contain a list of pharmacies identified by CMS as high risk and provide plan sponsors with information to initiate new investigations, conduct audits, and potentially terminate pharmacies from their network, if appropriate. CMS has also sent letters to prescribers that include educational information and comparative billing data and held webinars[15] for prescribers whose opioid prescribing patterns were different as compared with their peers on both a specialty and/or national level.

To assist clinicians, nurses, and other health-care providers to assess opioid-prescribing habits while continuing to ensure patients have access to the most effective pain treatment, CMS released an interactive online mapping tool. The mapping tool allows the user to see both the number and percentage of opioid claims at the local level and offers spatial analyses to identify "hot spots" or clusters in order to better understand how this critical issue impacts communities nationwide.[16]

The CMS Quality Innovation Network Quality Improvement Organization (QIN–QIO) program, consisting of 14 quality contractors, works to improve health-care quality and safety for Medicare beneficiaries. The QIN–QIO program[17] has established a methodology using CMS claims data to identify adverse events, hospital admissions, readmissions, emergency visits, and observation stays for high-risk Medicare beneficiaries who have taken an opioid medication in the outpatient setting. QIN–QIOs collaborate with providers and other community coalitions, using their reports to support local and national efforts to address the opioid epidemic and increase surveillance of adverse events.

Modernizing Medicaid Data Collection

CMS has been working with States to implement changes to the way in which administrative data is collected by moving from the Medicaid Statistical Information System (MSIS) to the Transformed-MSIS (T–MSIS). More robust, timely, and accurate data via T–MSIS will strengthen program monitoring, policy implementation, and oversight of Medicaid and CHIP programs. CMS is working to transition all States to T–MSIS and has made significant progress. As of March 8, 2018, 49 States plus the District of Columbia and Puerto Rico have begun submitting T–MSIS data. These entities represent 98 percent of the Medicaid and CHIP population. CMS continues to work with the remaining States to help them submit data and expects all States to report T–MSIS data.[18]

CMS has begun to develop tools for T–MSIS users, as well as work with States to improve the quality of data submitted. For example, CMS is developing a data quality assessment for users, which aggregates data quality findings in a user-friendly tool. These efforts will help States report complete and comparable T–MSIS data, which CMS plans to use for program oversight efforts. T–MSIS includes data on prescription opioids, and CMS looks forward to working with States to fully utilize this data in innovative ways that will augment efforts to combat opioid misuse.

The President's FY 2019 budget also includes a proposal to require States to monitor high-risk billing activity to identify and remediate prescribing and utilization patterns that may indicate abuse or excessive utilization of certain prescription drugs in the Medicaid program. States are currently authorized to implement prescription drug monitoring activities, but not all States have adopted such activities. States would have flexibility to choose one or more drug classes and must develop or review and update their care plans to reduce utilization and remediate any preventable episodes to improve Medicaid integrity and beneficiary quality of care.

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[15] *https://www.cbrinfo.net/cbr201801-webinar.*

[16] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/OpioidMap.html.*

[17] *http://qioprogram.org/about/why-cms-has-qios.*

[18] *https://www.medicaid.gov/medicaid/data-and-systems/macbis/tmsis/index.html.*

ACF Role in the Opioid Crisis

THE REGIONAL PARTNERSHIP GRANT PROGRAM

Since 2007, the Regional Partnership Grant (RPG) program has been a cornerstone to the ACF Children's Bureau's efforts to improve outcomes for children and families affected by parental substance use. The intent of the RPG program, authorized under sections 436 and 437 of the Social Security Act as part of the Promoting Safe and Stable Families program, is to increase the well-being, improve permanency outcomes, and enhance the safety of children and families in the child welfare system who are affected by parental substance use. The grants are funded to support collaborative partnerships among child welfare, substance use disorder treatment, court systems, and other family support systems and organizations to implement evidence-based, evidence-informed, and promising programs and strategies with children and families. To date, there have been four rounds of Regional Partnership Grants, with round 4, consisting of 17 grants in 17 States, awarded in September 2017.

REGIONAL PARTNERSHIP GRANTS ROUND 2 (2012–2017) INTERIM FINDINGS

The cross-site evaluation has resulted in several significant, interim findings that will be formally shared in a forthcoming Report to Congress. From October 2012 to April 2017, the 17 RPG round 2 grantees enrolled 11,416 adults and children—55 percent of whom were children, the majority under 5 years old. The strategies and services provided by the RPGs included: expanded and timely access to comprehensive family-centered treatment; creation or expansion of family treatment drug courts; in-home services; case management and case conferencing; and use of evidence-based and evidence-informed practice approaches, such as recovery coaches, mental health, and trauma-informed services; parent-child interventions; and strengthening of cross-system collaboration. Most RPG round 2 families received at least one evidence-based program.

Interim findings demonstrate many adult and child outcomes improved significantly following entry into RPG. These findings include a significant decrease in adult drug and alcohol use between program entry and exit, and adult mental health and parenting attitudes improved significantly with fewer attitudes about parenting that placed their children at risk of maltreatment. Additionally, there was a significant reduction in rates of substantiated maltreatment. Thirty-six percent of children in RPG had an instance of substantiated maltreatment in the year before RPG, and this decreased to just 7 percent of children in the year after RPG enrollment. Removals of children from the home were also less common. Twenty-nine percent of children experienced a removal in the year before RPG enrollment, and only 6 percent of children were removed from the home after entering RPG. Reunifications with the family of origin or other permanent placements were also more common in the year after RPG entry than in the year before. The cross-site evaluation also completed analysis of the adults in RPG round 2 that indicated at program entry they were opioid users. As a result of participation in RPG program, opioid use in particular appears to be an area of significant improvement. Approximately 16 percent of adults were recent prescription opioid users at program entry, and only 4 percent of adults indicated at program exit that they were recent prescription opiate users.

NATIONAL CENTER ON SUBSTANCE ABUSE AND CHILD WELFARE'S (NCSACW) WORK TO ADDRESS THE IMPACT ON THE OPIOID CRISIS ON THE CHILD WELFARE SYSTEM

The National Center on Substance Abuse and Child Welfare (NCSACW) is a HHS initiative jointly funded by SAMHSA's Center for Substance Abuse Treatment and the Administration for Children and Families' Children's Bureau and administered by SAMHSA. The mission of the NCSACW is to improve family recovery, safety, and stability by advancing practices and collaboration among agencies, organizations, and courts working with families affected by substance use and co-occurring mental health disorders and child abuse or neglect. The NCSACW provides training and technical assistance (TA) to families affected by substance use disorders, including opioid use disorders, and involved with the child welfare system. The NCSACW saw a dramatic and sizable increase in TA responses related to opioids from 2009 to 2017. TA responses included sharing of information on related topics such as best practices in the treatment of opioid use disorders during pregnancy and collaboration to support infants with prenatal substance exposure and their families. The NCSACW also creates written materials that support communities in addressing the opioid epidemic. In 2016, the NCSACW released "A Collaborative Approach to

the Treatment of Pregnant Women With Opioid Use Disorders." This publication continues to be the most-downloaded resource from the NCSACW website with 2,148 downloads to date. Web-based tutorials are also provided to train substance use disorder treatment, child welfare, and court professionals. The content of these tutorials includes information on opioid use disorders, Child Abuse Prevention and Treatment Act (CAPTA), and Plans of Safe Care.

NCSACW also provides a limited amount of in-depth TA to State, tribal, and local agencies to assist in developing cross-system partnerships and the implementation of best practices to address the needs of this population. The NCSCAW's Substance-Exposed Infants In-Depth Technical Assistance (SEI–IDTA) program is working to advance the capacity of agencies to improve the safety, health, permanency, and well-being of infants with prenatal substance exposure and the recovery of pregnant and parenting women and their families. Currently, Delaware, New York, Florida, Maryland, North Carolina, and West Virginia are receiving time-limited SEI–IDTA to develop policy and protocols on the prenatal substance exposure provisions CAPTA.

THE ROLE OF OASH, SAMHSA, CDC, NIH, AND FDA IN ADDRESSING THE OPIOID CRISIS

OASH coordinates multiple efforts across HHS and other Federal agencies that address cross-cutting issues related to opioids and pain.

- Pain Management Best Practices Inter-Agency Task Force (Task Force)—The Task Force was established by the Comprehensive Addiction and Recovery Act of 2016 to: (1) identify gaps or inconsistencies in pain management best practices, (2) propose recommendations on addressing identified gaps or inconsistencies, and (3) develop a strategy for disseminating information about the Task Force recommendations. The Task Force will include a broad spectrum of stakeholders Task Force representatives will include a variety of Federal and non-Federal stakeholders including patients, veteran services, first responders, health-care providers, and experts in pain, addiction, mental health, and other areas of expertise.
- National Pain Strategy (NPS)—OASH and NIH are implementing the NPS, which is a coordinated plan to reduce the burden of chronic pain in the United States; and to achieve a system of care in which all people receive high quality, evidence-based pain care. Areas of focus include population research, disparities, and education and training, among others.
- Behavioral Health Coordinating Council (BHCC)—The Assistant Secretary for Health and the Assistant Secretary for Mental Health and Substance Use co-lead the BHCC, which is a convening body that provides guidance and recommendations on the HHS behavioral health agenda. Areas of focus include prescription drug and opioid abuse, behavioral health and primary care integration, and serious mental illness, among others.
- The Surgeon General is also within OASH. U.S. Surgeon General Jerome M. Adams, M.D., recently released a public health advisory to urge more Americans to carry a potentially lifesaving medication that can reverse the effects of an opioid overdose. The medication, naloxone, is already carried by many first responders, such as EMTs and police officers. The Surgeon General is now recommending that more individuals, including family, friends and those who are personally at risk for an opioid overdose, also keep the drug on hand. Expanding the use of the overdose-reversing drug naloxone is a key part of the public health response to the opioid crisis, and is one of the five components of the HHS Opioid Strategy.

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

SAMHSA administers the Opioid State Targeted Response (STR) grants, a 2-year program authorized by the 21st Century Cures Act (Pub. L. 114–255). By providing $485 million to States and U.S. territories in fiscal year (FY) 2017, this program allows States to focus on areas of greatest need, including increasing access to treatment, reducing unmet treatment need, and reducing opioid overdose related deaths through the provision of the full range of prevention, treatment and recovery services for opioid use disorder.

In November 2017, SAMHSA announced that it was accepting applications for $1 million in grants for Opioid State Targeted Response (STR) Supplements. The purpose of this program is to expand and enhance prevention, treatment, and recovery support efforts in the States hardest hit by the Nation's opioid epidemic. The purpose of the supplemental funding is to bolster efforts already being made through the STR grant program. On March 19, 2018, SAMHSA awarded grants to three States that are among those with the highest overdose death rates and greatest increases in death rates. This funding follows the STR grants which SAMHSA distributed to States and territories based on number of overdose deaths and the number of people needing treatment.

SAMHSA also has several initiatives aimed specifically at advancing the utilization of medication-assisted treatment (MAT) for opioid use disorder, which is proven effective but is highly underutilized. SAMHSA's Medication Assisted Treatment for Prescription Drug and Opioid Addiction (MAT–PDOA) program expands MAT access by providing grants to States with the highest rates of treatment admissions for opioid addiction. Twenty-two States are currently funded by MAT–PDOA, and in September 2017, SAMHSA awarded $35 million dollars over 3 years in additional MAT–PDOA grants to six States.

As the Nation's public health and prevention agency, CDC is applying scientific expertise to understand the epidemic and use that information to create interventions to prevent further harms, including the spread of infectious disease and the impact of opioids on mothers and babies. CDC continues to be committed to the comprehensive priorities outlined in the HHS strategy and to saving the lives of those touched by this epidemic. CDC's work falls into five key strategies to address opioid overdose and other opioid-related harms: (1) conducting surveillance and research; (2) building State, local, and tribal capacity; (3) supporting providers, health systems, and payers; (4) partnering with public safety; and (5) empowering consumers to make safe choices.

CDC tracks and analyzes data to improve our understanding of this epidemic. Since 1999, more than 632,000 Americans have died from drug overdoses. In 2016, the death toll continued to rise. Over 63,600 deaths resulted from drug overdoses.[19] More than 42,000 of those deaths involved opioids.[20] According to the most recent provisional data, there were 67,344 drug overdose deaths in the 12-month period ending August 2017. This is an increase of nearly 8,000 deaths attributed to drug overdose compared to the 12-month period ending August 2016. CDC's data indicate that these increases were primarily driven by synthetic opioids, including illicitly manufactured fentanyl. Given the evolving nature of this epidemic, it is essential that we continue to track and analyze data to target prevention efforts.

Data are crucial in driving public health action. Timely, high-quality data can help public health, public safety, and mental health experts better understand the problem, focus resources where they are needed most, and evaluate the success of prevention and response efforts. During the past few years, CDC has invested in strengthening the capacity of States to monitor the opioid overdose epidemic and target their prevention activities. CDC currently provides funding and scientific support to 45 States and Washington, DC to equip States with the tools and technical expertise they need to implement a comprehensive prevention program within their communities. States utilize their funding to enhance Prescription Drug Monitoring Programs (PDMPs) and leverage them as public health tools, improve health system and insurer practices for safer opioid prescribing, support community-level response and prevention activities, and evaluate policies that may impact the opioid epidemic (*e.g.,* naloxone distribution and Good Samaritan laws). In addition, CDC funds 32 States and Washington, DC to improve the timeliness and comprehensiveness of fatal and non-fatal opioid-involved overdose reporting and to disseminate data to stakeholders.

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

[19] *https://www.cdc.gov/mmwr/volumes/67/wr/mm6709e1.htm.*
[20] *https://www.cdc.gov/mmwr/volumes/67/wr/mm6709e1.htm.*

ease surveillance is essential to know the true scale of the epidemic and facilitate more effective State and local responses.

NIH is the lead HHS agency providing support for cutting-edge research on pain and opioid misuse, opioid use disorder, and overdose. Drug addiction and pain are complex neurological conditions, driven by many biological, environmental, social, and developmental factors. Continued research will be key to understanding the opioid crisis, informing future efforts, and developing more effective, safer, and less addictive pain treatments.

Over the last year, NIH has continued its work with stakeholders and experts across scientific disciplines and sectors to identify areas of opportunity for research to combat the opioid crisis. These discussions have centered on ways to reduce the over prescription of opioids, accelerate development of effective non-opioid therapies for pain, and provide more flexible options for treating opioid addiction. The result of these discussions is the recently launched NIH Helping to End Addiction Long-term (HEAL) Initiative. This new Initiative will: (1) advance our understanding of the genetic, social, and other factors that put patients at increased risk for opioid misuse and addiction; (2) expand the therapeutic options available for treating opioid use disorder and overdose; (3) explore the effectiveness of medication-assisted treatment in conjunction with nondrug treatment approaches such as cognitive therapy and meditation; (4) develop new treatments for OUD, including immunotherapies that can block the effects of opioids on the brain; and (5) evaluate treatment options for neonatal abstinence syndrome. The HEAL Initiative also will also include a demonstration study to test the integration of multiple addiction prevention and treatment approaches into health-care and criminal justice settings in States with the highest rates of opioid misuse and overdose.

The HEAL Initiative will also prevent addiction through enhanced pain management. A longitudinal study will explore the transition from acute to chronic pain, non-addictive pain medications development efforts will be enhanced by data sharing, and a clinical trials network for pain therapeutics development will be developed. Best practices for pain management will be further explored, including nondrug and integrated therapies. Finally, innovative neurotechnologies will be used to identify potential new targets for the treatment of chronic pain, and biomarkers that can be used to predict individual treatment response will be explored and validated.

The NIH HEAL Initiative will build on extensive, well-established NIH research that has led to successes such as the development of the nasal form of naloxone, the most commonly used nasal spray for reversing an opioid overdose; the development of buprenorphine for the treatment of opioid use disorder; and the use of nondrug and mind/body techniques to help patients control and manage pain, such as yoga, tai chi, acupuncture, and mindfulness meditation.

Advances that NIH is working to promote may occur rapidly, such as improved formulations of existing medications, longer-acting overdose-reversing drugs, and repurposing of medications approved for other conditions to treat pain and addiction. Others may take longer, such as novel overdose-reversal medications, identifying biomarkers to measure pain in patients, and new non-addictive pain medications.

Finally, NIH is engaged in efforts to advance the HHS Opioid Strategy pillar of advancing the practice of pain management. NIH worked with HHS and agencies across government to develop the National Pain Strategy, the government's first broad-ranging effort to improve how pain is perceived, assessed, and treated, and is now working with other Departments and Agencies and external stakeholders to implement this Strategy. NIH is also involved in implementing the Federal Pain Research Strategy, a long-term strategic plan developed by the Interagency Pain Research Coordinating Committee (IPRCC) and the National Institutes of Health to advance the Federal pain research agenda.

The issue of opioid misuse and abuse remains one of FDA's highest priorities and the agency has a critical and unique role to play in addressing this national crisis. FDA's regulatory oversight of lawfully prescribed drugs gives the agency important opportunities to impact prescribing in ways that can reduce the rate of new addiction while making sure patients with medical needs have access to appropriate therapy. FDA also plays an important role in interdiction of unlawful drugs, in particular, illegal drugs that are shipped through international mail facilities.

Some percentage of patients who are prescribed opioids will develop an addiction to these drugs. Addiction is characterized by a pronounced craving for the drug, ob-

sessive thinking about the drug, erosion of inhibitory control over efforts to refrain from drug use, and compulsive drug taking. This is very different than physical dependence on opioids. The repeated administration of any opioid almost inevitably results in the development of tolerance and physical dependence. These short-term results of physical dependence from repeated opioid administration require dose tapering. FDA has taken steps to address both the risk of addiction and physical dependence. FDA recently announced its plans to expand the risk management plans, known as Risk Evaluation and Mitigation Strategies or REMS, to incorporate, for the first time, all opioid analgesics that are intended for use in the outpatient setting, including the immediate-release formulations. FDA has revised the associated Blueprint[21] for how providers should be educated about pain management in general, and prescribing opioid analgesics specifically. And we are requiring that this training be extended to all providers likely to come into contact with patients who are prescribed these medicines, including nurses and pharmacists.

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

One key to reducing the rate of new addiction is to rationalize prescribing to help make sure that patients are prescribed opioids only when medically indicated. When a prescription is written, it should be for a dose and duration of use that comports closely with the clinical purpose. FDA is considering several potential strategies to promote proper opioid prescribing and dispensing that involve new measures with respect to how opioid products are packaged and labeled, and how providers are educated about their proper prescribing.

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

To address these risks, last year, FDA tripled the number of import investigators we have in the IMFs, allowing us to nearly quadruple the number of suspicious packages that we're able to open and inspect. This has taken our footprint from 8 to 22 full time employees (FTEs), the maximum capacity that our space in these facilities allows.

CONCLUSION

HHS is actively engaged in addressing the opioid epidemic and is committed to implementing effective tools across our programs. We look forward to continuing to work with this committee and the Congress on these efforts.

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

QUESTIONS SUBMITTED FOR THE RECORD TO ADM. BRETT P. GIROIR, M.D. AND KIMBERLY BRANDT

QUESTIONS SUBMITTED BY HON. ORRIN G. HATCH

Question. Dr. Giroir, given the focus of the new Family First law on helping families with substance abuse issues, how will HHS coordinate the implementation of this new law with other efforts across the department focused on the opioid epidemic?

Answer. The Substance Abuse and Mental Health Services Administration (SAMHSA) and the Administration on Children, Youth and Families (ACYF) are committed to supporting States' efforts to improve outcomes for infants and families affected by substance use disorders. Through the National Center on Substance Abuse and Child Welfare (NCSACW), these agencies build the capacity of States to respond to growing concerns about opioid misuse, the increasing number of infants with prenatal exposure, and the lack of coordinated and ongoing services needed to support infants and families during the critical postpartum and infancy period. Technical assistance from the NCSACW is available to assist States with implementing plans of safe care for infants and their families or caregivers, and develop collaborative practices to expand access to family-centered treatment services on a system-wide basis. Also, as you know, the statute requires the Secretary to develop criteria that interventions must meet in order to receive funding under the title IV–E prevention services program. Over the course of the next few months, the Administration for Children and Families (ACF) will consult broadly across the Department of Health and Human Services (HHS) and the field in the development of those criteria. Once the criteria are established, ACF will take an equally broad approach for identifying interventions that meet the criteria, including interventions related to opioid use disorder.

Question. Given Medicaid's critical role in addressing the opioid crisis, Congress needs timely and accurate demographic and payment data information to oversee the program. Without better information, we won't be able to judge the effectiveness of our policies, including those on opioid and substance use disorders. Ms. Brandt, how can CMS and Congress work together to improve the accuracy and timeliness of information from State Medicaid programs to help address the opioid epidemic?

Answer. CMS understands the importance of having complete, accurate data. The Transformed Medicaid Statistical Information System (T–MSIS) is a critical data and systems component of CMS's efforts to gather information from State Medicaid programs. CMS has made significant progress with its Federal T–MSIS information technology (IT) platform, and CMS is continuing to work with States on T–MSIS data quality and technical compliance as a priority for 2018.

CMS continues to focus on improving the quality and completeness of the State submissions, technical compliance and building the agency's Medicaid and CHIP data analytic capacity. We look forward to making data more widely available as quality improves.

Question. The CDC has guidelines for opioid prescribing that are meant to prevent against excessive supply. While we shouldn't expect every prescription to be consistent with these guidelines, assessing the extent to which they are followed could be helpful in identifying outliers.

Ms. Brandt, does CMS have the data to determine prescriber adherence to the CDC guidelines?

Answer. CMS is taking a number of steps to reduce overprescribing in order to help prevent the development of new opioid use disorders that originate from opioid prescriptions while balancing the need for continued access to prescription opioids for certain medical conditions and pain management. Due to the structure of the Medicare Part D program, Medicare Advantage Organizations (MAOs) and Medicare Part D sponsors have a primary role in detecting and preventing potential misuse of opioids.

CMS uses the Overutilization Monitoring System (OMS) to help CMS ensure that Medicare Part D sponsors have established reasonable and appropriate drug utilization management programs to assist in preventing overutilization of certain prescribed medications, including opioid pain medications. CMS has continued to refine and improve the criteria used in OMS, including recent updates that align with CDC guidelines. For example:

- CDC recommends that clinicians should avoid or carefully justify a decision to titrate dosage of opioids to over 90 morphine milligram equivalents (MME) per day.[1] Starting this year, beneficiaries are now identified as at-risk and reported to plans if, in the most recent 6 months, their daily dose of opioids exceeds 90 MME; and if they have received opioids from more than three prescribers and more than three pharmacies, or from more than five prescribers, regardless of the number of opioid dispensing pharmacies.[2]
- CDC advises clinicians to avoid prescribing opioids and benzodiazepines concurrently whenever possible to avoid putting patients at greater risk for potentially fatal overdose.[3] Beginning in October 2016, CMS added a concurrent benzodiazepine use flag to OMS reports to alert sponsors that high-risk beneficiaries have concurrent use of these medications.[4]

In addition, CDC's Guideline for Prescribing Opioids for Chronic Pain[5] States that opioids prescribed for acute pain in most cases should be limited to 3 days or fewer, and that more than a 7-day supply is rarely necessary. Beginning in 2019, CMS expects all Part D sponsors to limit initial opioid prescription fills for the treatment of acute pain to no more than a 7 day supply.

CMS will continue to work with our Federal partners, including CDC, along with Medicare Part D sponsors and other health plans, beneficiary and advocacy groups, States, clinicians, and other stakeholders to ensure safe prescribing.

Question. As an alternative to high doses of oral opioid, some patients with severe chronic pain are prescribed an implantable pain pump. These pumps deliver medication that is tailored to a specific patient and their needs. The method of delivery requires less medication, avoids the risk of overdose, and prevents diversion. After years of allowing pharmacies to bill and be paid for the medication, CMS ruled that claims could only be made by physicians as "incident to." This policy reversal has limited the availability of patients to access this service. Some physicians are reluctant to take on the financial risk to purchase and bill for these drugs, and some States prohibit pharmacies from selling products to a physician or a third party for sale to a patient, making the arrangement illegal under State law.

Considering these barriers, which diminish the availability of a pain management alternative less likely to inflame the opioid epidemic, would CMS be willing to correct this issue in the CY 2019 Physician Fee Schedule rule and allow for intrathecal medications to be billed by pharmacies or physicians in these limited circumstances?

Answer. Under Medicare statute, Part B covers drugs and biologicals furnished "incident to" a physician's service. These drugs furnished under the "incident to" provision are typically injectable drugs that are bought by the physician, administered in the physician's office, and billed by the physician to Medicare. In the Calendar Year 2013 Medicare Physician Fee Schedule final rule, CMS clarified a Part B payment policy that drugs used by a physician to refill an implanted item of durable medical equipment would be considered under the "incident to" benefit. Based on this policy, physicians, but not pharmacies, must purchase the drugs used to refill intrathecal pumps and bill for them under Medicare Part B. However, these drugs may be payable to the pharmacy under Part D if the ingredients that are being compounded independently meet the definition of a Part D drug. Medicare Part B payment to pharmacies (or suppliers) for drugs used to refill an implanted pump can be made under the DME benefit category where the drug is directly dispensed to a patient and the implanted pump is refilled without a physician's service.

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

Question. Nonpharmacological alternatives exist for treating chronic pain management. What is CMS doing to ensure that evidence-based, nonpharmacological pain management alternatives are available to CMS beneficiaries?

Answer. The opioid crisis cannot be tackled by CMS alone, and that is why we are collaborating with other HHS agencies, such as the National Institutes of

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[1] *https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf.*
[2] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf.*
[3] *http://www.cdc.gov/drugoverdose/prescribing/guideline.html.*
[4] *https://www.cms.gov/Medicare/Prescription-Drug-coverage/PrescriptionDrugCovContra/RxUtilization.html.*
[5] *See https://www.cdc.gov/drugoverdose/prescribing/guideline.html.*

Health (NIH), to identify services that need more evidence to support coverage by Medicare and other health plans.

Both medicinal and non-medicinal therapeutic alternatives to opioid-based pain medications exist; although Medicare coverage and payment varies. In general, Medicare covers items and services that are "reasonable and necessary." This includes several non-pharmacologic therapies and other non-opioid pharmaceuticals. CMS uses the national and local coverage determination process to evaluate new or promising items and services with respect to Medicare Parts A and B, through well-delineated processes set forth in statute. Those items and services for which evidence demonstrates improvement in health outcomes in the Medicare population are more likely to be coverable, while those items and services for which such evidence is insufficient or lacking warrant further research.

CMS has partnered with the CDC to develop the Opioid Safety Commitment poster campaign,[6] which promotes the most effective pain management treatments and strategies. This campaign emphasizes patient engagement, clinician counseling regarding opioid alternative pain management strategies, and discussion with patients of the risks and benefits of opioids when opioids are prescribed.

CMS has a number of initiatives underway to increase the use of recommended evidence-based practices for pain management. CMS provides outreach regarding best practices and technical assistance through the Transforming Clinical Practice Initiative's (TCPI's) Practice Transformation Networks.[7] TCPI is designed to use peer-based learning networks for information sharing, outreach, and dissemination of evidence-based practices to educate prescribers on safe and appropriate methods of pain treatment. For example, the TCPI Medication Management and Opioid Initiative is mobilizing the existing network of more than 100,000 clinicians into action to address the opioid crisis, generating collaborations with other CMS quality improvement projects, showcasing successful strategies in engaging providers and patients on proper opioid utilization and spreading the successful strategies throughout all CMS communities.

The CMS Quality Innovation Network Quality Improvement Organization (QIN–QIO) program, consisting of 14 quality contractors, works to improve health-care quality and safety for Medicare beneficiaries. The QIN–QIO program has established a methodology using CMS claims data to identify adverse events, hospital admissions, readmissions, emergency visits, and observation stays for high-risk Medicare beneficiaries who have taken an opioid medication in the outpatient setting. QIN–QIOs collaborate with providers and other community coalitions, using their reports to support local and national efforts to address the opioid epidemic and increase surveillance of adverse events.

CMS also promotes free educational materials for health-care professionals on CMS programs, policies, and initiatives through the Medicare Learning Network (MLN).[8] The CDC Guidelines for Prescribing Opioids for Chronic Pain is featured in the January 12, 2017[9] MLN Connects newsletter.

Question. For years we have heard problems with the quality of Medicaid data. How is the T–MSIS different from previous attempts to gather information from each of the States and territories?

Answer. CMS has made significant investments to meet the organizational and information technology (IT) infrastructure to adequately represent CMS's role in the ever-changing health-care marketplace. The Transformed Medicaid Statistical Information System (T–MSIS) is a critical data and systems component of the CMS Medicaid and CHIP Business Information Solution (MACBIS).

CMS has been working with States to transform our MSIS system, which was used to collect utilization and claims data as well as other key Medicaid and CHIP program information, to keep pace with the data needed to improve beneficiary quality of care, assess beneficiary access to care, improve program integrity, and support States, the private market, and other stakeholders with key information.

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[6] *https://www.cdc.gov/drugoverdose/prescribing/posters.html.*

[7] *https://innovation.cms.gov/initiatives/Transforming-Clinical-Practices/.*

[8] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNGenInfo/Index.html.*

[9] *https://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Provider-Partnership-Email-Archive-Items/2017-01-12-eNews.html?DLPage=7&DLEntries=10&DLSort=0&DLSortDir=descending#_Toc471878721.*

The enhanced data available from T–MSIS will support improved program and financial management and more robust evaluations of demonstration programs. It will also enhance the ability to identify potential fraud and improve program efficiency. Ultimately, the transformed infrastructure will offer States, CMS, and others the ability to do the following at the State and national levels:

- Study encounters, claims, and enrollment data by claim and beneficiary attributes;
- Analyze expenditures by medical assistance and administration categories;
- Monitor expenditures within delivery systems and assess the impact of different types of delivery system models on beneficiary outcomes;
- Examine the enrollment, service provision, and expenditure experience of providers who participate in our programs (as well as in Medicare);
- Observe trends or patterns indicating potential fraud, waste, and abuse in the programs so we can prevent or mitigate the impact of these activities.

In addition, T–MSIS benefits States in the following ways:

- It will reduce the number of reports and data requests CMS requires of States. T–MSIS will be a main source of Medicaid and CHIP operational data, and CMS intends to use the T–MSIS data to calculate and derive other reports States are currently required to submit, such as Early Periodic Screening, Diagnosis, and Treatment Program (EPSDT) and Children's Health Insurance Program Annual Reporting Template System (CARTS). Availability of T–MSIS will also reduce the number of ad hoc data requests CMS makes of States in the absence of a more robust reporting system.
- States will be able to analyze data in the national repository. Over time, CMS plans to incorporate capabilities for States to conduct their own analyses of data available in the national repository and, eventually, to enable States to bring their own data to analyze alongside the national repository.
- States will have enhanced anti-fraud, waste, and abuse capabilities. They will be able to analyze their data along with other information in the CMS data repositories, including Medicare data, enhancing abilities to better identify potential anomalies for further investigation.

Question. Will you commit to working with my office on implementation and analysis of the data you receive?

Answer. CMS is committed to transparency across our programs. We are always willing to work with stakeholders, including members of Congress and their staff, to gain feedback that is critical to our efforts to improve our programs.

Question. I am interested in your time at DARPA and your medical inventions. NIH Director Francis Collins recently outlined areas in need of accelerated research in terms of the opioid crisis. One area he mentioned was the need for non-addictive treatments for chronic pain.

What are your thoughts about innovation in this area?

Answer. Over 100 million American adults have painful conditions, while over 25 million suffer from daily or chronic pain. The opioid crisis highlights the urgent need for novel, non-addictive pain medications. This is why supporting cutting-edge research that advances our understanding of pain, overdose, and addiction, and leads to the development of new treatments is a key part of the comprehensive, five-point HHS Opioid Strategy. As an element of this strategy, a large-scale program to accelerate all phases of development of non-addictive medications—alternatives to opioids—is underway as part of the NIH Helping to End Addiction Long-term (HEAL) Initiative *(https://www.nih.gov/research-training/medical-research-initiatives/heal-initiative).* Through this program, NIH will support research to understand how chronic pain develops, making patients susceptible to risks associated with opioid use to relieve pain. NIH will work with partners from the biopharmaceutical industry to develop a data sharing collaborative, new biomarkers for pain and response to pain treatments, and a clinical trials network for testing new pain therapies. NIH also will expand the pipeline of treatments for pain and enhance clinical practice for pain management.

Development of both non-addictive drugs and devices to better assess and to treat chronic pain is a key element to addressing the opioid crisis. NIH is pursuing innovative strategies to develop technologies and medical devices to monitor and modu-

late peripheral nervous system activity through its Stimulating Peripheral Activity to Relieve Conditions (SPARC) project. Because chronic pain is associated with abnormal, persistent changes in the peripheral and central nervous system circuitry, SPARC is being leveraged to advance new targets and innovative technologies for pain relief. For example, SPARC supported investigators have developed noninvasive tools to "silence" peripheral nerves by photo-stimulation and reduce bladder pain. Another SPARC investigator explored the effects of noninvasive stimulation of the vagus nerve on brainstem activity and associated reduction in episodes of migraines. Moving forward, SPARC expects to expand its scope on pain and addiction research and to provide a more efficient medical device development pipeline.

The NIH BRAIN initiative is focused on development of technologies and knowledge to better understand the central nervous system circuitry and to be able to modulate its activity. Pain researchers are encouraged to explore the pain circuitry and how modulation of maladaptive changes in the central nervous system associated with chronic pain can be tapped as a therapeutic strategy. One study uses nano-particle based drug delivery to very precise regions of the brain, a technology for very targeted delivery of medications for pain and other brain disorders. Other studies target a range of approaches such as trans-cranial magnetic stimulation, to modulate specific brain circuits, which has clinical implications for chronic pain relief.

QUESTIONS SUBMITTED BY HON. PAT ROBERTS

Question. I am interested in the potential for electronic prior authorization, or e-prior authorization, within Medicare Part D to strike a proper balance between limiting the unnecessary dispensing of opioids and avoiding overly burdensome requirements on our providers. How can e-prior authorization be used by Medicare Part D or Medicare Advantage plans to help uphold responsible dispensing of opioids while reducing physician and patient burden?

Given that the majority of the commercial market already uses e-prior authorization, what affects can be expected should this practice be expanded in Medicare Part D?

How would streamlining prior authorization affect the way coverage issues are resolved at the pharmacy counter?

Answer. CMS is always interested in finding ways that will improve our programs and reduce physician and patient burden. Electronic prior authorization is one of many tools currently available to Medicare Part D and Medicare Advantage plans as they continue to work with CMS in identifying ways to further address the opioid epidemic. Prior authorization programs can protect beneficiaries from receiving unnecessary services or devices and help providers by ensuring they will get paid. Regarding prescriptions, prior authorization allows providers and patients to avoid the risk of a future claim denial, as well as its subsequent delay in care, by determining a beneficiary's eligibility to receive the medication before he or she reaches the pharmacy counter. While interoperability is important for the tools used by plans and providers to combat the opioid epidemic, we are cognizant of the potential for administrative burden and expense for providers any time we introduce new requirements. Across our programs, we are looking for ways to streamline regulations and reduce provider burden to better allow clinicians to focus on their patients.

CMS is committed to working with plans and making sure they have the flexibility they need in order to best serve beneficiaries.

Question. I understand there is some interest in adding Medicare patients who are at-risk for prescription drug abuse to the list of eligible beneficiaries for MTM. Additionally, in the recent Part D Final Rule, CMS clarified that MTM programs will fall under "quality improving activities" when calculating medical loss ratio requirements. Do you expect this clarification will encourage plans to expand access to MTM programs to more beneficiaries?

Answer. CMS believes that the Medication Therapy Management (MTM) programs improve quality and care coordination for Medicare beneficiaries. We also believe that allowing Part D sponsors to include compliant MTM programs as quality improving activities (QIA) in the calculation of the Medicare MLR will encourage sponsors to ensure that MTM is better utilized, particularly among standalone Part D plans that may currently lack strong incentives to promote MTM. Furthermore, we have expressed concern that Part D sponsors may be restricting MTM eligibility

criteria to limit the number of qualified enrollees, and we believe that explicitly including MTM program expenditures in the MLR numerator as QIA-related expenditures could provide an incentive to reduce any such restrictions.

Question. What impact would including these at-risk beneficiaries to MTM have in addressing the opioid epidemic?

Answer. CMS hopes that, by removing any restrictions or uncertainty about whether compliant MTM programs will qualify for inclusion in the MLR numerator as QIA, the proposed changes will encourage Part D sponsors to strengthen their MTM programs by implementing innovative strategies for this potentially vulnerable population. We believe that beneficiaries with higher rates of medication adherence have better health outcomes, and that medication adherence can also produce medical spending offsets, which could lead to government and taxpayer savings in the trust fund as well as beneficiary savings in the form of reduced premiums.

Question. The Great Plains QIN is currently implementing a project to combat opioid use and abuse in rural southeast Kansas. This project has been successful in engaging providers, hospitals, and community organizations to coordinate their efforts in ways that more effectively help patients. How is CMS using data from projects like this to inform best practices and develop policies that help address substance use disorders in rural areas?

Answer. CMS's Quality Innovation Network Quality Improvement Organization (QIN–QIO) program, consisting of 14 quality contractors, works to improve healthcare quality and safety for Medicare beneficiaries. The QIN–QIO program has established a methodology using CMS claims data to identify adverse events, hospital admissions, readmissions, emergency visits, and observation stays for high-risk Medicare beneficiaries who have taken an opioid medication in the outpatient setting. QIN–QIOs collaborate with providers and other community coalitions, using their reports to support local and national efforts to address the opioid epidemic and increase surveillance of adverse events.

Question. I have heard from constituents that cost is a major barrier to accessing alternatives to opioids within Medicare. How can CMS encourage the use of opioid alternatives to treat both acute and chronic pain? What authorities does CMS have to reduce the cost barrier for patients to access alternatives to opioids?

Answer. The opioid crisis cannot be tackled by CMS alone, and that is why we are collaborating with other HHS agencies, such as the FDA, CDC, and NIH, to identify services that need more evidence to support coverage by Medicare and other health plans.

Both medicinal and non-medicinal therapeutic alternatives to opioid-based pain medications exist; although Medicare coverage and payment varies. In general, Medicare covers items and services that are "reasonable and necessary." This includes several non-pharmacologic therapies and other non-opioid pharmaceuticals. CMS uses the national and local coverage determination process to evaluate new or promising items and services with respect to Medicare Parts A and B, through well-delineated processes set forth in statute. Those items and services for which evidence demonstrates improvement in health outcomes in the Medicare population are more likely to be coverable, while those items and services for which such evidence is insufficient or lacking warrant further research.

CMS has partnered with the CDC to develop the Opioid Safety Commitment poster campaign,[10] which promotes the most effective pain management treatments and strategies. This campaign emphasizes patient engagement, clinician counseling regarding opioid alternative pain management strategies, and discussion with patients of the risks and benefits of opioids when opioids are prescribed.

CMS has a number of initiatives underway to increase the use of recommended evidence-based practices for pain management. In addition to the work of the Quality Innovation Network Quality Improvement Organization program, described above, CMS provides outreach regarding best practices and technical assistance through the Transforming Clinical Practice Initiative's (TCPI's) Practice Transformation Networks.[11] TCPI is designed to use peer-based learning networks for information sharing, outreach, and dissemination of evidence-based practices to educate prescribers on safe and appropriate methods of pain treatment. For example, the TCPI Medication Management and Opioid Initiative is mobilizing the existing

[10] *https://www.cdc.gov/drugoverdose/prescribing/posters.html.*
[11] *https://innovation.cms.gov/initiatives/Transforming-Clinical-Practices/.*

network of more than 100,000 clinicians into action to address the opioid crisis, generating collaborations with other CMS quality improvement projects, showcasing successful strategies in engaging providers and patients on proper opioid utilization and spreading the successful strategies throughout all CMS communities.

CMS also promotes free educational materials for health-care professionals on CMS programs, policies, and initiatives through the Medicare Learning Network (MLN).[12] The CDC Guidelines for Prescribing Opioids for Chronic Pain is featured in the January 12, 2017[13] MLN Connects newsletter.

QUESTIONS SUBMITTED BY HON. JOHNNY ISAKSON

Question. It's estimated that a little over 60 million patients are prescribed opioids for post-surgical pain every year. CMS has estimated that roughly one out of five patients with non-cancer related pain is prescribed opioids. While there are times that opioids may be a clinically justified option for the treatment of pain, evidence suggests that alternative methods of treating pain are being overlooked.[14]

There are a number of FDA-approved medical devices that are designed to manage chronic pain in lieu of opioids. My constituent, Halyard Health, located in Alpharetta, GA is one such innovative company, with FDA-approved products covered by Medicare. While it's critical that we're examining ways to identify individuals at risk of abusing opioids and how we might limit unnecessary prescribing, it's equally important that we're exploring non-opioid treatments on the front end that can effectively address people's legitimate pain before the first opioid prescription is written.

In fact, the President's Commission on Combating the Drug Addiction and the Opioid Crisis recommended that CMS review and modify rate-setting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors.[15]

What steps has CMS taken to implement this recommendation?

Does CMS currently have any payment mechanisms in place that incentivize the use of non-opioid treatments that are FDA-approved and covered by Medicare?

Is CMS working to revise existing policies under Medicare Part A and B to establish coverage and additional reimbursement for medical devices and other non-opioid options for pain management?

Answer. The opioid crisis cannot be tackled by CMS alone, and that is why we are collaborating with other HHS agencies, such as the FDA, CDC, and NIH, to identify services that need more evidence to support coverage by Medicare and other health plans.

Both medicinal and non-medicinal therapeutic alternatives to opioid-based pain medications exist; although Medicare coverage and payment varies. In general, Medicare covers items and services that are "reasonable and necessary." This includes several non-pharmacologic therapies and other non-opioid pharmaceuticals. CMS uses the national and local coverage determination process to evaluate new or promising items and services with respect to Medicare Parts A and B, through well-delineated processes set forth in statute. Those items and services for which evidence demonstrates improvement in health outcomes in the Medicare population are more likely to be coverable, while those items and services for which such evidence is insufficient or lacking warrant further research.

The President's Commission on Combating Drug Addiction and the Opioid Crisis recommended that CMS review its payment policies for certain drugs that function as a supply, specifically non-opioid pain management treatments. Drugs that function as a supply in surgical procedures or diagnostic tests are packaged under the

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[12] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNGenInfo/Index.html.*

[13] *https://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Provider-Partnership-Email-Archive-Items/2017-01-12-eNews.html?DLPage=7&DLEntries=10&DLSort=0&DLSortDir=descending#_Toc471878721.*

[14] *https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/CMS-Opioid-Misuse-Strategy-2016.pdf* (page 20).

[15] *https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf* (page 14).

Hospital Outpatient Prospective Payment System and the Ambulatory Surgical Center Payment System. In a proposed rule[16] released on July 25, 2018, (subsequent to the date of the hearing) in response to this recommendation as well as stakeholder requests, for calendar year 2019, CMS proposes to pay separately at Average Sale Price plus 6 percent for non-opioid pain management drugs that function as a supply when used in a covered surgical procedure performed in an Ambulatory Surgical Center. Further, we are seeking feedback on whether other non-opioid alternatives for acute or chronic pain have evidence demonstrating that they lead to a decrease in opioid prescriptions and addiction and may, therefore, warrant separate payment under the Hospital Outpatient Prospective Payment System and the Ambulatory Surgical Center Payment System.

Question. What sort of authorization from Congress does the agency need to continue expanding their role in the opioid space?

Answer. CMS, along with our State and plan partners, have many valuable tools available to assist our efforts to combat the opioid epidemic. This issue is a top priority of this administration, and we look forward to continuing our partnership with Congress to discuss additional changes that could be made to improve our efforts.

The President's FY 2019 budget included several proposals aimed at addressing the opioid epidemic. Within CMS, the budget proposes to:

- Provide the Secretary with authority to establish a mandatory prescriber and/or pharmacy lock-in program in Medicare Part D that all Part D plans will be required to participate in; this is estimated to save $100 million over 10 years.
- Allow CMS to conduct a demonstration to test the effectiveness of covering comprehensive substance abuse treatment in Medicare, including methadone.
- Provide the Secretary authority to suspend coverage and payment for drugs when those prescriptions present an imminent risk to patients or when they are prescribed by providers who have been engaged in misprescribing or overprescribing drugs with abuse potential. This proposal would also provide the Secretary authority to require additional clinical information on certain Part D prescriptions, such as diagnosis and incident codes, as a condition of coverage. The proposal is estimated to save $420 million over 10 years.
- Allow the Secretary to work with the Drug Enforcement Administration (DEA) to revoke a provider's DEA Certificate of Registration after CMS revokes a provider's Medicare enrollment based on a pattern of abusive prescribing of controlled substances via a newly established mandatory reporting requirement.
- Require States to monitor high-risk billing activity to identify and remediate prescribing and utilization patterns that may indicate abuse or excessive utilization of certain prescription drugs in the Medicaid program.
- Require State Medicaid programs to cover all FDA-approved medication-assisted treatments (MAT) for opioid use disorder; this is estimated to save $865 million over 10 years.

Question. Has the agency considered adding a pain management portion to the Welcome to Medicare visit? It seems like a basic enough idea, and a good first step in trying to prevent an opioid issue as soon as the beneficiary joins Medicare. Is this something CMS could do administratively or would they need congressional authorization?

Answer. Pain evaluation could be useful in helping to identify beneficiary needs for care, and CMS supports beneficiaries in getting the pain management they need and providing them access to non-opioid treatments. Providers always have the ability to discuss pain management during the Welcome to Medicare visit or any other visit, as they deem appropriate. We are always looking for ways to improve beneficiary education, and we encourage providers participating in our programs to educate their patients about pain management, particularly regarding the use and potential dangers of opioids.

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[16] *https://www.federalregister.gov/documents/2018/07/31/2018-15958/medicare-program-proposed-changes-to-hospital-outpatient-prospective-payment-and-ambulatory-surgical.*

QUESTIONS SUBMITTED BY HON. DEAN HELLER

Question. In the United States, incident rates of neonatal abstinence syndrome (NAS) have increased significantly over the years. In fact, according to a 2016 Centers for Disease Control and Prevention (CDC) report, overall prevalence of NAS increased by 300 percent in 28 States, including Nevada. More must be done to address this issue, which is why I was pleased that the Comprehensive Addiction and Recovery Act of 2016 (Pub. L. 114–198) required the Government Accountability Office (GAO) to publish a report on NAS. In its report, GAO concluded that "NAS is a rapidly increasing public health problem." However, upon evaluating the Department of Health and Human Services' (HHS) strategy document to address NAS in an effort to combat the opioid crisis, GAO found that HHS had not established a timeline for developing an implementation plan.

Is addressing NAS a priority for HHS?

Answer. Yes, addressing NAS is a priority for HHS. As just one example, in response to the Protecting Our Infants Act (POIA) and the subsequent GAO study, HHS developed a POIA Strategy to inform planning and policy across the Department. The 39 recommendations range from aspirational to practical and include preventing prenatal opioid exposure, providing evidence-based treatment for both mother and infant, increasing the accessibility of family-friendly services for pregnant and parenting women with OUD, supporting continuing education for health-care providers, and determining optimal family and developmental support services for children who have experienced prenatal opioid exposure.

Question. What steps has HHS taken so far to address NAS?

Answer. Congress passed the Protecting Our Infants Act of 2015, the purpose of which is to address opioid use by pregnant women and resultant consequences to newborn infants. The Act tasked the Department of Health and Human Services with producing a three-part report to include: (1) a review of gaps, overlap, or duplication regarding prenatal opioid use and neonatal abstinence syndrome (NAS); (2) state of the science and clinical practice; (3) and a strategy and set of recommendations. In January 2017, HHS provided the report to Congress. The updated Protecting Our Infants Act; Final Strategy—2017 was published in the Federal Register on May 25, 2017. The strategy was revised to reflect public comment on the Report to Congress. Subsequently, HHS convened a department-wide workgroup that is developing an implementation plan based on the strategy that will support decision-making by departmental leadership with regard to specific agency priorities.

In recognition of the need for an organizing framework to guide and track implementation of recommendations in the POIA Strategy, the HHS Behavioral Health Coordinating Council (BHCC) Opioid and Controlled Substances Subcommittee, NAS Workgroup developed an implementation work plan. This plan documents the NAS activities that are completed, in process, and planned by HHS agencies, targeting activities for research and evaluation, programs and services, data and surveillance, and education. The work plan shows that HHS is addressing all POIA recommendations, with the majority of recommendations being addressed through dedicated cross-agency collaboration.

In addition, SAMHSA developed "Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants." This Guidance, described in the POIA Strategy, outlines the optimal management of pregnant and postpartum women with an opioid use disorder (OUD) and their infants based on the recommendations of experts. In the past 12 months, the document had been downloaded 7,565 times. The guidance reflects recommendations of an expert steering committee and 13 other Federal agencies and offices, and assists health-care professionals to determine the most clinically appropriate care for a patient. The guide is a patient-focused clinical guide that considers the maternal—fetal and maternal—infant dyad as a unit with the expectation that the health-care professionals, in consultation with the patient, will make individualized treatment decisions for both a mother and her infant. The Guidance may be found here: *https://store.samhsa.gov/product/Clinical-Guidance-for-Treating-Pregnant-and-Parenting-Women-With-Opioid-Use-Disorder-and-Their-Infants/SMA18-5054).*

SAMHSA's Pregnant and Postpartum Women's program (PPW) expands the availability of comprehensive substance use disorder treatment, prevention, and recovery support services for PPW, their minor children, and other family members. In FY 2018, SAMHSA funded 19 new 5-year residential PPW grants, totaling $9 million annually and 19 continuing PPW 5-year residential grants, totaling $10.7 million annually. The PPW Pilot Program was created under the Comprehensive Addiction

and Recovery Act (CARA) of 2016 with the first three grants funded in FY 2017, totaling $3.2 million annually. SAMHSA funded three new 3-year PPW Pilot grants in FY 2018, totaling $3.2 million annually. PPW Pilot grants are awarded to State substance abuse agencies to increase outpatient treatment and recovery support services for substance use disorder, including opioid use disorder, across the continuum of care and promote new approaches and models of service delivery. In FY 2017, SAMHSA began a 3-year PPW cross-site evaluation to examine the effectiveness of the PPW Pilot Program. The evaluation results will be used broadly to improve the collective understanding about effective components of the continuum of care for pregnant and postpartum women with a primary diagnosis of a substance use disorder, including whether the PPW Pilot Program is an effective approach to increase access to the use of medication-assisted treatment.

SAMHSA and the Administration for Children and Families (ACF) jointly fund the National Center on Substance Abuse and Child Welfare (NCSACW), a national resource center providing information, expert consultation, training and technical assistance to child welfare, dependency court and substance abuse treatment professionals to improve the safety, permanency, well-being, and recovery outcomes for children, parents, and families. The NCSACW also makes available webinars, assessment instruments, training and program toolkits, resource lists, and other publications.

With SAMHSA and ACF support during 2017, NCSACW conducted 12 presentations and 11 web-based trainings/virtual meetings on opioids. During its September 2017 webinar, "Supporting Families Affected by Opioid and Other Substance Use Disorders, Child Abuse and Prevention Act, Plan of Safe Care," over 1,200 individuals attended. In addition, during the same period NCSACW received and responded to over 300 opioid-related technical assistance requests; produced and disseminated the Policy Academy brief, Improving Outcomes for Pregnant and Postpartum Women with Opioid Use Disorders and Their Infants, Families, and Caregivers; and developed a web-based directory of resources on best practices for the treatment of opioid use disorders and neonatal abstinence syndrome.

Question. What is HHS's time frame to complete implementation of its strategy related to addressing NAS?

Answer. The work plan is iterative and demonstrates that there are over 400 HHS NAS activities that are completed, in process, or in the planning stages. As the opioid epidemic continues to impact women and their children, and our communities, the BHCC Opioid and Controlled Substances Subcommittee will continue to monitor ongoing implementation and coordination of NAS activities to assess progress, evaluate effectiveness, and publicize NAS specific programs and tools, contingent on funding.

QUESTION SUBMITTED BY HON. BENJAMIN L. CARDIN, HON. BILL CASSIDY, AND HON. BILL NELSON

Question. We believe we need to take a comprehensive approach to prevent and treat the opioid epidemic before more lives are lost. Medicare Part D covers some, but not all FDA-approved forms of medication-assisted treatment (MAT). MAT has been shown to be most effective in treating opioid use disorders when coupled with counseling and other services. That's why we will be introducing a bill to allow Medicare to pay for MATs as a bundled payment to providers at opioid treatment centers. In the fiscal year 2019 budget, the Department of Health and Human Services (HHS) expressed support for a similar proposal.

What is the administration doing to test the effectiveness of covering comprehensive substance abuse treatment in Medicare?

Does the administration commit to working with our offices on this proposal?

Answer. Medication-Assisted Therapy (MAT) is a valuable intervention that has been proven to be the most effective treatment for OUD, particularly because it sustains long-term recovery and has been shown to reduce opioid-related morbidity and mortality.[17] To increase access to MAT, CMS requires that Medicare Part D formularies include covered Medicare Part D drugs used for MAT and mandates Medicare Part C coverage of the behavioral health element of MAT services. In addition, CMS issued guidance on best practices in Medicaid for covering MAT in a joint in-

[17] *https://www.ncbi.nlm.nih.gov/pubmed/24500948.*

formational bulletin with the Substance Abuse and Mental Health Services Administration (SAMHSA), the CDC, and the National Institute on Drug Abuse.[18] CMS also released an informational bulletin with SAMHSA on coverage of treatment services for youth with SUD.[19]

While Medicaid programs vary greatly by State, all 50 States currently offer some form of MAT. In addition, the President's FY 2019 budget includes a proposal that would require State Medicaid programs to cover all FDA-approved MAT for OUD, including associated counseling and other costs. These up-front investments in expanded MAT treatment are expected to reduce total Medicaid expenditures over time as more individuals recover from OUD; this provision would result in an estimated $865 million is savings over 10 years.

Under an additional proposal in the President's FY 2019 budget, CMS would conduct a demonstration to test the effectiveness of covering comprehensive substance abuse treatment in Medicare. This demonstration could be expanded nation-wide if successful in key metrics, such as reducing opioid-related deaths among beneficiaries, reducing hospitalization for opioid poisoning, and reducing emergency room utilization for opioid-related issues. Through this proposal, Medicare would provide bundled reimbursement on a per-week-per-patient basis to health-care providers for methadone treatment or similar MAT and would recognize opioid treatment programs and substance abuse treatment facilities as independent health-care provider types; outpatient counseling would be billed separately as clinically necessary. The model would be allowed to target beneficiaries determined to be at-risk, as defined by the Overutilization Monitoring System, to voluntarily receive comprehensive treatment, including MAT and SUD counseling.

CMS looks forward to working with Congress to implement these budget proposals. CMS is happy to work with the committee and provide technical assistance on the legislation you are considering.

QUESTIONS SUBMITTED BY HON. RON WYDEN

HOLDING MANUFACTURERS, DISTRIBUTORS, AND OTHER STAKEHOLDERS ACCOUNTABLE

Question. Between 1999 and 2014, sales of prescription opioids nearly quadrupled while the number of fatal opioid-related overdoses tripled nationwide. As the country comes to grips with this epidemic, it remains unclear whether entities that had a financial stake in opioid misuse—the manufacturers and distributors of opioids—will be held accountable for their culpability in a crisis that led to the loss of hundreds of thousands of American lives.

During your testimony before the committee, I expressed concerns regarding the administration's efforts to investigate these stakeholders for their actions. As I stated, "To me, opioid manufacturers, through twisted research, deceptive marketing, and bought and paid for patient advocacy groups had a significant role in fueling the crisis." When I asked whether you shared my concerns, you stated that rising numbers of opioid prescriptions occurred in part due to a misunderstanding in the medical community about the addictive nature of these drugs. These drugs, you stated, "were overprescribed by well-intentioned physicians who believed they were doing the best for the patients."

This misunderstanding was no doubt true for many health-care providers. However, attention must be paid to how manufacturers, distributors, physicians, and advocacy organizations deliberately conspired to mislead the American public, influence medical education, shape standards of practice, and suppress information on the risks associated with these drugs.

Does the administration believe opioid manufacturers and distributors bear some responsibility in the spread of the opioid epidemic?

If yes, how does the administration plan to hold these entities accountable?

If not, why not?

If other stakeholders are found to have willfully deceived or misled the American public on the addictiveness of opioids, how does HHS plan to hold these entities accountable?

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[18] *https://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-07-11-2014.pdf.*
[19] *https://www.medicaid.gov/federal-policy-guidance/downloads/cib-01-26-2015.pdf.*

Answer. The Department of Health and Human Services (HHS) has spent considerable time seeking to understand how this crisis developed, an issue I believe to be of paramount importance. Without understanding the root causes and learning the lessons of history, there will be no way to prevent similar problems in the future. However, as with most complex genetic-socio-behavioral-cultural problems, the etiology of the opioid crisis is complex and multi-factorial, and correlated with many individual events, some of which were causal and some of which were not. Specifically, your question whether manufacturers or distributors may have had a negligent role in driving the crisis is one that the Department of Justice (DOJ) is examining as that question arises in the context of ongoing litigation among parties other than the Federal Government.

Alongside DOJ, HHS is now implementing solutions to the crisis—solutions that will be effective despite the etiologic complexities. We are engaging all potential stakeholders and interest groups—from drug manufacturers, to health professionals, community and faith-based organizations, and family members—to assist in reversing the epidemic.

ONGOING CONFLICTS OF INTEREST AMONG STAKEHOLDERS

Question. Ongoing financial arrangements suggest that opioid manufacturers may still be bankrolling advocacy groups and others to undermine the Federal response to the opioid epidemic.

In 2016, I sent a letter to HHS after learning that certain members of the Interagency Pain Research Coordinating Committee (IPRCC) had attempted to undermine CDC efforts to develop guidance on opioid prescribing practices.[20] As described in that letter, some members of the IPRCC had financial relationships with major opioid manufacturers, including Purdue Pharma, the maker of OxyContin. In 2017, I wrote again to HHS regarding a workshop hosted by the Food and Drug Administration on safe opioid prescribing when it was revealed that some participants shared financial ties with Purdue Pharma and other prominent manufacturers.[21] Most recently, in February 2018, an investigation led by Senator McCaskill through the U.S. Senate Homeland Security and Governmental Affairs Committee reported that manufacturers of the top five prescription opioids in worldwide sales gave more than $10 million to 14 advocacy groups and affiliated doctors between 2012 and 2017.[22] Purdue accounted for nearly half of the $9 million in funding granted to advocacy groups alone.

Greater transparency is needed to understand how manufacturers and distributors may be continuing to influence advocates, physicians, and other stakeholders in ways that undercut Federal efforts to curb prescription opioid misuse.

Please explain whether the administration is examining ongoing financial arrangements among opioid manufacturers, distributors, pain advocates, and/or physicians.

What steps is HHS taking to ensure that these financial relationships are subject to greater transparency and scrutiny going forward?

Answer. We share your interest in building greater transparency to ensure that there are no financial conflicts of interest among the opioid manufacturers and distributors and those in the medical and patient advocacy community who are working closely with the Federal Government to address the public health crisis resulting from the opioid epidemic.

In terms of the membership on the IPRCC, as relayed in our response to your inquiry in 2016, the policies and appointments to and terms for service for non-Federal members of the IPRCC are mandated by the Affordable Care Act (Pub. L. 111–148) and agency policy for Federal advisory committees. The members are not

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[20] Letter from Ranking Member Ron Wyden to HHS Secretary Sylvia Matthews Burwell (February 5, 2016), *https://www.finance.senate.gov/imo/media/doc/Wyden%20Letter%20to%20HHS_Opioid%20Conflicts.pdf.*

[21] Letter from Ranking Member Ron Wyden to HHS Secretary Sylvia Matthews Burwell (May 5, 2017), *https://www.finance.senate.gov/imo/media/doc/050817%20corrected%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group%20(5%20May%202017).pdf.*

[22] "Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups," U.S. Senate Homeland Security and Governmental Affairs Committee, Office of the Ranking Member (February 2018), *https://www.hsgac.senate.gov/media/minority-media/breaking-millions-in-payments-among-findings-of-mccaskill-opioid-investigation-into-ties-between-manufacturers-and-third-party-advocacy-groups-.*

representatives of their organizations, employers, or institutions and provide advice based on their own points of view. HHS will continue to ensure that all members of advisory groups follow agency policies and disclosure requirements.

With respect to the administration's activities related to examining ongoing financial arrangements among the opioid manufacturers, distributors, pain advocates, and/or physicians, I can share the work of the HHS Office of the Inspector General (OIG). Since March of 2017, OIG has excluded six individuals and entities and participated in eight civil settlements under the False Claims Act related to opioids. These cases have involved allegations of fraud in sober homes and excessive prescribing of opioids, and have resulted in $52,748,965 recovered and 133 years of exclusion.

The OIG excluded Dr. Xiulu Ruan and Dr. John Couch for 50 years as a result of their convictions for running a massive pill mill in Mobile, AL. Of particular importance in the trial were two brand name instant-release fentanyl drugs—Subsys and Abstral. Both Subsys and Abstral are only FDA-indicated for breakthrough cancer pain in opioid-tolerant adult patients. However, evidence showed that Dr. Ruan and Dr. Couch almost exclusively prescribed these drugs off-label for neck, back, and joint pain. Dr. Ruan and Dr. Couch received illegal kickbacks from Insys Therapeutics, the manufacturer of Subsys, in exchange for the defendants prescribing massive quantities of this drug.

We do not have any Corporate Integrity Agreements (CIAs) with opioid manufacturers (or more specifically, any such CIAs that are directed at or resulting from opioid-related conduct specifically) to report.

The following links below provide some additional info on oversight and investigation cases related to financial relationships between opioid manufacturers and physicians:

- *https://www.reuters.com/article/us-insys-opioids/doctor-tied-to-insys-opioid-kickback-probe-gets-prison-term-idUSKCN1GA2WE.*
- *https://www.reuters.com/article/us-insys-opioids/ex-insys-employee-in-u-s-opioid-case-sentenced-to-home-confinement-idUSKBN1HU2U1.*
- *https://www.justice.gov/usao-ri/pr/doctor-sentenced-healthcare-fraud-accepting-kickbacks-prescribe-highly-addictive-version.*

Regarding HHS efforts to create transparency, we refer you to the Open Payments data at the CMS website *(https://www.cms.gov/openpayments/).* The law requires CMS to collect and display information reported by applicable manufacturers and group purchasing organizations (GPOs) about the payments and other transfers of value these organizations have made to physicians and teaching hospitals. Researchers and others have used the data to study a variety of related issues, including opioids. The Open Payments data does not gather information on payments to patient advocacy groups or other supply chain participants, such as distributors.

Question. What steps is HHS taking to protect consumers from misleading research or marketing practices that may suppress or distort accurate information about prescription opioids?

Answer. The Office of Prescription Drug Promotion (OPDP) within FDA's Center for Drug Evaluation and Research (CDER) is responsible for ensuring prescription drug information is truthful, balanced, and accurately communicated. FDA issued warning letters in January to 11 online entities for selling illegal opioid cessation products using deceptive claims. In June, FDA issued warning letters to 53 websites for marketing unapproved opioid medications. In April, the FDA Commissioner asked certain social media companies (*e.g.,* Facebook, Twitter) to help stop illegal opioid sales on their platforms.

In addition, FDA's Bad Ad program is an outreach program designed to educate health-care providers about the role they can play in helping the agency make sure that prescription drug advertising and promotion is truthful and not misleading.

The Bad Ad Program is administered by the agency's Office of Prescription Drug Promotion (OPDP) in the CDR. The program's goal is to help raise awareness among health-care providers about misleading prescription drug promotion and provide them with an easy way to report this activity to the agency by emailing BadAd@fda.gov or calling 855–RX–BADAD.

The President's Initiative to stop Opioid Abuse and Reduce Drug Supply and Demand includes aggressively deploying appropriate criminal and civil actions to hold

opioid manufacturers accountable for any unlawful practices. As part of this effort HHS is participating in investigations of unlawful marketing (such as *https://www.justice.gov/opa/pr/united-states-intervenes-false-claims-act-lawsuits-accusing-insys-therapeutics-paying* and *https://www.justice.gov/opa/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering*).

ROLLBACK OF ACCESS RULE

Question. The Medicaid statute requires State Medicaid provider payments to be "sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area."[23] In January 2016, the previous administration released final regulations to help implement this longstanding statutory protection.[24]

However, in March 2018, the Trump administration announced two proposed amendments to the equal access rule that would exempt additional States from oversight and undermine the ability of CMS and others to understand how provider payment cuts will impact access to care.[25] First, the Trump administration proposed exempting States from AMRP requirements if States had 85 percent or more of their Medicaid enrollees in managed care organizations (MCOs). As a result, these States would not be required to assess impacts for access to care even if these States propose cuts in fee-for-service payment rates. Second, the administration proposed *exempting* States from key requirements if cuts to fee-for-service providers did not exceed 4 percent in a single fiscal year or 6 percent over 2 consecutive years. These States would no longer be required to obtain beneficiary and provider input on the impact of proposed cuts, use AMRPs to assess a proposed cut's effects, or monitor access to care for 3 years after a rate cut's implementation.

As the country grapples with the opioid epidemic, protecting access to Medicaid is essential to ensuring that beneficiaries are able to receive the mental health and substance use disorder (SUD) services they need to overcome addiction.

Why is the administration proposing to eliminate information on access to SUD and mental health services in States with high managed care enrollment?

The administration's proposal would allow more States to cut payments to mental health and SUD providers without holding States accountable for compromising access to care. Why would CMS permit these cuts without protecting access to essential services for individuals struggling with opioid use disorder?

Answer. States have raised concerns over undue administrative burden associated with meeting the requirements of the final rule, Medicaid Program; Methods for Assuring Access to Covered Medicaid Services (published in November 2015). Specifically, States with few Medicaid members enrolled in their fee-for-service program or when members are only temporarily enrolled, and States making small reductions to fee-for-service payment rates, have urged CMS to consider whether analyzing data and monitoring access in that program is a beneficial use of State resources. To respond to these concerns, a notice of proposed rulemaking (NPRM) issued by CMS last March that includes a proposal exempting States with an overall Medicaid managed care penetration rate of 85 percent or greater (currently, 17 States) from most access monitoring requirements.

These proposed regulatory changes do not change the underlying statutory responsibilities for States to ensure that Medicaid recipients have appropriate access to services. States proposing payment reductions that meet the exceptions described in the NPRM would need to provide alternative information to support compliance with the Social Security Act. In addition, States would still be required to inform providers of changes to Medicaid payment rates through the public notice process.

The NPRM is designed to support CMS efforts to move away from micromanaging State programs and instead focus on measuring program outcomes and holding States accountable for achieving results. Addressing the opioid epidemic, including

[23] 42 U.S.C. § 1396a(a)(30)(A).

[24] "Medicaid Program; Methods for Assuring Access to Covered Medicaid Services," 80 Federal Register 67575 (January 4, 2016), *https://www.federalregister.gov/documents/2015/11/02/2015-27697/medicaid-program-methods-for-assuring-access-to-covered-medicaid-services.*

[25] "Medicaid Program; Methods for Assuring Access to Covered Medicaid Services-Exemptions for States With High Managed Care Penetration Rates and Rate Reduction Threshold," 83 Federal Register 12696 (March 23, 2018), *https://www.federalregister.gov/documents/2018/03/23/2018-05898/medicaid-program-methods-for-assuring-access-to-covered-medicaid-services-exemptions-for-states-with.*

making sure Medicaid enrollees have adequate access to treatment for opioid use disorder, is a top priority to this administration and we will continue to work with our Federal and State partners, beneficiary and patient advocate groups, plans, providers, and other interested stakeholders to combat this crisis.

MEDICAID CUTS AND STATE EFFORTS TO COMBAT THE EPIDEMIC

Question. As the largest single payer of substance use disorder (SUD) services in the Nation, Medicaid plays an essential role in the national fight against the opioid epidemic. Medicaid pays for roughly one quarter of all prescriptions for buprenorphine in the U.S. and covers 4 of every 10 people battling opioid dependence. In States bearing the brunt of the crisis—including Kentucky, Ohio, and West Virginia—Medicaid pays for roughly half of all Medication Assisted Treatment (MAT), thanks in large part to the Medicaid expansion. In fact, nearly one of three people who gained coverage under the expansion had a SUD, mental health condition, or both.

States have also leveraged Medicaid expansion dollars to provide innovative and comprehensive SUD programs to individuals struggling with addiction. For example, when Ohio adopted the Medicaid expansion in 2014, the State extended coverage to an estimated 500,000 individuals with mental health or SUD needs and added more than $1 billion to the State's behavioral health system capacity, allowing the State to undertake an initiative to modernize mental health benefits, expand services for those with high-intensity needs, and integrate behavioral and physical health services.[26] In Kentucky, Medicaid expansion significantly helped reduce the unmet need for SUD services, as reported by a study in 2016.[27] From 2014 to mid-2016, Kentucky saw a 740 percent increase in the use of treatment services for SUD among expansion beneficiaries. Many other States have also been able to employ the Medicaid expansion to help tackle the opioid epidemic.

Despite the expansion's clear role in supporting State efforts in this space, the President's budget for fiscal year 2019 proposed eliminating the Medicaid expansion and capping the traditional Medicaid program, the sum of which would gut an estimated $1.4 trillion from Medicaid over the next 10 years. These severe cuts would likely cripple State efforts to expand access to comprehensive mental health services, particularly in expansion States that have used increased Federal funding to transform their behavioral health systems.

How does CMS expect to help States combat the opioid epidemic if States are forced to restrict eligibility, reduce payments for mental health providers, and roll back mental health and SUD benefits in the face of trillion-dollar cuts to Medicaid? Please explain whether and how CMS would provide different resources or supports to expansion versus non-expansion States.

Answer. Our Medicaid program is an important tool in providing health care to many Americans but we must put it on a stable long-term sustainable footing for it to be there for this and future generations. That is the challenge that we have as we seek to empower the States with the right incentives to deliver quality service. The FY 2019 budget provides additional flexibilities to States, puts Medicaid on a path to fiscal stability by restructuring Medicaid financing, and refocuses on the populations Medicaid was intended to serve—the elderly, people with disabilities, children, and pregnant women. Annual Federal Medicaid spending will grow from $421 billion in FY19 to $702 billion in FY28 over the budget window. The Medicaid expansion does get rescinded, but is replaced along with the individual subsidy program with a $1.2 trillion grant program through the Graham-Cassidy legislation.

Opioid misuse, abuse, and overdose impose immense costs on the Nation, contributing to two-thirds of deaths by drug overdose. Deaths by drug overdose are the leading cause of injury death in the United States. The FY 2019 President's budget recognizes the devastation caused by the opioid crisis in communities across America and fulfills the President's promise to mobilize resources across the Federal Government to address the epidemic. The budget provides a historic level of new re-

[26] Ohio Governor's Office of Health Transformation, "Rebuild Community Behavioral Health System Capacity" (January 30, 2017), *http://healthtransformation.ohio.gov/Portals/0/18-19%2005%20Rebuild%20Community%20Behavioral%20Health%20System%20Capacity%20v2.pdf?ver=2017-02-16-171817-497.*

[27] Foundation for a Healthy Kentucky, "Substance Use Treatment Services Covered by Medicaid Expansion Jumped 740 Percent Over 2.5 Years" (December 28, 2016), *https://www.healthy-ky.org/newsroom/news-releases/article/60/substance-use-treatment-services-covered-by-medicaid-expansion-jumped-740-percent-over-2.5-years.*

sources across HHS to combat the opioid epidemic and serious mental illness—$10 billion—to build upon the work started under the 21st Century Cures Act.

The budget's targeted investments advance the Department's five-part strategy, which involves:

- Improving access to prevention, treatment, and recovery services, including medication assisted therapies;
- Targeting availability and distribution of overdose-reversing drugs;
- Strengthening our understanding of the epidemic through better public health data and reporting;
- Supporting cutting edge research on pain and addiction; and
- Advancing better practices for pain management.

Question. During your testimony before the committee, in response to a question regarding these cuts to Medicaid, you stated that the Department of Health and Human Services has approved grants for States to combat this epidemic. Does CMS expect these grants to fully compensate for the $1.4 trillion in Federal dollars that would be gutted from Medicaid programs under the administration's proposed budget?

Answer. CMS is committed to working with all States to provide flexibility, so that they can provide the right treatment to the right people in the right setting. The recently approved demonstration projects that focus on substance use disorder are examples of such flexibility so States can tailor their response to the opioid crisis to the needs of their State.

SECTION 1115 WAIVERS AND CARE IN IMD SETTINGS

Question. In July 2015, CMS released guidance outlining opportunities for States to use section 1115 waivers to cover additional substance use disorder (SUD) services through Medicaid. In addition to describing other flexibilities, this guidance outlined how States could use section 1115 waivers to cover SUD care in residential settings called Institutions for Mental Diseases (IMDs), which are hospitals, nursing facilities, or other institutions with more than 16 beds that are primarily focused on the provision of mental health care. Under current law, without a section 1115 waiver, Medicaid does not pay for services provided to beneficiaries between the ages of 21 and 65 in IMD settings. In November 2017, the administration released its own letter to State Medicaid Directors revising and reinforcing the previous administration's guidance. According to the Kaiser Family Foundation, as of April 2018, 10 States have waivers approved to provide care for individuals suffering from SUD in residential settings like IMDs. An additional 12 States have waivers pending.

Please highlight how States are using these waivers and other flexibilities in Medicaid to provide expanded SUD and mental health services to individuals with opioid use disorder in IMDs.

Answer. Addressing the opioid epidemic is a top priority of this administration, and CMS is committed to providing States with the tools and flexibility they need to best address the issues in their States. The substance use demonstration projects are a critical part of these efforts. Under the leadership provided by this administration, CMS has approved SUD demonstration projects for five States as of April 2018 that take advantage of the IMD flexibility announced in November of 2017—Louisiana, New Jersey, Utah, Indiana, and Kentucky.

Under these SUD 1115 demonstration projects, States develop a 5-year demonstration allowing them to receive Federal financial participation for services to treat addiction to opioids or other substances for Medicaid beneficiaries residing in IMDs, including those aged 21 to 64 for whom Medicaid otherwise would not pay for services while the beneficiary is residing in an IMD, as these States work to improve access to treatment in outpatient settings as well. In addition, we are working with States that operate these demonstrations to establish strong quality of care standards, particularly for residential treatment settings.

This initiative offers a more flexible, streamlined approach to accelerate States' ability to respond to the national opioid crisis while enhancing States' monitoring and reporting of the impact of any changes implemented through these demonstrations. In addition to being budget neutral, demonstrations must include a rigorous evaluation based on goals and milestones approved by CMS. States must also make

available on *Medicaid.gov* information on the progress and outcomes of these demonstrations and evaluations so that other States can learn from these projects; this cycle of evaluation and reporting will be critical to informing our evolving response to the national opioid crisis.

Addendum: Since the time of this hearing, CMS has approved a demonstration project for a sixth State, Illinois.

Question. This epidemic grows more urgent and deadly every day that passes. How is CMS ensuring that these waivers are reviewed and approved as soon as possible so that States can use the full extent of Medicaid's flexibility and Federal resources to address this crisis?

Answer. CMS is working hard to facilitate the development of substance use demonstrations and encourage States to apply for a demonstration project, as discussed in the November 2017 State Medicaid Director Letter. To further support this initiative, throughout 2018, the Medicaid Innovation Accelerator Program (IAP) will be available to States that would benefit from strategic design support related to improving their treatment delivery systems. The IAP provides States with access to national learning opportunities and technical expert resources, including strategic design support to States planning targeted addiction treatment delivery system reforms and developing 1115 proposals. In addition, CMS is available to provide technical assistance to States on how to meet Federal transparency requirements as well as to preview States' draft 1115 proposals and public notice documentation to help ensure States successfully meet Federal requirements. CMS is committed to helping States implement these important flexibilities, and we are in regular communication to help interested States through the demonstration application process. We look forward to reviewing the results of the State demonstration projects that we have already approved and applying lessons learned to further reduce barriers and assist States with their efforts to combat the opioid crisis.

PART D AND OPIOID OVERPRESCRIBING

Question. To monitor opioid overutilization among Medicare Part D beneficiaries, CMS requires plan sponsors to implement drug utilization review systems for beneficiaries determined to be most at risk of opioid misuse, as defined by CMS criteria. However, in October 2017, the Governmental Accountability Office (GAO) released a report stating that Medicare needed to expand its oversight efforts to effectively reduce OUDs, overdoses, inappropriate prescribing, and drug diversion.[28] For example, GAO found that CMS's criteria for at-risk beneficiaries misses individuals vulnerable to opioid misuse. Further, GAO reported that CMS lacks the information necessary to adequately determine which providers overprescribe opioids because CMS tracks providers who generally prescribe drugs at high risk for abuse (rather than opioids specifically). Moreover, CMS does not require plan sponsors to report actions taken against providers, making it difficult for CMS to understand which plan sponsors are actively taking steps to reduce overprescribing.

Does CMS plan to address the gaps identified by GAO and pursue the three recommendations outlined by the report? If so, please explain the steps CMS is taking to improve Part D monitoring of opioid overprescribing and misuse.

Answer. CMS greatly appreciates the work of the GAO, particularly with how we can strengthen our systems and programs to assist in the fight against the opioid epidemic.

CMS uses the Overutilization Monitoring System (OMS) to help CMS ensure that sponsors have established reasonable and appropriate drug utilization management programs to assist in preventing overutilization of certain prescribed medications, including opioid pain medications. CMS has continued to refine and improve the criteria used in OMS. OMS identifies and reports on beneficiaries with a high risk of misusing opioids and plan sponsors can then use these reports generated by OMS to conduct case management and beneficiary-specific edits. Starting this year, beneficiaries are now identified as at-risk and reported to plans if, in the most recent 6 months, their daily dose of opioids exceeds 90 morphine milligram equivalent (MME); and if they have received opioids from more than three prescribers and

[28] GAO, "Prescription Opioids: Medicare Needs to Expand Oversight Efforts to Reduce the Risk of Harm" (October 2017), *https://www.gao.gov/assets/690/687629.pdf.*

more than three pharmacies, or from more than five prescribers, regardless of the number of opioid dispensing pharmacies.[29]

In the 2019 Final Call Letter,[30] CMS finalized additional enhancements to the OMS including revised metrics to track high opioid overuse and to provide additional information to sponsors about high risk beneficiaries who take opioids and "potentiator" drugs, such as benzodiazepines (which when taken with an opioid increase the risk of an adverse event). To help identify and prevent opioid users from taking duplicate or key "potentiator" drugs, in 2019 we also expect sponsors to implement additional safety edits to alert the pharmacist about duplicative opioid therapy and concurrent use of opioids and benzodiazepines.

CMS utilizes the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC) to conduct data analysis that is shared with plan sponsors to help them identify outlier prescribers or pharmacies. For example, plans receive Quarterly Outlier Prescriber Schedule II Controlled Substances Reports, which provide a peer comparison of prescribers of Schedule II controlled substances. This report now provides a separate analysis of just opioids. Plans also receive quarterly pharmacy risk assessment reports, which contain a list of pharmacies identified by CMS as high risk and provide plan sponsors with information to initiate new investigations, conduct audits, and potentially terminate pharmacies from their network, if appropriate. CMS has also sent letters to prescribers that include educational information and comparative billing data to, and held webinars[31] for, prescribers whose opioid prescribing patterns were different as compared with their peers on both a specialty and/or national level.

Additionally, plan sponsors report potential fraud to the NBI MEDIC. The NBI MEDIC uses the PLATO system, which is a voluntary, web-based system that allows CMS, the NBI MEDIC, and plan sponsors to more easily share information and help combat potential fraud, waste, and abuse in the Medicare Advantage and Medicare Part D programs. CMS's Federal law enforcement partners can also access PLATO data.

CMS looks forward to continuing to work with the GAO to strengthen and improve our programs.

QUALITY IN MEDICARE PART D

Question. In 2016, one in three beneficiaries enrolled in Medicare Part D received at least one opioid prescription.[32] To discourage the overprescribing and abuse of prescription opioids through this program, CMS could explore basing payments to Part D plans on a plan's performance in appropriately preventing opioid misuse. In other words, CMS could adjust Part D payments according to the quality of care delivered to beneficiaries. To achieve this, CMS could employ already established and endorsed opioid-related quality measures, including: (1) the prevalence of high opioid utilization in combination with multiple prescribers or pharmacies and (2) the prevalence of beneficiaries taking an opioid and benzodiazepine prescription at the same time.

Has CMS taken steps to incentivize Part D plans to target opioid misuse through quality-adjusted payments?

If so, please discuss the steps CMS has taken, and how CMS plans to continue implementing such a policy.

If not, please explain the barriers to rewarding Part D plans for preventing opioid misuse.

Answer. CMS is taking a number of steps to reduce overprescribing in order to help prevent the development of new opioid use disorders that originate from opioid prescriptions while balancing the need for continued access to prescription opioids for certain medical conditions and pain management. Due to the structure of the Medicare Part D program, Medicare Advantage Organizations (MAOs) and Medicare Part D sponsors have a primary role in detecting and preventing potential misuse

[29] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf.*

[30] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf.*

[31] *https://www.cbrinfo.net/cbr201801-webinar.*

[32] "Data Brief: Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing," Office of Inspector General, Department of Health and Human Services, July 2017, *https://oig.hhs.gov/oei/reports/oei-02-17-00250.pdf.*

of opioids. CMS is always interested in pursuing new ways to incentivize our plan partners to provide high-quality care.

On April 2, 2018, the Centers for Medicare and Medicaid Services (CMS) issued a final rule[33] that updates Medicare Advantage (MA) and the prescription drug benefit program (Part D) by promoting innovation and empowering MA and Part D sponsors with new tools to improve quality of care and provide more plan choices for MA and Part D enrollees. For example, in the final rule, we incentivize Part D plans to expand Medication Therapy Management (MTM) services to additional beneficiaries. Under current law, Part D plans are required to calculate a medical loss ratio (MLR), expressed as a percentage that generally represents the percentage of revenue used for patient care rather than for such other items as administrative expenses or profit. If a plan fails to meet minimum MLR requirements, they are subject to financial and other penalties. Our rule will allow Part D plans to include MTM services as patient care as opposed to administrative expenses. We hope that, by removing any restrictions or uncertainty about whether compliant MTM programs will qualify for inclusion in the MLR numerator as QIA, the finalized changes will encourage Part D sponsors to strengthen their MTM programs by implementing innovative strategies for this potentially vulnerable population. We believe that beneficiaries with higher rates of medication adherence have better health outcomes, and that medication adherence can also produce medical spending offsets, which could lead to government and taxpayer savings in the trust fund as well as beneficiary savings in the form of reduced premiums.

CMS encourages Part D plans to offer MTM services to beneficiaries who meet the plan's criteria for retrospective identification of opioid overutilization, but do not otherwise qualify for MTM. These beneficiaries may benefit from MTM services including targeted medication reviews and interventions with their prescribers.

CMS will continue to work with our plan partners, along with beneficiary and advocacy groups, States, clinicians, and other stakeholders to address this devastating epidemic.

SENIORS AND OPIOID USE DISORDER

Question. In 2016, 14.4 million of the 43.6 million beneficiaries enrolled in Medicare Part D received at least one opioid prescription.[34] Despite the widespread use of these medications in the Medicare program, opioid use disorder (OUD) in seniors often goes overlooked. As a result, many seniors experience falls, confusion or other secondary complications due to opioid misuse that can lead to injury or hospitalization. The data bear this out: between 1993 and 2012, hospitalizations among seniors related to opioid overuse quintupled.[35]

What educational initiatives are being supported by CMS to help front line health care providers effectively use risk assessment tools specific to seniors?

Answer. CMS's primary role with respect to Medicare is to serve as a payer, and we do not establish prescription guidelines or recommend specific treatments. However, we have published several educational materials for providers and prescribers that we also make available online to raise awareness on the non-medical use or abuse of opioids by patients. Information in these materials includes signs of opioid diversion and symptoms of abuse and clinical practices to minimize the non-medical use of medication.

In addition, CMS provides outreach regarding best practices and technical assistance through the Transforming Clinical Practice Initiative's (TCPI's) Practice Transformation Networks.[36] TCPI is designed to use peer-based learning networks for information sharing, outreach, and dissemination of evidence-based practices to educate prescribers on safe and appropriate methods of pain treatment. For example, the TCPI Medication Management and Opioid Initiative is mobilizing the existing network of more than 100,000 clinicians into action to address the opioid crisis, generating collaborations with other CMS quality improvement projects, showcasing

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[33] *https://www.federalregister.gov/documents/2018/04/16/2018-07179/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare.*

[34] Data Brief: "Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing," Office of Inspector General, Department of Health and Human Services, July 2017, *https://oig.hhs.gov/oei/reports/oei-02-17-00250.pdf.*

[35] Pamela Owens et al., "Hospital Inpatient Utilization Related to Opioid Overuse Among Adults, 1993–2012" (August 2014), *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb177-Hospitalizations-for-Opioid-Overuse.jsp.*

[36] *https://innovation.cms.gov/initiatives/Transforming-Clinical-Practices/.*

successful strategies in engaging providers and patients on proper opioid utilization and spreading the successful strategies throughout all CMS communities.

The CMS Quality Innovation Network Quality Improvement Organization (QIN–QIO) program, consisting of 14 quality contractors, also works to improve healthcare quality and safety for Medicare beneficiaries. The QIN–QIO program has established a methodology using CMS claims data to identify adverse events, hospital admissions, readmissions, emergency visits, and observation stays for high-risk Medicare beneficiaries who have taken an opioid medication in the outpatient setting. QIN–QIOs collaborate with providers and other community coalitions, using their reports to support local and national efforts to address the opioid epidemic and increase surveillance of adverse events.

Question. What steps is CMS taking to support and improve procedures to screen seniors for opioid misuse at the point of care after seniors are prescribed an opioid pain reliever?

Answer. In addition to the work of the QIN–QIO program, CMS continues to make enhancements in our work with and oversight of plan sponsors to help prevent the misuse of opioids. Safety edits alert a pharmacist of possible overutilization at the point of sale. In real-time they can flag for a pharmacist that they should conduct additional review and/or consultation with the plan sponsor or prescriber to ensure that a prescription is appropriate. In 2018, all plan sponsors are utilizing these safety edits. Beginning in 2019, we expect all sponsors to implement a new opioid care coordination safety-edit. This new edit would create an alert for pharmacists when a beneficiary's total daily opioid usage reaches high levels. When this occurs, plan sponsors are expected to direct pharmacists to consult with the prescriber to confirm their intent. This new policy aims to strike a balance between addressing opioid overuse without a negative impact on the patient-doctor relationship, preserving access to medically necessary drug regimens, and reducing the potential for unintended consequences.

BEHAVIORAL HEALTH INTEGRATION CODES

Question. In its December 2015 Policy Options Document, the Senate Finance Committee's Chronic Care Working Group discussed the need to improve the integration of care for Medicare beneficiaries managing both chronic disease and behavioral health conditions, such as substance use disorder. In July 2016, in the Physician Fee Schedule proposed rule, CMS acted on this recommendation by proposing the creation of four new payment codes for behavioral health integration (BHI) services, which are services that integrate behavioral health care into the primary care setting, to compensate primary care providers for team-based behavioral health care. These BHI codes were finalized in November 2016 and went into effect on January 1, 2017.

Please provide an update on the utilization of these new behavioral health integration (BHI) codes over the past year.

Answer. CMS began making separate payment for behavioral health integration services beginning in 2017. In 2017, approximately 10,200 of these services were utilized by Medicare fee-for-service beneficiaries. (A beneficiary may have received multiple behavioral health integration services.) Medicare payments totaled roughly $450,000 for these services in 2017. These data were drawn from Medicare Part B non-institutional claims, which are the Medicare claims submitted by physicians, practitioners, and other suppliers for Part B services/items. These data may not be complete for 2017 because claims can be submitted to Medicare up to 1 year after the date of service and because of lags in claims processing.

Question. Has CMS identified any barriers related to the implementation or utilization of the BHI codes? If so, please describe those barriers and how CMS is addressing them.

Answer. CMS began making separate payment for behavioral health integration services beginning in 2017. Since that time, the agency has issued a fact sheet and a frequently asked questions document on these services to help physicians and practitioners learn about and bill for them. We will continue to work to ensure that beneficiaries have access to these important services.

Question. The Medicare program should continue to promote the integration of behavioral health services into primary care to support access to treatment for beneficiaries suffering from substance use disorders. Has CMS considered any further

steps to improve access to BHI services for Medicare beneficiaries? If so, please describe those steps.

Answer. CMS supports access to behavioral health integration services for Medicare beneficiaries. Care management and the integration of behavioral health care with primary care have crucial roles in the care of beneficiaries with mental or behavioral health conditions. Since CMS began paying for these services in 2017, the agency has issued a fact sheet and a frequently asked questions document on these services to help physicians and practitioners learn about and bill for them. CMS will continue to work to ensure that beneficiaries have access to these important services.

MEDICARE DEMONSTRATION PROPOSAL FOR SUBSTANCE USE DISORDER TREATMENT

Question. The President's budget for fiscal year 2019 proposed requiring CMS to conduct a demonstration to test the effectiveness of covering comprehensive substance use disorder treatments under Medicare. As described in the budget in Brief for the Department of Health and Human Services, this demonstration would specifically test the use of a bundled payment for methadone treatment or similar Medication Assisted Treatment for the treatment of opioid use disorder. Additionally, the demonstration would recognize opioid treatment programs and substance abuse treatment facilities as independent provider types. The administration noted that this demonstration could be expanded nationwide if it successfully reduced opioid-related deaths, hospitalizations, and emergency room utilization over time.

Please describe in detail the proposed structure of this demonstration, including how CMS and/or the Center for Medicare and Medicaid Innovation (CMMI) would design this bundled payment.

Answer. Under the proposal, CMS would conduct a demonstration to test the effectiveness of covering comprehensive substance abuse treatment in Medicare. Medicare would provide bundled reimbursement on a per-week per-patient basis to health-care providers for methadone treatment or similar medication-assisted therapy and would recognize opioid treatment programs and substance abuse treatment facilities as independent health-care provider types. Outpatient counseling would be billed separately as clinically necessary. Payment for methadone treatment or other similar medication-assisted therapy would be site-neutral. The model would be allowed to target beneficiaries determined to be at-risk, as defined by the Overutilization Monitoring System, to voluntarily receive comprehensive substance abuse treatment, including medication assisted treatment and substance use disorder counseling.

Question. Has CMS and/or CMMI taken any steps to move forward with this proposed demonstration? If so, please describe any action taken by CMS and/or CMMI with respect to this proposed model to date.

Answer. This is a priority of the administration, and we are committed to implementing it appropriately. With this in mind, CMS continues to examine options for this demonstration given statutory limitations and other considerations.

FAMILY FIRST PREVENTION SERVICES ACT

Question. As you know, the Family First Prevention Services Act (FFPSA) allows States to receive a Federal match for evidence-based substance use and mental health treatment services, among other things. Given these services are often provided through State mental health, public health, or home visiting networks, effective implementation of FFPSA will require more than just a traditional "child welfare" response. Accordingly, it is critical that HHS engage multiple agencies as it develops guidance and aids States in implementation.

Please describe the process that HHS and ACF in particular are utilizing to ensure coordination between the relevant agencies (*e.g.,* ACF, CMS, SAMHSA, HRSA, etc.) in the development of the clearinghouse of eligible evidence-based programs and practice criteria under the Family First Prevention Services Act.

How are programs that have been funded under various HHS grants (*e.g.,* RPGs, PPWs, home visiting) being consulted to provide input into this list of evidence-based programs?

After the development of the original list, what will HHS's process be in updating the list of eligible interventions and how often does HHS plan to update the list of eligible services to ensure States are able to avail themselves to the most up-to-date research and best practices?

When does HHS plan to issue guidance to States on how to draw down funding for these evidence-based services?

Will the guidance be issued to State authorities on home visiting, substance use disorder treatment, mental health, and other relevant State agencies in addition to State child welfare agencies?

Answer. To respond to all of your questions, I believe it's helpful to give an overview of the plan for implementation. As you know, the statute requires the Secretary to develop criteria that interventions must meet in order to receive funding under the title IV–E prevention services program. Over the course of the next few months, ACF will consult broadly across HHS and the field in the development of those criteria. Once the criteria are established, ACF will take an equally broad approach for identifying interventions that meet the criteria, including interventions related to opioid use disorder. The vendor that operates the clearinghouse will assess interventions for inclusion in the clearinghouse and elevation within the levels of evidence on an ongoing basis. ACF will issue instructions to States and tribes on what must be included in plans submitted to operate a title IV–E prevention services program in conjunction with publication of the criteria for allowable interventions. The Department would be happy to provide you and your staff with updates on our progress.

Question. As you know, starting October 1, 2018, States are eligible to receive Federal matching funds for maintenance payments on behalf of children in foster care who are placed with a parent in a residential family treatment facility.

What activities are underway to inform substance use treatment agencies of the availability of title IV–E foster care maintenance funds for candidates for foster care effective October 1, 2018?

When does HHS plan to issue guidance to States on this provision?

Will the guidance be issued to both child welfare agencies and the State authorities on substance use disorder treatment?

Answer. ACF's implementation plan includes the provision of training and technical assistance to States as we roll out guidance over the summer of 2018. For example, SAMHSA and ACF jointly fund the National Center on Substance Abuse and Child Welfare, which is available to assist States with developing collaborative practices to expand access to family-centered treatment services on a system-wide basis.

QUESTIONS SUBMITTED BY HON. DEBBIE STABENOW

SCHOOL-BASED HEALTH CENTERS

Question. In addition to recognizing the need to help and treat those afflicted by addiction, I also want to make sure we are also meeting the needs of the so-called "secondary victims" of addiction, or the children of those struggling.

Senator Grassley and I co-chair the Senate Foster Care Caucus, and as many news reports have documented, tens of thousands of children are entering into foster care due to the opioid epidemic.

And we are seeing opioid addiction happening at a much younger age: last year, a study presented at the American Academy of Pediatrics conference found that an average of 135 children each day were testing positive for opioid addiction or dependency in emergency departments.

I want to know what the administration is doing to break down the barriers to make sure children and adolescents receive the mental health services they may need to address the trauma from an adverse experience.

For example, I am working on improving reimbursement for school health services and school based health centers and on building the school nurse workforce. Many schools and local communities would like to provide cost-effective, accessible services on campus, but there are many challenges to do so.

Can you tell me how the administration is working with schools and school-based health centers as well as health plans to ensure that students can receive mental health services and counseling while at school?

Answer. On March 12, 2018, President Trump established a Federal Commission on School Safety to address school safety and the culture of school violence. The

Commission will also address mental health issues. U.S. Secretary Betsy DeVos was appointed to chair the commission by President Trump, and it is comprised with department heads who agencies have jurisdiction over key school safety issues, including Attorney General Jeff Sessions, Secretary of Health and Human Services Alex Azar and Secretary of Homeland Security Kirstjen Nielsen.

HHS has hosted an in-person meeting, a site visit, and is contributing to the development of the final report in support of the Commission's work. Specifically, HHS hosted the third of five Commission meetings on July 11, 2018, the title of which was "Curating a Healthier and Safer Approach: Issues of Mental Health and Counseling for Our Young." The HHS Assistant Secretary for Mental Health and Substance Abuse Elinore McCance-Katz developed the agenda for this meeting. Panel 1 focused on Integrating Behavioral Health Services into Schools.

In addition, HHS facilitated the Commission's second site visit to Adams County, WI to learn about and observe a model statewide initiative used to guide districts in transforming school climate and culture to meet the behavioral health needs of students.

HHS also supports several activities to ensure that children of all ages have access to evidence-based early mental health treatment and interventions. For example, to help ensure that our youth get the best start possible early on in life, SAMHSA supports the Center of Excellence for Infant and Early Childhood Mental Health Consultation (IECMHC) and the Project LAUNCH (Linking Actions for Unmet Needs in Children's Health) grant program. Both of these resources serve to not only support the healthy social and emotional development of young children, but also to support, educate, and strengthen personnel and systems, including early childcare and preschool.

SAMHSA also supports activities that are focused on addressing the needs of school-aged youth and adolescents, including Project AWARE (Advancing Wellness and Resilience in Education), Safe Schools/Healthy Students, Mental Awareness Training, and the Garrett Lee Smith Campus Suicide Prevention grant programs.

Project AWARE grants provide funding to build and expand capacity at the State and local levels to improve student mental health, increase awareness of mental health issues among school-aged youth, provide training for school personnel and other adults who interact with school-aged youth to detect and respond to mental health issues in children and young adults, and connect children, youth, and families who may have behavioral health issues with appropriate services.

These efforts help to develop a comprehensive, coordinated, and integrated program for advancing wellness and resilience in educational settings for school-aged youth that leads to better student mental health and lower rates of addiction. To date, outcomes of this program include over 50,000 teachers, student support personnel, parents, and others trained in mental health awareness; over 117,000 youth connected to services and additional resources; and an increase in early and accurate identification of student mental health needs. Since 2014, SAMHSA has provided funding of up to $1.95 million per year for up to 5 years to 20 States and subsequent to the date of the hearing has awarded 24 new grants in FY 2018.

The Safe Schools/Healthy Students program has provided services to more than 13 million youth and has offered resources to 365 communities in 49 States across the Nation. A 5-year study found that the initiative decreased school violence and substance use, and it significantly increased the number of students who received school-based mental health services and community-based services.

Mental Health First Aid Training is also provided to train and educate school personnel and other adults to recognize the signs and symptoms of mental health issues; know how to appropriately respond; and be able to refer the child, youth, or young adult to the appropriate services and supports. In April 2018, SAMHSA issued a Funding Opportunity Announcement for up to 126 new Mental Health Awareness Training grants at up to $125,000 per year for up to 3 years.

In addition to support for programs focused on children, youth, and adolescents, SAMHSA also provides support for programs that focus on college-age students, through programs such as the Garrett Lee Smith (GLS) Campus Suicide Prevention Grant Program. The purpose of the GLS Campus Suicide Prevention Program is to develop a comprehensive, collaborative, well-coordinated and evidence-based approach to enhance services for college students, including improving prevention, identification and treatment of those at risk for suicide, depression, serious mental illness, and/or substance use disorders. The program enables colleges and univer-

sities to build essential capacity and infrastructure to expand mental health and substance use disorder services and supports to all students. In fiscal year 2018, SAMHSA awarded 20 new GLS Campus grants at up to $102,000 per year for up to 3 years.

Furthermore, the Health Resources and Services Administration (HRSA) funds nearly 1,400 health centers operating more than 11,000 service delivery sites, 1,900 of which are located in schools. In 2017, more than 800,000 students and their families relied on school-based health center sites to meet their needs for a full range of age-appropriate health-care services, including primary medical care, mental health care, substance use disorder counseling, health education and promotion, and case management.

Question. What can the administration do to reduce barriers for schools and school-based health centers to bill and be reimbursed for mental health services?

Answer. School-based services play an important role in assuring that Medicaid-eligible adolescents and children receive needed health care. States have been innovative in their financing strategies for school-based mental health care, including the use of Medicaid, and in 2015, the Federal share of Medicaid funding for school-based services was more than $2 billion, with States matching nearly $1.8 billion. Examples of State innovation include efforts by Louisiana, which authorized the use of Advanced Practice Registered Nurses with specialized experience in psychiatric services to deliver Medicaid-funded mental health and substance use disorder services Medicaid-eligible students with Individualized Education Plans (IEPs), and Arkansas, which developed administrative procedures to finance school-based mental health programs. Additionally, 46 States offer reimbursement for some school-based services through Medicaid. However, some States may not be fully aware of the scope of Medicaid services and activities available within school settings that may be reimbursed under the Medicaid program. In an effort to assist States in leveraging current Federal statutory and regulatory authorities for school-based services, CMS issued a State Medicaid Director Letter, #14–006, entitled, "Medicaid Payment for Services Provided without Charge (Free Care): *https://www.medicaid.gov/federal-policy-guidance/downloads/smd-medicaid-payment-for-services-provided-without-charge-free-care.pdf.* Medicaid reimburses for Medicaid-coverable services that are provided by Medicaid qualified practitioners to Medicaid-eligible and enrolled children who are determined to need the services. CMS also issued the EPSDT Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents,[37] which discussed screening and rehabilitation services that could be delivered in school-based settings under Early and Periodic Screening Detection and Treatment provisions of Medicaid.

Question. And would the administration be willing to work with me on my legislation, Hallways to Health, to improve school-health services?

Answer. HHS is happy to work with members of Congress and their staff, including providing TA on pending or proposed legislation.

QUESTIONS SUBMITTED BY HON. MARIA CANTWELL

Question. I introduced S. 2440 with Senator Harris to increase current law penalties for the negligent distribution and marketing of prescription opioids. I appreciate your commitment to review this legislation and provide feedback to my office. In our exchange at the committee's hearing, you also indicated that the Centers for Medicare and Medicaid Services (CMS) is working on controls to prevent improper prescribing, billing, and dispensing of prescription opioids covered by Medicare and Medicaid. Please elaborate on your answer by describing: (a) CMS's current authorities and work related to tracking and preventing prescription opioid diversion in Medicare Parts A, B, Medicare Advantage, Part D, and State Medicaid and CHIP programs, including coordination with insurers and States; (b) how CMS is specifically working to strengthen such controls across its programs, as you indicated during the hearing; and (c) to what extent CMS faces limitations or barriers that inhibit your ability to track and prevent such diversion.

Answer. CMS is committed to preventing inappropriate prescribing and diversion of opioids across our programs. With regards to the Medicare program, CMS utilizes the NBI MEDIC to identify and investigate potential fraud, waste, and abuse in

[37] *https://www.medicaid.gov/medicaid/benefits/downloads/epsdt_coverage_guide.pdf.*

Medicare Part C and Part D, and to refer cases to law enforcement agencies when necessary. In particular, the NBI MEDIC identifies prescribers of drug combinations known to increase the effects of opioids, those with prescribing behavior that indicates they may be operating a pill mill, and those who prescribe Transmucosal Immediate-Release Fentanyl products to non-cancer patients. CMS shares this information with plans to assist in their investigation of fraud, waste, and abuse.

The NBI MEDIC also conducts data analysis and other work to support ongoing law enforcement activities. Examples include impact calculations, medical review of claims and medical records, and prescription drug invoice reconciliation reviews. As a result of its work, the NBI MEDIC makes recommendations for administrative action to both CMS and the OIG, including revocations of Medicare billing privileges and exclusions from Federally funded health-care programs, respectively.

Additionally, plan sponsors report potential fraud to the NBI MEDIC. The NBI MEDIC uses the PLATO system, which is a voluntary, web-based system that allows CMS, the NBI MEDIC, and plan sponsors to more easily share information and help combat potential fraud, waste, and abuse in the Medicare Advantage and Medicare Part D programs. CMS's Federal law enforcement partners can also access PLATO data.

To strengthen and improve our controls and oversight, CMS has directed the NBI MEDIC to increase its focus on proactive data analysis in Part D, including producing, at a minimum, quarterly reports to plan sponsors on specific data projects, such as high risk pharmacy assessments. These assessments contain a list of pharmacies identified by CMS as high risk and provide plan sponsors with information to initiate new investigations, conduct audits, and potentially terminate pharmacies from their network, if appropriate. In addition to the Quarterly Pharmacy Risk Assessment, the NBI MEDIC produces a Quarterly Outlier Prescriber Schedule II Controlled Substances Report, which provides a peer comparison of Schedule II controlled substances.

With regard to Medicaid, States design, implement, and administer their own programs under general guidelines established by the Federal Government. To reduce opioid misuse without restricting access to legitimate services, Medicaid programs can utilize medical management techniques such as step therapy, prior authorization, and quantity limits. As of FY 2016, 37 States have edits in place to limit the quantity of short-acting opioids that will be covered for a beneficiary and 39 States have similar edits in place to limit the quantity of long-acting opioids. Additionally, to increase oversight of certain prescription opioids, States have the option of amending their Preferred Drug Lists and Non-Preferred Drug Lists to require prior authorization for certain opioids.

States are required to report on their providers' prescribing patterns, including prescription opioids, as part of the Medicaid Drug Utilization Review (DUR) program. This is a two-phase process that is conducted by the State Medicaid agencies. During the first phase, (prospective DUR), the State agency's electronic monitoring system screens prescription drug claims to identify problems such as therapeutic duplication, contraindications, incorrect dosage, and clinical misuse or abuse. The second phase (retrospective DUR) involves ongoing and periodic examination of claims to identify patterns of fraud, abuse, gross overuse, or medically unnecessary care.

The President's FY 2019 budget includes a proposal that would establish minimum standards for Medicaid Drug Utilization Review programs. Currently, CMS does not set minimum requirements for these programs, and there is substantial variation in how States approach this issue. Establishing minimum standards would not only help increase oversight of opioid prescriptions and dispensing in Medicaid, but would save the program an estimated $245 million over 10 years.

Question. During our exchange at the committee's hearing, you indicated that CMS does not work directly with the Drug Enforcement Administration (DEA) to prevent the diversion of prescription opioids covered by CMS programs. Is there a reason CMS does not work directly with the DEA in this area?

Would such direct collaboration between CMS and DEA (and other appropriate agencies within the Departments of Justice and Health and Human Services) allow the Federal Government to more effectively deter the diversion of prescription opioids?

Answer. CMS works closely with the HHS Office of Inspector General (HHS OIG) and other Federal partners in law enforcement, including the Department of Justice. HHS OIG and DOJ are important Federal partners in the Healthcare Fraud

Prevention Partnership (HFPP), which is a voluntary, public-private partnership consisting of the Federal Government, State agencies, law enforcement, private health insurance plans, and health-care anti-fraud associations. Established in July 2012 by the Secretary of HHS and the U.S. Attorney General, the HFPP provides visibility into the larger universe of health-care claims and claimants beyond those encountered by any single partner. The ultimate goal of the HFPP is to exchange facts and information to identify trends and patterns that will uncover potential fraud, waste, and abuse that may not otherwise be identified. The HFPP provides a unique opportunity for payers to combat the opioid crisis by identifying and sharing strategies to prevent prescription opioid misuse and opioid use disorder. By sharing information among payers, the HFPP aims to identify and intervene on behalf of patients at risk of opioid-related harm, as well as to target fraud, waste, and abuse in opioid prescribing.

To address potentially abusive prescribing practices, the President's FY 2019 budget proposes to allow the Secretary to work with the Drug Enforcement Administration (DEA) to revoke a provider's DEA Certificate of Registration after CMS revokes a provider's Medicare enrollment based on a pattern of abusive prescribing via a newly established mandatory reporting requirement. Under this proposal, CMS will be required to report all revocation actions to DEA that are based totally or in part on abusive prescribing of controlled substances and the DEA would be able to use this data to establish revocation of a provider's certification of registration.

CMS is always eager for opportunities to strengthen our partnerships and work together to address the opioid epidemic.

Question. During your testimony, you outlined CMS's overutilization monitoring systems and fraud investigation unit. I understand that CMS employs these tools to track beneficiaries who receive high amounts of prescription opioids and access prescribing data for pharmacies and prescribers who are outliers. However, watching suspicious prescribing or utilization patterns is different than acting to stop them when their activities constitute fraud or violate Federal rules. What tools does CMS currently have to stop, or penalize, fraudulent opioid prescribing within CMS programs?

Answer. CMS has a variety of tools to stop potentially problematic prescribing. Plan sponsors utilize safety edits, which alert a pharmacist of possible overutilization at the point of sale. In real-time they can flag for a pharmacist that they should conduct additional review and/or consultation with the plan sponsor or prescriber to ensure that a prescription is appropriate. In 2018, all plan sponsors are utilizing these safety edits. Beginning in 2019, we expect all sponsors to implement a new opioid care coordination safety-edit. This new edit would create an alert for pharmacists when a beneficiary's daily opioid usage reaches high levels. When this occurs, plan sponsors are expected to direct pharmacists to consult with the prescriber to confirm their intent. This new policy aims to strike a balance between addressing opioid overuse without a negative impact on the patient-doctor relationship, preserving access to medically necessary drug regimens, and reducing the potential for unintended consequences.

To help protect beneficiaries from potentially problematic prescribers, CMS is also compiling a "Preclusion List" of prescribers, individuals, and entities that fall within either of the following categories: (a) are currently revoked from Medicare, are under an active reenrollment bar, and CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program; or (b) have engaged in behavior for which CMS could have revoked the prescriber, individual, or entity to the extent applicable if they had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program. Under this option, CMS will make the Preclusion List available to Part D prescription drug plans and Medicare Advantage plans. Plans would be required to deny payment for claims submitted by, or associated with prescriptions written by prescribers and providers on the list. Additionally, the NBI MEDIC can refer suspected fraud to the HHS OIG for investigation.

Addendum: In April 2018, CMS finalized a rule[38] adopting the Preclusion list and prohibiting Medicare Advantage plans and Part D prescription drug plans from paying prescribers, individuals, and entities on that list. In addition, under the final

[38] *https://www.federalregister.gov/documents/2018/04/16/2018-07179/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare.*

rule, CMS will make the Preclusion List available to Medicare Advantage plans and Part D prescription drug plans.

QUESTIONS SUBMITTED BY HON. BILL NELSON

Question. About one in three people on Medicare across the United States received at least one opioid prescription in 2016. A 2017 HHS Inspector General report found that approximately 500,000 Medicare recipients received a high amount of opioids and around 400 prescribers were identified as having questionable opioid prescribing patterns.

Almost 90,000 people on Medicare are at serious risk of misuse or overdose. In one example, the report pointed to a Florida physician who repeatedly ordered three opioids for one person in a single day. In total, this physician prescribed opioids to 125 beneficiaries who received extreme amounts.

What else does CMS plan to do to inform seniors on Medicare about safe opioid use and non-opioid alternatives? Do you currently make Medicare patients aware of opioid prescribing practices?

Answer. Evidence-based practice is an integral part of all of CMS's priority areas, but expanding the evidence base of effective and alternative treatments for acute and chronic pain is especially vital. The opioid crisis cannot be tackled by CMS alone, and that is why we are collaborating with research-focused HHS agencies, such as the NIH, to identify services that need more evidence to support coverage by Medicare and other health plans.

CMS has partnered with the CDC to develop the Opioid Safety Commitment poster campaign,[39] which promotes the most effective pain management treatments and strategies. This campaign emphasizes patient engagement, clinician counseling regarding opioid alternative pain management strategies, and discussion with patients of the risks and benefits of opioids when opioids are prescribed.

Question. Senator Heller and I introduced a bill to update the "Medicare and You" handbook to include information about opioid use, pain management, and alternative pain management treatments. This handbook is mailed to all Medicare households each year, and is sometimes the starting point to learn about various benefits, plans, rights, and protections. Yet, it doesn't include anything about opioids. Do I have your commitment that your agency will work with my staff on this bill?

Answer. The "Medicare and You" handbook is only one of many ways that CMS communicates with beneficiaries. CMS is working with the Centers for Disease Control and Prevention and other Federal partners to make information about opioids and pain management available to our beneficiaries through a variety of channels. While CMS can make changes to the Handbook contents without legislation, we are happy to provide any technical assistance that you and your staff may require.

Question. There are some exciting things happening with research and development of opioid-alternative drugs that mitigate high-intensity pain. These drugs include injections administered at the site of a surgery by health-care professionals, keeping them out of the hands of the patient. Another such drug works as a long-acting anesthetic to control pain and inflammation after a surgery.

Could these products help alleviate opioid addiction and diversion?

Answer. CMS is exploring a variety of options to help alleviate opioid addiction and diversion. Regarding injectable pain medications, Medicare Part B covers drugs and biologicals furnished "incident to" a physician's service. These drugs furnished under the "incident to" provision are typically injectable drugs that are bought by the physician, administered in the physician's office, and billed by the physician to Medicare. In the Calendar Year 2013 Medicare Physician Fee Schedule final rule, CMS clarified a Part B payment policy that drugs used by a physician to refill an implanted item of durable medical equipment would be considered under the "incident to" benefit. Based on this policy, physicians, but not pharmacies, must purchase the drugs used to refill intrathecal pumps and bill for them under Medicare Part B. However, these drugs may be payable to the pharmacy under Part D if the ingredients that are being compounded independently meet the definition of a Part D drug.

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[39] *https://www.cdc.gov/drugoverdose/prescribing/posters.html.*

Supporting cutting-edge research that advances our understanding of pain, overdose, and addiction and leads to the development of new treatments is a key part of the comprehensive, five-point HHS Opioid Strategy. There are many opportunities for development of opioid alternatives for acute pain. Plans to facilitate research to develop potential non-addictive treatments for acute and/or chronic pain are underway through the NIH Helping to End Addiction Long-term (HEAL) Initiative *(https://www.nih.gov/research-training/medical-research-initiatives/heal-initiative).* As a part of the HEAL Initiative, a program will be established to identify potential candidates for pain medication through rapid screening of a large volumes of molecules for pain-relevant biological activity, bringing more options into the drug pipeline. NIH is working to develop a platform for pain biomarker discovery and validation to inform early stage clinical studies of potential drug effectiveness and safety. In addition, NIH will facilitate the sharing of data on past and future drug development across industry and academia, to focus more research on bringing new pain medications to patients.

To accelerate testing of novel non-addictive pain medications and devices in humans, NIH is establishing a Clinical Trial Network to optimize analgesic trial design, target appropriate patient populations for trials, and engage research expertise at existing clinical sites. A related initiative is to pursue through the Network, development and validation of biomarkers of pharmacodynamic response, to show if tested drugs are working at pain circuits. These efforts provide a valuable set of basic and clinical research resources to accelerate safe, non-addictive drug development.

Injection of anesthetic agents, *i.e.,* nerve blocks, to a surgical site are sometimes administered with analgesics or general anesthesia to reduce opioid dosing during surgery. They provide temporary analgesia, and some evidence suggests that their use reduces the severity of post-operative pain, although may not improve other pain related measures *(https://www.ncbi.nlm.nih.gov/pubmed/25501884).*

NIH is exploring many avenues to accelerate development of non-addictive medications that may reduce or ultimately eliminate the need for opioids for acute, severe pain management such as during or following surgical procedures or injuries. One program that is underway at NIH is a large-scale clinical study to understand the mechanisms that lead some people to develop chronic pain after an acute pain event such as surgery or musculoskeletal trauma. Patients who are about to undergo surgery or have a bone fracture will be followed for 6 months from the injury. Many different bio-psychosocial characteristics, such as gene variants, inflammation markers, and mental health will be collected and correlated with risk for chronic pain. This information will provide mechanistic targets for novel drugs for acute pain treatment. It also will help us to develop precision medicine treatment guidelines that should reduce opioid use for those who don't need it—those who are not likely to develop persistent pain.

Current NIH programs for discovery of new formulations and combinations of existing medicines, as well as for finding existing molecules developed for treatment of other disorders that will provide safe and effective pain relief are being leveraged for rapid expansion. NIH supports an initiative, the Blueprint Neurotherapeutics Program for small molecule drug discovery and development. It funds studies that aim to develop non-addictive kappa opioid receptor antagonists for migraine and a safe, non-opioid analgesic that can be taken orally to reduce diabetic nerve pain.

Question. I introduced the Protecting Newborns from Opioids Act with Senator Rubio, to improve the quality of care provided to newborn babies suffering from opioid withdrawal. The bill would provide Federal funding to States to ramp up the tracking, analysis, and research on babies born with neonatal abstinence syndrome.

In addition to enhanced surveillance and research, what can we do to protect our newborns from this terrible syndrome?

Answer. Addressing neonatal abstinence syndrome is a priority for HHS, and we appreciate your interest in this critical health consequence of opioid use by pregnant women. As you are aware, in November 2015, Congress passed the Protecting our Infants Act (POIA) of 2015 to address the needs of pregnant women and their newborns. As a result of this Act and a subsequent Government Accountability Office (GAO) report, HHS developed the POIA strategy to inform planning and policy across the Department. The recommendations in this report range from aspirational to practical and include preventing prenatal opioid exposure, providing evidence-based treatment for both mother and infant, increasing the accessibility of family-friendly services for pregnant and parenting women with opioid use disorder, sup-

porting continuing education for health-care providers, and determining optimal family and development support services for children who have experienced prenatal opioid exposure. The recommendations are critical to addressing the needs of infants and their mothers who are caught in the midst of this unprecedented opioid use crisis, and HHS is actively working across agencies to implement these recommendations.

SAMHSA developed "Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants. (The Guidance can be accessed here: *https://store.samhsa.gov/product/Clinical-Guidance-for-Treating-Pregnant-and-Parenting-Women-With-Opioid-Use-Disorder-and-Their-Infants/SMA18-5054*). This Guidance outlines optimal management of pregnant and parenting women with an opioid use disorder and their infants based on the recommendations of experts. This Guidance also provides information for healthcare professionals to determine the most clinically appropriate action for a particular circumstance. HHS, through SAMHSA, is supporting a number of grant programs aimed at pregnant and parenting women with substance use and opioid use disorder. These include grants for residential treatment centers that provide comprehensive services to women with substance use disorders and their families, and three new State Pilot Grants for Pregnant and Post-Partum women, the goal of which is to expand outpatient services for this population.

In addition to implementing what we know about the prevention of and treatment for NAS, continuing to support biomedical research to further our understanding of this syndrome is equally critical. The National Institutes of Health (NIH) announced in 2017 a new study called the Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome (ACT NOW), which will evaluate treatment options and improve clinical care of infants with NAS/NOWS. The study is a collaboration between the Eunice Kennedy National Institute of Child Health and Human Development (NICHD) Neonatal Research Network (which has 30 years of experience in conducting clinical trials with newborns) and the new IDeA States Pediatric Clinical Trials Network (within the NIH Office of the Director's Environmental Influences on Child Health Outcomes (ECHO) program), with sites located in rural and medically underserved communities. This joint research effort will use the reach of both networks to assess the prevalence of NAS, understand current approaches to managing NOWS cases (including non-pharmacological approaches), and develop protocols for conducting large scale studies across the country to inform clinical care for affected infants. As part of the recently-launched NIH Helping to End Addiction Long-term (HEAL) Initiative *(https://www.nih.gov/research-training/medical-research-initiatives/heal-initiative),* NIH will use the results of this study to conduct clinical trials aimed at determining best practices for clinical care of infants with NOWS, including assessment of currently used medications and of drug-free treatment approaches."

Question. The opioid epidemic is now a national public health emergency. Medicaid is the single largest payer substance use services across the country, giving millions access to life-saving treatments. In fact, adults on Medicaid are more than twice as likely as those with private insurance to get treatment for a substance use disorder.

In 2015, Medicaid covered a quarter of people in our Nation with opioid use disorders. This program covers a broad range of important services to treat opioid abuse, including counseling, peer support services, medication-assisted treatment, intensive outpatient treatment, and in some circumstances, inpatient and residential care.

The President's budget for fiscal year 2019 proposes to cut Medicaid and our Nation's health-care system by hundreds of billions of dollars by reviving repeal legislation that came before this committee last year to block grant or cap Medicaid.

This legislation, along with the other Medicaid proposals in the President's budget would result in more than $1 trillion in cuts to Medicaid, undoubtedly shifting cost to States. States would ultimately have to cut Medicaid benefits, drop people from the program, and cut payments to providers.

The administration said its top priority is fighting the opioid epidemic. How does slashing Medicaid and kicking people with opioid use disorders off their insurance fight the opioid epidemic?

Answer. Our Medicaid program is an important tool in providing health care to many Americans, but we must put it on a stable long-term sustainable footing for it to be there for this and future generations. That is the challenge that we have

as we seek to empower the States with the right incentives to deliver quality service. The FY 2019 budget provides additional flexibilities to States, puts Medicaid on a path to fiscal stability by restructuring Medicaid financing, and refocuses on the populations Medicaid was intended to serve—the elderly, people with disabilities, children, and pregnant women. The traditional Medicaid program will grow under our budget from about $400 billion over 10 years. The Medicaid expansion does get rescinded, but is replaced along with the individual subsidy program with a $1.2 trillion grant program through the Graham-Cassidy legislation.

Opioid misuse, abuse, and overdose impose immense costs on the Nation, contributing to two-thirds of deaths by drug overdose. Deaths by drug overdose are the leading cause of injury death in the United States. The FY 2019 President's budget recognizes the devastation caused by the opioid crisis in communities across America and fulfills the President's promise to mobilize resources across the Federal Government to address the epidemic. The budget provides a historic level of new resources across HHS to combat the opioid epidemic and serious mental illness—$10 billion—to build upon the work started under the 21st Century Cures Act.

The budget's targeted investments advance the Department's five-part strategy, which involves:

- Improving access to prevention, treatment, and recovery services, including medication-assisted therapies;
- Targeting availability and distribution of overdose-reversing drugs;
- Strengthening our understanding of the epidemic through better public health data and reporting;
- Supporting cutting edge research on pain and addiction; and
- Advancing better practices for pain management.

QUESTIONS SUBMITTED BY HON. ROBERT MENENDEZ

Question. Last month, Secretary Azar said, "there is no such thing as medical marijuana." Yet, a recent study published in *JAMA Internal Medicine* and led by researchers at the Perelman School of Medicine at the University of Pennsylvania, examined the rate of deaths caused by opioid overdoses between 1999 and 2010. Results reveal that on average, the 13 States allowing the use of medical marijuana had a 24.8-percent lower annual opioid overdose mortality rate after the laws were enacted than States without the laws, indicating that the alternative treatment may be safer for patients suffering from chronic pain related to cancer and other conditions. Another study, also published in JAMA Internal Medicine and led by researchers at the University of Kentucky College of Public Health found that laws that permit both medical marijuana and recreational marijuana for adults "have the potential to reduce opioid prescribing for Medicaid enrollees, a segment of population with disproportionately high risk for chronic pain, opioid use disorder and opioid overdose."

Will HHS continue to ignore scientifically proven medical marijuana as a treatment alternative to opioids?

Answer. HHS believes that more research is needed on both the harms associated with marijuana use and the therapeutic potential of marijuana and its constituent compounds. To this end, NIH welcomes investigator-initiated research proposals for pre-clinical and clinical research evaluating marijuana and its constituent cannabinoids for treating disease. The current research portfolio includes some studies utilizing the whole marijuana plant, however most studies focus on individual cannabinoid compounds or other strategies to manipulate the function of the endogenous cannabinoid system. The marijuana plant itself is not considered an ideal medication candidate because: (1) it is an unpurified plant containing numerous chemicals that have not been fully characterized; (2) the variability of active components makes it difficult to reproduce a consistent dose; (3) it is often consumed by smoking, potentially contributing to adverse effects on lung health; and (4) its cognitive- and motor-impairing effects may limit its utility.

In order to facilitate more research on the therapeutic potential of cannabinoids, NIH has released funding opportunity announcements (FOAs) on:

- Developing the Therapeutic Potential of the Endocannabinoid System for Pain Treatment.[40, 41]
- Clinical Evaluation of Adjuncts to Opioid Therapies for the Treatment of Chronic Pain.[42]
- Blueprint Neurotherapeutics Network Small Molecule Drug Discovery and Development for Disorders of the Nervous System.[43]
- Effects of Cannabis Use and Cannabinoids on the Developing Brain.[44]

In addition, FDA has issued the guidance for industry, Botanical Drug Development, for companies developing new therapies that are plant-derived, such as from the cannabis plant. FDA's recent approval of a product containing a purified form of cannabidiol to treat seizures associated with two rare, severe forms of epilepsy in patients 2 years of age and older demonstrates that advancing sound scientific research to investigate ingredients derived from marijuana can lead to important therapies. FDA will continue to support the development of potential medical treatments using marijuana and its components through the appropriate scientific channels and the drug approval process.

Question. Is there a circumstance under which HHS would commit to further study of the risks and rewards to the use of medical marijuana in pain management?

Answer. HHS is committed to working with Congress and our Federal partners to facilitate more research on marijuana and cannabinoids, and to reduce barriers to research. For example, NIH supports a broad portfolio of research on cannabinoids and the endocannabinoid system (ECS). In FY 2016, NIH supported 292 projects totaling over $115 million[45] on cannabinoid research including 53 projects ($28 million) on research evaluating the therapeutic potential of cannabinoids.[46] Research on the therapeutic potential of cannabinoids included 26 studies related to pain. These studies include:

- A randomized controlled trial of dronabinol (a synthetic form of THC) and vaporized cannabis for neuropathic low back pain.[47]
- An observational study of the effects of edible cannabis and its constituent cannabinoids on pain, inflammation, and cognition.[48]
- Research on the use of cannabinoid receptor type 2 (CB2) agonists for treating breast cancer induced bone pain.[49]
- Cannabinoid based therapeutics for pain in sickle cell disease.[50]
- Studies exploring the therapeutic potential of compounds that modulate the ECS such as diacylglycerol kinase, fatty acid amide hydrolase (FAAH), fatty acid binding proteins (FABPs), and G-protein receptor 55.[51]
- Research on the use of cannabinoid compounds as adjunct therapies with opioids or non-steroidal anti-inflammatories (NSAIDs) to improve pain control and reduce adverse events.[52]

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[40] *https://grants.nih.gov/grants/guide/pa-files/pa-15-188.html.*
[41] *https://grants.nih.gov/grants/guide/pa-files/PAR-14-225.html.*
[42] *https://grants.nih.gov/grants/guide/pa-files/PAR-14-225.html.*
[43] *https://grants.nih.gov/grants/guide/pa-files/PAR-17-205.html.*
[44] *https://grants.nih.gov/grants/guide/pa-files/PA-14-162.html.*
[45] *https://report.nih.gov/categorical_spending_project_listing.aspx?FY=2016&ARRA=N&DCat=Cannabinoid%20Research.*
[46] *https://report.nih.gov/categorical_spending_project_listing.aspx?FY=2016&ARRA=N&DCat=Therapeutic%20Cannabinoid%20Research.*
[47] *https://projectreporter.nih.gov/project_info_description.cfm?icde=0&aid=8964406.*
[48] *https://projectreporter.nih.gov/project_info_description.cfm?icde=0&aid=9361825.*
[49] *https://projectreporter.nih.gov/project_info_description.cfm?icde=0&aid=9329913.*
[50] *https://projectreporter.nih.gov/project_info_description.cfm?icde=0&aid=9301005.*
[51] *https://projectreporter.nih.gov/project_info_description.cfm?icde=0&aid=9205939, https://projectreporter.nih.gov/project_info_description.cfm?icde=0&aid=9328534, https://projectreporter.nih.gov/project_info_description.cfm?icde=0&aid=9222649, https://projectreporter.nih.gov/project_info_description.cfm?icde=0&aid=9040444, https://projectreporter.nih.gov/project_info_description.cfm?icde=0&aid=8878443,* and *https://projectreporter.nih.gov/project_info_description.cfm?icde=0&aid=9247769.*
[52] *https://projectreporter.nih.gov/project_info_description.cfm?icde=0&aid=9329184, https://projectreporter.nih.gov/project_info_description.cfm?icde=0&aid=9324176,* and *https://projectreporter.nih.gov/project_info_description.cfm?icde=0&aid=9557937.*

- Studies of the therapeutic effects of cannabis and cannabinoids on HIV-related pain.[53]
- Studies of the efficacy of peripherally restricted cannabinoids for cancer and chemotherapy-induced pain.[54]
- Basic research on:
  - The mechanisms through which cannabinoids and the ECS modulate pain;[55]
  - The role of cannabinoids in modulating hyperalgesia;[56]
  - The role of CB2 receptors in peripheral neuropathy;[57] and
  - The role of the ECS in the efficacy of spinal manipulation therapy for neuropathic pain.[58]

FDA will continue to support the development of potential medical treatments using marijuana and its components, including for the treatment of pain, through the appropriate scientific channels and the drug approval process.

Question. Speaking in February 2018, Attorney General Jeff Sessions stated that "The DEA said that a huge percentage of the heroin addiction starts with prescriptions. That may be an exaggerated number; they had it as high as 80 percent. . . . We think a lot of this is starting with marijuana and other drugs too." Research indicates however, that there is no causal link between marijuana and harder drug use.

Do you agree with the statements made by the Attorney General?

Answer. Prescription opioids and heroin belong to the same drug class, act on the same receptors in the brain, produce similar effects, and alleviate opioid withdrawal symptoms. The available data clearly demonstrate the intertwined nature of prescription opioid misuse and heroin use.

Analysis of nationally representative data collected in 2011 showed that 80 percent of people who started using heroin that year had previously misused prescription opioids,[59] a finding that aligned with other reports that prescription opioids were the most common opioids of initiation.[60] More recent data, however, suggest that heroin may have become more common as an opioid of first abuse, at least among people entering treatment. Based on data regarding people who have opioid use disorder upon entering treatment, Cicero et al., found that approximately one-third reported heroin as the first opioid they used regularly to get high.[61]

It is important to note that many people who use drugs use multiple substances, and many people who initiate drug use will do so with substances that are easiest to obtain, such as nicotine, alcohol, and marijuana. However, the majority of people who use nicotine, alcohol, and/or marijuana do not go on to use more potent illicit substances. There is evidence of an association between marijuana use and opioid misuse, including:

- A recent nationally representative study found that adults who reported marijuana use in 2001–2002 were nearly 6 times as likely to have initiated prescription opioid misuse and nearly 8 times as likely to have a prescription opioid use disorder by 2001–2005 compared to adults who did not report marijuana use in 2001–2002.[62]

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[53] *https://projectreporter.nih.gov/project_info_description.cfm?icde=0&aid=9271603.*
[54] *https://projectreporter.nih.gov/project_info_description.cfm?icde=0&aid=9056010.*
[55] *https://projectreporter.nih.gov/project_info_description.cfm?icde=0&aid=9309675,* and *https://projectreporter.nih.gov/project_info_description.cfm?icde=0&aid=8918260.*
[56] *https://projectreporter.nih.gov/project_info_description.cfm?icde=0&aid=9107004.*
[57] *https://projectreporter.nih.gov/project_info_description.cfm?icde=0&aid=9279120.*
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[59] Muhuri, P.K., Gfroerer, J.C., Davies, C., "Associations of nonmedical pain reliever use and initiation of heroin use in the United States," CBHSQ Data Review, 2013.
[60] Compton, W.M., Jones, C.M., Baldwin, G.T., "Relationship Between Nonmedical Prescription-Opioid Use and Heroin Use," *N. Engl. J. Med.* 2016 January 14;374(2):154–63. doi: 10.1056/NEJMra1508490. Review. PubMed PMID: 26760086.
[61] Cicero, T.J., Ellis, M.S., Kasper, Z.A., increased use of heroin as an initiating opioid of abuse. *Addict. Behav.* 2017 November 74:63–66. doi: 10.1016/j.addbeh.2017.05.030. Epub 2017 May 23. PubMed PMID: 28582659.
[62] Olfson, M., Wall, M.W., Liu, S.M., Blanco, C., "Cannabis use and risk of prescription opioid use disorder in the United States," *Am. J. Psychiatry,* 2018;175(1):47–53.

- An analysis by SAMHSA researchers among youth aged 12 to 17 years old found that youth who had ever used marijuana had elevated risk for prescription opioid misuse and use of other illicit drugs compared with youth who had never used marijuana, even after accounting for tobacco and alcohol use.[63]
- A 2015 study by HHS researchers found that nearly 1 in 4 people who used heroin in the past year had a marijuana (cannabis) use disorder and that people with marijuana use disorder were nearly three times as likely to have a heroin use disorder, compared to people without a marijuana use disorder.[64]

These findings are consistent with a large volume of literature demonstrating that marijuana use, especially early and frequent use, is associated with use of other illicit substances,[65, 66] though more research is needed to determine the degree to which cross-sensitization, shared underlying risk factors, and social environment underlie this association.

Question. During the hearing, we spoke about leveraging Medicaid data to inform policy on the opioid epidemic. What additional Federal supports would aid CMS and States in using the data of the States and territories to inform policy and programs? Are there statutory limitations or changes that require congressional action to advance the use of data?

Answer. CMS understands the importance of having complete, accurate data. The Transformed Medicaid Statistical Information System (T–MSIS) is a critical data and systems component of CMS's efforts to gather information from State Medicaid programs. CMS has made significant progress with its Federal T–MSIS information technology (IT) platform, and CMS is continuing to work with States on T–MSIS data quality and technical compliance as a priority for 2018. CMS continues to focus on improving the quality and completeness of the State submissions, technical compliance and building the agency's Medicaid and CHIP data analytic capacity. We look forward to making data more widely available as quality improves.

Question. As mentioned in the hearing, the Family First Preventions Services Act is of critical importance to many programs. What is the timeline for guidance to be issued so programs can access funds for their programs? What is the proposed timeline for continuous updates to the list of eligible programs for the clearinghouse of evidence-based programs?

Answer. To respond to your questions, I believe it's helpful to give an overview of the plan for implementation. As you know, the statute requires the Secretary to develop criteria that interventions must meet in order to receive funding under the title IV–E prevention services program. Over the course of the next few months, we intend to consult broadly across HHS and the field in the development of those criteria. Once the criteria are established, ACF will take an equally broad approach for identifying interventions that meet the criteria. The vendor that operates the clearinghouse will assess interventions for inclusion in the clearinghouse and elevation within the levels of evidence on an ongoing basis. ACF will issue instructions to States and tribes on what must be included in plans submitted to operate a title IV–E prevention services program in conjunction with publication of the criteria for allowable interventions.

Question. Prescription Drug Monitoring Programs continue to evolve. What would the benefits be of establishing a new, national PDMP that integrates developing prescribing technology as well as data from law enforcement to better track abuses and pressure points in and allow cross-agency collaboration to further stem the flow of opioids into our communities?

Answer. PDMPs are State-run databases that collect patient-specific prescription information at the point of dispensing. The use of PDMPs among all providers is a promising State-level intervention to improve opioid prescribing, inform clinical practice, and protect patients at heightened risk of opioid misuse, abuse, and over-

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[63] Jones, C.M., McCance-Katz, E.F., Unpublished analysis of the 2015–2016 National Survey on Drug Use and Health data.

[64] Jones C.M., Logan J., Gladden R.M., Bohm M.K., "Vital Signs: Demographic and substance use trends among heroin users—United States, 2002–2013," *MMWR Morb. Mortal. Wkly. Rep.* 2015;64(26):719–725.

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[66] Silins, E., Horwood, L.J., Patton, G.C., Fergusson, D.M., Olsson, C.A., Hutchinson, D.M., Spry, E., Toumbourou, J.W., Degenhardt, L., Swift, W., Coffey, C., Tait, R.J., Letcher, P., Copeland, J., Mattick, R.P., "Young adult sequelae of adolescent cannabis use: An integrative analysis," *Lancet Psychiatry,* 2014;1:286–2.

dose. Clinicians can use PDMPs to help inform their prescribing decisions by checking to see if a patient already has an opioid prescription, has prescriptions from multiple providers, or has both opioids and benzodiazepine prescriptions—all risk factors for an overdose.

PDMPs also can provide public health authorities with timely information about prescribing and patient behaviors that contribute to the epidemic. In addition, States can use PDMP data to determine "hot spots" or geographic areas within a State with disproportionately higher rates of opioid prescribing and dispensing and therefore target interventions.

CDC's primary goal pertaining to PDMPs is to maximize their utility as both a public health surveillance and clinical decision support tool. CDC is working to actualize such outcomes through State-based programs as well as within the context of health systems.

The establishment and operation of PDMPs vary given that each PDMP is subject to existing policies and management of their own respective State. While PDMPs may operate differently, there are system components that CDC promotes to improve PDMP functionality as a public health tool. Those include:

- Universal use among providers and/or their delegates (for example, nurse practitioners or physician assistants) within a State;
- More timely or real-time data contained within a PDMP;
- Actively managing the PDMP in part by sending proactive reports to providers to inform prescribing; and
- Ensuring that PDMPs are easy to use and accessible by providers.

In addition to those strategies that enhance the functionality of a PDMP as a public health surveillance and clinical decision support tool, there are additional strategies that can assist States in scaling up the widespread use of PDMP data. States can implement strategies to improve integration of PDMP data within a State (intrastate) and interstate interoperability.

Intrastate interoperability refers to the ability of a State to share PDMP data with other technologies utilized within the State including electronic health records (EHRs), pharmacy dispensing software (PDS) systems, and Health Information Technology (Health IT) infrastructure. Integrating PDMP data into Health IT systems (*e.g.,* EHRs, PDS systems) allows providers to access PDMP data and reports as seamlessly as possible in their clinical workflow. Through such integration, the PDMP report is automatically accessed when an EHR/Health Information Exchange (HIE) patient record is opened. In addition, the ONC Interoperability Standards Advisory includes updated National Council for Prescription Drug Programs Standards for exchanging controlled substance prescription history from State PDMPs so that prescription history may be integrated into Health IT systems. Health IT developers and implementers can use these standards to provide prescribers a more complete picture of their patients' prescription history. Efforts such as these can lead to improved patient care by ensuring clinicians easier access to data, such as consolidated prescription history (including, daily opioid dosage).

In addition to integrating PDMP data within Health IT systems, intrastate interoperability strategies also include linking PDMP data to other data systems within the same State. Examples include linking PDMP data to the following data sources:

- Pharmacy Benefit Managers.
- Medical Examiners/Coroners.
- Medicaid.
- Worker's compensation.
- VA.
- Indian Health Service providers.

Leveraging PDMP data with other data sources within the same State can provide a more comprehensive picture of prescribing behavior, care and treatment services, and/or resultant fatalities following an overdose. Doing so improves a State's understanding of risk factors associated with opioid misuse, opioid use disorders and overdose and allows for targeting of strategies to reverse the epidemic.

Interstate interoperability refers to the ability of a State to share PDMP data across State lines. Interstate interoperability involves accessing a shared national

platform/resource that supports and creates more sustainable and higher-functioning State PDMPs by virtue of their ability to share data across State boundaries.

A national means to connect PDMP data from one State to another is essential. Two national platforms (RxCheck from the U.S. Department of Justice's Bureau of Justice Assistance and PMP Interconnect from the National Association of Boards of Pharmacy, which was developed by Appriss Inc.) facilitate bilateral exchange of data across States. Currently 46 States and Washington, DC are exchanging data with other States via one or both of these existing data hubs. Given that CDC's opioid overdose prevention programs emphasize strategies that maximize the utility of PDMPs to support a sustained infrastructure that promotes mindful stewardship of Federal resources, CDC has been collaborating with Federal partners on how best to improve State access to tools and other resources to advance interoperability at the national level. CDC has been collaborating with Federal partners, including DOH's Bureau of Justice Assistance and the Office of the National Coordinator for Health IT to improve State access to tools and other resources to advance interoperability at the national level, which has been identified as a White House Priority discussed in the President Trump's Initiative to Stop Opioid Abuse.[67]

QUESTIONS SUBMITTED BY HON. THOMAS R. CARPER

Question. According to the CDC, 11 percent of American adults suffer from chronic, daily pain and 20 percent of patients who go to the doctor with pain-related concerns receive an opioids prescription. In 2012, health-care providers wrote more than 250 million prescriptions for opioids, enough for every adult to have a bottle of pills, even though opioids are not the first line of treatment for chronic pain.

What are HHS and CMS doing to ensure that Medicare and Medicaid enrollees have better access to evidence-based non-opioid treatments for pain, such as physical therapy, counseling, non-addictive medications, and FDA-approved medical technologies?

Answer. The opioid crisis cannot be tackled by CMS alone, and that is why we are collaborating with other HHS agencies, such as the FDA, CDC, and NIH, to identify services that need more evidence to support coverage by Medicare and other health plans.

Both medicinal and non-medicinal therapeutic alternatives to opioid-based pain medications exist; although Medicare coverage and payment varies. In general, Medicare covers items and services that are "reasonable and necessary." This includes several non-pharmacologic therapies and other non-opioid pharmaceuticals. CMS uses the national and local coverage determination process to evaluate new or promising items and services with respect to Medicare Parts A and B, through well-delineated processes set forth in statute. Those items and services for which evidence demonstrates improvement in health outcomes in the Medicare population are more likely to be coverable, while those items and services for which such evidence is insufficient or lacking warrant further research.

CMS has partnered with the CDC to develop the Opioid Safety Commitment poster campaign,[68] which promotes the most effective pain management treatments and strategies. This campaign emphasizes patient engagement, clinician counseling regarding opioid alternative pain management strategies, and discussion with patients of the risks and benefits of opioids when opioids are prescribed.

CMS has a number of initiatives underway to increase the use of recommended evidence-based practices for pain management. In addition to the work of the Quality Innovation Network Quality Improvement Organization program, described above, CMS provides outreach regarding best practices and technical assistance through the Transforming Clinical Practice Initiative's (TCPI's) Practice Transformation Networks.[69] TCPI is designed to use peer-based learning networks for information sharing, outreach, and dissemination of evidence-based practices to educate prescribers on safe and appropriate methods of pain treatment. For example, the TCPI Medication Management and Opioid Initiative is mobilizing the existing network of more than 100,000 clinicians into action to address the opioid crisis, gen-

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[67] *https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-initiative-stop-opioid-abuse-reduce-drug-supply-demand/.*
[68] *https://www.cdc.gov/drugoverdose/prescribing/posters.html.*
[69] *https://innovation.cms.gov/initiatives/Transforming-Clinical-Practices/.*

erating collaborations with other CMS quality improvement projects, showcasing successful strategies in engaging providers and patients on proper opioid utilization and spreading the successful strategies throughout all CMS communities.

CMS also promotes free educational materials for health-care professionals on CMS programs, policies, and initiatives through the Medicare Learning Network (MLN).[70] The "CDC Guidelines for Prescribing Opioids for Chronic Pain" is featured in the January 12, 2017[71] MLN Connects newsletter.

Question. Patients in Medicaid and their providers often wrestle with prior authorization requirements for medication assisted treatments for opioid abuse, increasing the odds that these patients will relapse and return to their use of opioids.

Would increasing use of electronic prior authorization in Medicaid, Medicare, and private health insurance plans help improve access to medication-assisted treatment?

What do you need from Congress to increase the use of electronic prior authorization for medication-assisted treatment?

Answer. CMS is always interested in finding ways that will improve our programs and reduce physician and patient burden. Electronic prior authorization is one of many tools currently available to Medicare Part D and/or Medicare Advantage plans as they continue to work with CMS in identifying ways to further address the opioid epidemic. While interoperability is important among the tools used by plans and providers to combat the opioid epidemic, we are cognizant of the potential for administrative burden and expense for providers any time we introduce new requirements.

CMS is committed to working with plans and making sure they have the flexibility they need in order to best serve beneficiaries.

Question. As Governor of Delaware, I convened a special council to advise me on how to strengthen families in our State. We knew that stronger families led to better academic results for children and stronger communities and economies. As we confront the opioid epidemic, I urge you to focus not just on treatment but also on the root causes for this crisis. Our child and family experts tell us that individuals with mental health conditions and adverse childhood experiences are at greater risk for abusing drugs.

What are HHS and CMS doing to ensure at-risk children and families have adequate access to early mental health treatments and interventions that could reduce drug abuse and addiction?

Answer. The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit[72] provides comprehensive and preventive health-care services for children under age 21 who are enrolled in Medicaid. EPSDT is key to ensuring that children and adolescents receive appropriate preventive, dental, mental health, and developmental, and specialty services.

Periodic developmental and behavioral health screenings are required for all children enrolled in Medicaid, through the EPSDT benefit, and they are also covered for children enrolled in the Children's Health Insurance Program (CHIP). In addition to the required periodic screenings, Medicaid-eligible children are entitled to inter-periodic screenings in order to identify a suspected illness or condition not present or discovered during the periodic exam. A change in living circumstance, presentation of acute behavioral needs, and entry into the foster care system are all events that may elicit the need for an inter-periodic screening. Federal matching funds are available for States that provide additional reimbursement to providers who perform developmental and behavioral screenings during a well-child visit.

The Department of Health and Human Services supports several activities to ensure that at-risk children of all ages and their families are identified as early as possible, and have adequate access to evidence-based early mental health treatments and interventions. SAMHSA's Project LAUNCH (Linking Actions of Unmet Needs in Children's Health) provides funding to States to implement strategies spe-

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[70] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNGenInfo/Index.html.*

[71] *https://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Provider-Partnership-Email-Archive-Items/2017-01-12-eNews.html?DLPage=7&DLEntries=10&DLSort=0&DLSortDir=descending#_Toc471878721.*

[72] Additional resource at *https://www.medicaid.gov/medicaid/benefits/downloads/epsdt_coverage_guide.pdf.*

cific to addressing the needs of children from birth through age 8. This program aims to: increase access to mental health screening; assessment, and referral to appropriate services for young children and families: expand use of culturally relevant, evidence-based prevention and wellness promotion practices in a range of child-serving settings; increase integration of behavioral health into primary care settings; improve coordination and collaboration across disciplines at the local, State, territorial, tribal, and Federal level; and increase workforce knowledge of children's social and emotional development and skills to respond to behavioral health challenges of young children and families. These strategies have been shown to help prevent future substance use and addiction. SAMHSA is currently funding 55 grants to States, tribes, and territories and will fund a cohort of grants specifically to serve tribal populations this fiscal year.

The Infant and Early Childhood Mental Health Grant Program is a new fiscal year 2018 effort to provide funding of up to $500,000 per year for up to 5 years to organizations to address gaps in the continuum of services for youth from birth through age 12 who are at risk for, show early signs of, or have been diagnosed with mental illness. The purpose of this program is to improve outcomes for these children by developing, maintaining, or enhancing infant and early childhood mental health promotion, intervention, and treatment services. SAMHSA anticipates making nine awards this fiscal year.

SAMHSA also supports grant programs that are focused on addressing the needs of school-aged youth. Project AWARE (Advancing Wellness and Resilience in Education) State grants provide funding to State Education Agencies (SEAs) to partner with State Behavioral Health Authorities (SBHAs) to build and expand the capacity to improve student mental health. The program aims to increase awareness of mental health issues among school-aged youth, provide training for school personnel and other adults who interact with school-aged youth to detect and respond to mental health issues in children and young adults, and connect children, youth, and families who may have behavioral health issues with appropriate services. These efforts will help develop a comprehensive, coordinated, and integrated program for advancing wellness and resilience in educational settings for school-aged youth that leads to better student mental health and lower rates of addiction. Current grantees are implementing or enhancing comprehensive school mental health systems, improving early identification and referral systems, increasing access to qualified behavioral health providers, improving school climates, and implementing prevention programming to reduce youth violence, including bullying, among other activities. Since 2014, SAMHSA has provided funding of up to $1.95 million per year for up to 5 years to 20 States. Subsequent to the date of the hearing, SAMHSA awarded 24 grants for a second cohort, funding $1.8 million per grant for up to 5 years.

To further train providers and others who interact with children to identify mental health issues and connect children and families to services, SAMHSA funds the Center of Excellence for Infant and Childhood Mental Health Consultation (IECMHC) in partnership with HHS's Health Resources and Services Administration and Administration for Children and Families. This Center of Excellence provides supports to States, tribes, and communities to implement quality training. SAMHSA also currently funds 70 grants to community organizations to implement mental health awareness training and establish referral mechanisms through the Project AWARE Community grants. These are 3-year grants funded at up to $125,000 per year. SAMHSA is currently accepting applications to support up to an additional 126 grants through the Mental Health Awareness Training grant program, which expands current activities by adding a priority focus area of military veterans and families, and by adding a requirement of crisis de-escalation training.

Finally, SAMHSA supports the Children's Mental Health Initiative, which is designed to support States and communities in developing evidence-based systems of care approaches for children and families with serious emotional disturbances that lead to improved outcomes in such areas as school retention, juvenile justice involvement, and rates of addiction. On April 10, 2018, SAMHSA issued the Community Programs for Outreach and Intervention with Youth and Young Adults at Clinical High Risk for Psychosis funding opportunity announcement. This grant program will identify youth and young adults (up to 25 years old) at clinical high risk for psychosis and provide evidence-based interventions to prevent the onset of psychosis or lessen the severity of the psychotic disorder.

Additionally, the SAMHSA's Community Mental Health Services Block Grant (MHBG) and Substance Abuse Prevention and Treatment Block Grant (SABG) include set-aside provisions applicable to all grantees (States, territories and the tribal

grantee). For example, since 2016, grantees have been required to use 10 percent of their MHBG funds to assist individuals experiencing first episode psychosis (FEP). With this funding and SAMHSA's support, the number of specialty programs providing evidence-based care for FEP has increased from just a few programs in 17 States to over 250 programs in 49 States. As psychosis often begins when an individual is in their late teens to mid-twenties, these programs primarily focus on adolescents and young adults. Through the SABG grantees were required to establish a base of expenditures for special treatment services for pregnant women and women with dependent children. Grantees must ensure that programs that receive funds set-aside for pregnant women and women with dependent children provide or arrange for:

- Primary medical care, including prenatal care;
- Primary pediatric care for the woman's children, including immunizations;
- Gender-specific substance abuse treatment; and
- Other therapeutic interventions for women addressing issues such as relationships, sexual and physical abuse, and parenting.

Grantees must require all SABG-funded programs to give pregnant women preference in admissions to treatment.

Question. How can we make better use of telehealth in Medicaid and CHIP to improve access to mental health treatment, especially for at-risk kids?

Answer. CMS believes that telehealth can be an important tool in our efforts to fight this epidemic. Expanding the use of telehealth is a priority of CMS Administrator Verma. To promote the use of telehealth, CMS is seeking to reduce some of the barriers to telehealth such as reimbursement and cross-state licensure issues, particularly for rural areas and we are committed to working with States to ensure that they have the flexibility to provide the right care in the right setting.

QUESTIONS SUBMITTED BY HON. BENJAMIN L. CARDIN, HON. BILL CASSIDY, AND HON. BILL NELSON

STABILIZATION CENTERS

Question. I am following up on the conversation we had regarding stabilization centers, which provide an alternative to the emergency room, and can also act as diversion from incarceration. Admiral Giroir and Deputy Administrator Brandt, you both expressed a willingness to work with me in finding solutions to encourage the appropriate placement of those who are suffering from substance use disorder, so that they can get referred to the appropriate care.

Can you provide me with a list of suggestions on ways we can leverage existing resources available at the Federal level to increase the creation of and to provide more access to stabilization centers?

Answer. One way to leverage existing resources at the Federal level is to clearly define the stabilization center model as an evidence based practice-utilizing Medication-Assisted Treatment (MAT). This emphasis can be through communications to the field that stabilization centers, utilized appropriately, enhance the continuity of care in the outpatient setting increasing the potential for positive recovery outcomes. In particular, SAMHSA communicates that its preference is to fund such models with stronger evidence of effectiveness as opposed to those that facilitate repetitious revolving door detoxification only service episodes.

In addition, emergency departments and first responders can be the critical link between the crisis and the connection to care to a stabilization center or similar program when an individual experiences an overdose and/or a substance use disorder (SUD) related crisis. This presents an opportunity to leverage the crisis and connect the individual to a system of care that will address their comprehensive SUD and related health-care needs. For example, in spring 2019, the Baltimore City Health Department will open the State's first Stabilization Center, a place for individuals who are under the influence of drugs and/or alcohol to receive short-term medical and targeted interventions. Through emergency medical system transport, the Center will divert patients who meet specific criteria from emergency departments and provide stronger links to community-based behavioral health care. Services provided will include medical screening and monitoring, connections to behavioral health and social services, and buprenorphine induction to treat opioid addiction. Part of the

funding for this program is from the SAMHSA's Opioid State Targeted Response (STR) grant program authorized by the 21st Centuries Cures Act.

Question. Alternatively, are there new approaches that we can take through legislative action that would encourage expanding the creation of these centers?

Answer. Through our funding, training, and technical assistance, the Department is supporting State, local, tribal, and territorial efforts to expand capacity for treatment and recovery support services that match the clinical needs of the individual with the appropriate level of care. With the additional resources provided by Congress in the FY 2018 Omnibus, HHS is significantly expanding its resources to communities to advance this work. A number of service delivery models that provide the full spectrum of care such as the Hub and Spoke model, the nurse care manager model, and the Centers of Excellence model are being supported by HHS funding.

Question. Admiral Giroir, in your testimony you also expressed support for community based programs, as well as discussed the flexibility that States possess in utilizing State Targeted Response (STR) grants in order to test programs.

Would you support and encourage States to use their current STR grant funding to invest in stabilization centers?

Answer. Crisis Stabilization Centers are typically used as alternatives to patient admission to inpatient hospitalization, emergency department care, or detention centers for individuals with significant mental health or substance use disorders, including those who are intoxicated or present a danger to self or others. Persons with opioid use disorders typically can benefit from this level of care with rapid medical assessment, referral, and induction into a program of medication-assisted treatment with psychosocial services and community recovery supports. This meets the criteria for services supported by the Opioid STR Grant Program. SAMHSA does not recommend medically managed withdrawal ("detox") from opioids in the absence of transition to medication assisted treatment (MAT) for people with an opioid use disorder, as the evidence indicates poor outcomes for these individuals who are withdrawing from opioids without MAT. In fact, through SAMHSA's Opioid STR program, States and territories are using funding to implement a broad range of evidence-based interventions that span prevention, treatment, and recovery support services. SAMHSA is encouraging States to implement innovative service delivery models that can provide the full complement of treatment and recovery support services matched to the clinical needs of individuals with opioid use disorder. A number of service delivery models are being pursued with STR funds including Centers of Excellence, Hub and Spoke, Project ECHO, and emergency department initiated buprenorphine.

Question. Would you support Congress increasing the funding for STR grants with the intent of funding stabilization centers?

Answer. The President's fiscal year 2019 budget includes $10 billion in new resources across HHS to combat the opioid epidemic and address serious mental illness. In FY 2019, an initial allocation provides $1.2 billion in SAMHSA for a variety of new and expanded efforts to fight the opioid crisis. Of that amount, $1 billion is included to expand State Targeted Response Grants. As noted above, States are currently using Opioid STR funding for stabilization centers. However, persons with opioid use disorders typically can benefit from a lower level of care with rapid medical assessment, referral, and induction into a program of medication-assisted treatment.

NALOXONE PRICING

Question. I have heard from first responders and local health departments across Maryland that the rising cost of naloxone is pricing them out of saving lives—despite the fact that naloxone is a generic drug that costs pennies in other countries. For example, the Baltimore City Health Department spent $118,236 for 3,340 doses in fiscal 2016. That was up from $33,540 for 1,540 doses in fiscal 2014—an increase of almost 63 percent per dose. As you know, the Federal Government has the statutory authority to purchase naloxone at a price that it determines.

Will HHS support the use of this authority to get naloxone into the hands of those who desperately need it?

Answer. Targeting the availability and distribution of overdose reversing drugs like naloxone is a key part of the comprehensive, five-point HHS Opioid Strategy. We recognize the critical role naloxone plays in supporting communities' response to the opioid epidemic, especially with the increasing supply of highly potent syn-

thetic opioids like illicitly made fentanyl and carfentanil. To support these efforts, HHS has prioritized making funding available to States for the direct purchase of and training on over-dose reversing drugs. Specifically, States can use a portion of the $485 million in funding through SAMHSA's STR grants for the purchase and training on appropriate use of overdose reversing drugs. SAMHSA also has other naloxone-specific programs including the CARA First Responders program and a State-based naloxone program that provide funding to purchase and train individuals on the use of naloxone. In addition, HHS has provided guidance to States informing them that they can utilize their Substance Abuse Prevention and Treatment Block Grant funds to support overdose prevention education and training and to support the purchase and distribution of naloxone. Finally, HHS is working to ensure that there is adequate competition for naloxone, which would lead to lower pricing. FDA has indicated the agency is identifying ways to encourage over-the-counter naloxone applications. Additionally, Commissioner Gottlieb is already working on ways to increase generic competition, which can help drive down drug costs.

QUESTION SUBMITTED BY HON. BENJAMIN L. CARDIN, HON. THOMAS R. CARPER, AND HON. SHERROD BROWN

Question. As you know, Medicaid plays a central role in the Nation's efforts to address the opioid epidemic. While all State Medicaid programs cover at least one Food and Drug Administration (FDA)-approved form of MAT, not all States cover all current FDA-approved forms of MAT (methadone, buprenorphine (Suboxone), and naltrexone (Vivatrol)). In the fiscal year 2019 budget, the Department of Health and Human Services (HHS), expressed support to require that State Medicaid programs cover all FDA-approved MAT for opioid use disorder, including associated counseling and other costs.

What is CMS doing to provide States with information and technical assistance on best practices for covering MAT in their Medicaid programs?

What is CMS doing to encourage States to update their policies to cover all three FDA-approved forms of MAT as well as associated counseling and behavioral supports?

Answer. Medication-Assisted Therapy (MAT) is a valuable intervention that has been proven to be the most effective treatment for OUD, particularly because it sustains long-term recovery and has been shown to reduce opioid-related morbidity and mortality.[73]

While Medicaid programs vary greatly by State, all 50 States currently offer some form of MAT. CMS has issued guidance on best practices in Medicaid for covering MAT in a joint informational bulletin with the Substance Abuse and Mental Health Services Administration (SAMHSA), the CDC, and the National Institute on Drug Abuse.[74] CMS also released an informational bulletin with SAMHSA on coverage of treatment services for youth with SUD.[75]

The President's FY 2019 budget includes a proposal that would require State Medicaid programs to cover all FDA-approved MAT for opioid use disorder, including associated counseling and other costs. These up-front investments in expanded MAT treatment are expected to reduce total Medicaid expenditures over time as more individuals recover from opioid use disorder; this provision would result in an estimated $865 million is savings over 10 years.

Under the demonstration authority granted by section 1115 of the Social Security Act, CMS can also waive certain Federal requirements and pay Federal matching funds certain expenditures that otherwise would not be matchable so that States can test new or existing ways to deliver and pay for health-care services in Medicaid.

We are encouraging States to apply for CMS approval of a 5-year demonstration allowing them to receive Federal financial participation for services to treat addiction to opioids or other substances for Medicaid beneficiaries residing in IMDs, including those aged 21 to 64 for whom Medicaid otherwise would not pay for services while the beneficiary is residing in an IMD, as these States work to improve access to treatment in outpatient settings as well. In addition, we are working with States

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[73] *https://www.ncbi.nlm.nih.gov/pubmed/24500948.*
[74] *https://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-07-11-2014.pdf.*
[75] *https://www.medicaid.gov/federal-policy-guidance/downloads/cib-01-26-2015.pdf.*

that operate these demonstrations to establish strong quality of care standards, particularly for residential treatment settings.

This initiative offers a more flexible, streamlined approach to accelerate States' ability to respond to the national opioid crisis while enhancing States' monitoring and reporting of the impact of any changes implemented through these demonstrations. In addition to being budget neutral, demonstrations must include a rigorous evaluation based on goals and milestones established by CMS. States must also make available on *Medicaid.gov* information on the progress and outcomes of these demonstrations and evaluations so that other States can learn from these programs; this cycle of evaluation and reporting will be critical to informing our evolving response to the national opioid crisis. To date, we have approved these SUD demonstration projects for five States—Louisiana, New Jersey, Utah, Indiana, and Kentucky.

Addendum: Since the time of this hearing, CMS has approved a demonstration project for a sixth State: Illinois.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN

MEDICATION-ASSISTED TREATMENT

Question. As you know, Medicaid plays a central role in the Nation's efforts to address the opioid epidemic. While all State Medicaid programs cover at least one Food and Drug Administration (FDA)-approved form of MAT, not all States cover all current FDA-approved forms of MAT (methadone, buprenorphine (Suboxone), and naltrexone (Vivatrol)).

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[76] *https://www.ncbi.nlm.nih.gov/pubmed/24500948.*
[77] *https://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-07-11-2014.pdf.*
[78] *https://www.medicaid.gov/federal-policy-guidance/downloads/cib-01-26-2015.pdf.*

while the beneficiary is residing in an IMD, as these States work to improve access to treatment in outpatient settings as well. In addition, we are working with States that operate these demonstrations to establish strong quality of care standards, particularly for residential treatment settings.

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QUALITY MEASURES

Question. Together, Medicaid and the Children's Health Insurance Program (CHIP) provide vital health-care coverage for nearly 80 million low-income Americans, including pregnant women and children, individuals with mental and physical disabilities, and the elderly. However, despite the fact that so many Americans receive their health-care services through these two programs, nobody truly understands the quality of care provided to all enrollees.

Data collection is essential to ensure quality care. The only way to reduce costs, address health-care disparities, or improve quality of care is by gathering and understanding such data. Over the past decade, Congress has prioritized the importance of data collection to measure, compare, and improve the quality of health care for all Americans. Although there is some understanding of the quality of care provided to enrollees in Medicaid health plans, it is time that the same standard applies to all Medicaid enrollees across all delivery systems—fee-for-service, managed-care, and primary-care case management—throughout the country.

Congress took action just a few weeks ago to require States to submit Medicaid and CHIP pediatric quality measures to HHS. Unfortunately, reporting on adult quality measures remains entirely voluntary.

The 2018 Core Set of Adult Health Care Quality measures for Medicaid includes 10 behavioral health measures. How many States consistently report quality data across these measures?

What other measures does CMS have in development to measure quality in behavioral health, specifically substance use disorder that may be added to the adult core set in the future?

Answer. As the single largest payer for mental health services in the United States, Medicaid plays an important role in providing behavioral health care to adults, and monitoring the effectiveness of that care. CMS annually releases information on State progress in reporting the Adult Core Set measures that are reported by at least 25 States and which met internal standards of data quality. Our 2017 measures release includes data from FFY 2016.

For FFY 2016, 41 States voluntarily provided data for the Adult Core Set. Since the release of the Core Set in 2012, the number of States voluntarily reporting at least one measure has increased steadily from 30 States in FFY13, 34 States for FFY14, and 39 States for FFY15. Additionally, the median number of measures reported by States is 17 for FFY16, up from 16 measures for FFY15. In addition, 21 States reported more measures for FFY16 than for FFY15, including two States reporting for the first time.

CMS recognizes the importance of State's abilities to measure the quality of care for Medicaid beneficiaries with substance use disorders (SUD). Of the 33 measures on the 2018 Adult Core Set, four of them specifically focus on SUD. CMS has added to the number of SUD related measures on the Adult Core Set annually for the last 3 years.

- Initiation and Engagement of Alcohol and Other Drug Dependence Treatment (NQF #0004)—on the initial Adult Core Set.

- Use of Opioids at High Dosage in Persons Without Cancer (NQF #2940)—added in 2016.
- Follow-up After Discharge from Emergency Department for Mental Health or Alcohol or Other Drug Dependence (NQF #2605)—added in 2017.
- Concurrent Use of Opioids and Benzodiazepines (PQA)—added in 2018.

MEDICAID SUSPENSION VS. TERMINATION FOR INCARCERATED POPULATIONS

Question. The Medicaid Inmate Exclusion prohibits Medicaid from paying for health-care services for "inmates of a public institution," meaning Medicaid will not pay for health-care services provided to otherwise eligible individuals during incarceration. In order to ensure compliance with this provision—which has been in place since the creation of Medicaid more than 50 years ago—States can either suspend or terminate an individual's Medicaid coverage upon entry into a correctional facility. As of last year, 31 States suspend Medicaid enrollment for either a portion or the entire duration of an inmate's incarceration, and 19 States terminate Medicaid enrollment for inmates.

Terminating Medicaid enrollment during incarceration presents a continuity of care issue, particularly for individuals suffering opioid use disorders. Re-enrolling can take months, becoming a barrier for individuals who need to access mental health care or medication-assisted treatment. Not only can lapsing coverage contribute to recidivism, but it could be a life or death situation, given that inmates are 129 times more likely to die from a drug overdose within the first 2 weeks of release compared to the general population.

Does CMS need additional statutory authority to require States to suspend, rather than terminate, Medicaid coverage for incarcerated individuals?

What is CMS doing to continue to encourage States to suspend, rather than terminate, Medicaid coverage for incarcerated individuals?

How is CMS engaging with States where there are structural or administrative barriers that make suspending Medicaid enrollment more difficult than terminating Medicaid for an inmate and re-enrolling upon community reentry?

In light of the opioid crisis, does CMS possess statistical or anecdotal on the public health impact of suspending Medicaid for inmates?

How does CMS intend to study or evaluate the difference in both access to care and health outcomes in States that suspend Medicaid coverage for inmates compared to those that terminate coverage?

Answer. Facilitating enrollment in Medicaid and supporting access to services following incarceration has the potential to make a significant difference in the health of this population and in eligible individuals' ability to obtain health services that can promote their well-being.

States have the authority to determine Medicaid coverage transitions for incarcerated individuals. CMS welcomes the opportunity to work closely with States to identify ways to improve access to needed health care for individuals returning to the community following incarceration. Increased Federal support is available to assist States with upgrading Medicaid eligibility and enrollment technologies.

We addressed frequently asked questions regarding eligibility and coverage issues for individuals reentering their communities after incarceration in an April 2016 State Health Official letter (SHO #16–007),[79] including how States can facilitate access to Medicaid for eligible individuals before and after time in a correctional institution.

CMS also began facilitating a Learning Collaborative in February 2016 that reviewed Medicaid eligibility rules and enrollment strategies for justice-involved populations. CMS hosted another Learning Collaborative discussion on this issue in August 2017.[80]

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[79] *https://www.medicaid.gov/federal-policy-guidance/downloads/sho16007.pdf.*

[80] *https://www.medicaid.gov/state-resource-center/downloads/mac-learning-collaboratives/justice-involved-populations.pdf.*

IMD EXCLUSION

Question. Only 12 percent of Americans who need substance abuse treatment actually receive it. We need to expand access to care. One way to do this would be to allow adult Medicaid beneficiaries to get help at residential facilities with more than 16 beds. Because of an arcane law—the "IMD Exclusion"—this is currently prohibited. Public health experts and a large bipartisan group of Senators and Governors want to fix this outdated policy, and the President's own Opioid Commission supports it. While States can receive waivers from the 16-bed limit, we need a comprehensive, long-term national solution. I am an original sponsor of the Medicaid CARE Act, the leading bipartisan bill in Congress to provide relief from this arbitrary limit.

How would fixing the IMD Exclusion expand patient access to opioid addiction treatment?

Answer. Current law prohibits Medicaid from making payments for services rendered to Medicaid beneficiaries ages 21 to 64 who are residing in an IMD. Last November, we announced an opportunity for States to apply for section 1115 demonstration projects through a streamlined process for States interested in increasing access to treatment for OUDs and other SUDs by permitting services to be covered in an institution for mental diseases (IMD) as part of a State's comprehensive OUD/SUD strategy. Previously, States seeking to cover services otherwise subject to the exclusion of coverage for beneficiaries residing in an IMD had been required to meet rigid CMS standards concerning operational details for implementation before Medicaid demonstration approvals would be granted.

We are encouraging States to apply for CMS approval of a 5-year demonstration allowing them to receive Federal financial participation for services to treat addiction to opioids or other substances for Medicaid beneficiaries residing in IMDs, including those aged 21 to 64 for whom Medicaid otherwise would not pay for services while the beneficiary is residing in an IMD, as these States work to improve access to treatment in outpatient settings as well. In addition, we are working with States that operate these demonstrations to establish strong quality of care standards, particularly for residential treatment settings. The new policy will allow States to begin to provide better treatment options more quickly while improving the continuum of care over time.

This initiative offers a more flexible, streamlined approach to accelerate States' ability to respond to the national opioid crisis while enhancing States' monitoring and reporting of the impact of any changes implemented through these demonstrations. In addition to being budget neutral, demonstrations must include a rigorous evaluation based on goals and milestones established by CMS. States must also make available on *Medicaid.gov* information on the progress and outcomes of these demonstrations and evaluations so that other States can learn from these programs; this cycle of evaluation and reporting will be critical to informing our evolving response to the national opioid crisis. To date, we have approved these SUD demonstration projects for five States—Louisiana, New Jersey, Utah, Indiana, and Kentucky.

Addendum: Since the time of this hearing, CMS has approved a demonstration project for a sixth State: Illinois.

PRESIDENT'S COMMISSION ON COMBATING DRUG ADDICTION AND THE OPIOID CRISIS

Question. Nearly 6 months ago, the President's Commission on Combating Drug Addiction and the Opioid Crisis submitted a report on the crisis, which included a long list of recommendations. Many of these recommendations were specific to CMS and other entities under the purview of both Adm. Giroir and Ms. Brandt.

Please provide an update on your respective agency's and program's status in implementing the recommendations included in the Commission's report.

Recognizing that some of the recommendations would require congressional action, of the other recommendations included in the report, does CMS plan on implementing any of the proposals which do not require additional statutory authority?

Answer. CMS is always looking to improve our programs, and the opioid epidemic is a top priority for this administration. HHS has a five-part strategy to address the epidemic, which involves: improving access to prevention, treatment, and recovery services, including medication-assisted therapies; targeting availability and distribution of overdose-reversing drugs; strengthening our understanding of the epidemic

through better public health data and reporting; supporting cutting edge research on pain and addiction; and advancing better practices for pain management.

As a payer, CMS plays an important part in this plan by working to make sure providers are providing the right services to the right patients at the right time. Beneficiaries are our top priority across all of our programs, and we work hard to protect their safety and put them in the driver's seat of their care. CMS is keenly focused on three areas—preventing and reducing opioid use disorders by promoting CDC guidelines for opioid prescriptions and encouraging non-opioid pain treatments; increasing access to evidence-based treatment for opioid use disorder; and leveraging data to target prevention and treatment efforts and to support fraud, waste, and abuse detection efforts. Our efforts align with many of the recommendations outlined in the President's commission, as well as with input from various stakeholders.

CMS is actively engaged in addressing the opioid epidemic and is committed to implementing effective tools across our programs. CMS will continue to work with beneficiary and advocacy groups, health plans, States, our Federal and State partners, and other interested stakeholders to address this devastating epidemic. This epidemic is devastating families and communities, and CMS is committed to using all the tools at its disposal to take meaningful action to stem this tide.

The HHS Opioid Strategy is well aligned with the Commission's recommendations and much work is underway that is consistent with the vision of the Commission. Following are some examples.

Prevention Through a Public Awareness Campaign—On June 7th, the White House launched the first phase of its anti-opioid media campaign, a part of the administration's efforts to address the opioid crisis. The first ads target young adults, warning them of the dangers of opioid addiction, and it includes four television and digital ads featuring true stories of young people who have struggled with addiction. The goal of the campaign is to show the dangers of misusing opioids and how quickly one can become addicted. The effort is a partnership among the White House and the Ad Council, the organization behind many of the government's public service announcements, including the Truth Initiative, a national anti-tobacco campaign. The campaign is funded largely from donations, including free media time from NBC Universal, Turner Broadcasting, Facebook, YouTube, Google and the Ad Council. ONDCP is providing $380,000 to the campaign.

Improving Access to Prevention, Treatment, and Support Services

- *SAMHSA's State Targeted Response to the Opioid Crisis (STR) Grant Program*—On April 18th, SAMHSA released the second year of funding to States and territories totaling $485 million. States can use the funds to focus on areas of greatest need, including increasing access to treatment, supporting prevention and recovery services, and paying for naloxone. HHS has been criticized for the formula on the grounds that it does not target funding to the hardest hit States. SAMHSA issued a supplemental STR grant FOA targeted to the hardest hit States and in March 2018, SAMHSA awarded grants totaling $1 million to New Hampshire, Massachusetts, and West Virginia. The 2018 omnibus provides for an additional $1 billion for a new State Opioid Response Grant. Subsequent to the date of the hearing, SAMHSA released funding opportunity announcements (FOAs) that include the required 15 percent set aside for hardest hit States and $50 million for tribes.
- *Programs Targeting Medication-Assisted Treatment (MAT)*—SAMHSA has several initiatives aimed at advancing the utilization of MAT, which is proven effective but is highly underutilized. The Medication Assisted Treatment for Prescription Drug and Opioid Addiction (MAT–PDOA) program aims to increase the number of people receiving MAT for their opioid use disorders, leading to a decrease in illicit opioid use and prescription opioid misuse. In May 2018, SAMHSA announced a new Funding Opportunity Announcement for States, political subdivisions within States, and public and private nonprofit organizations in States with the highest rates of primary treatment admissions for heroin and opioids per capita.
- *Pregnant and Postpartum Women (PPW)*—The PPW Program expands the availability of comprehensive, substance use disorder treatment, prevention, and recovery support services for PPW, their minor children, and other family members. Under this CARA program, grantees are encouraged to ensure access to MAT for opioid addiction, which has been shown to improve outcomes. In FY 2018, SAMHSA will fund three new 3-year PPW Pilot grants, totaling

$3.2 million annually and three continuing PPW Pilot grants also at $3.2 million annually. Additionally, in FY 2018, SAMHSA will fund 18 new 5-year residential PPW grants, totaling $9.5 million annually and 19 continuing PPW 5-year residential grants, totaling $10.7 million annually.

- *Offender Reentry Program (ORP)*—The purpose of this program is to expand substance use disorder treatment and related recovery and reentry services to sentenced adult offenders/ex-offenders who are returning to their families and communities from incarceration in State and local facilities, including prisons, jails, or detention centers. Grant recipients receiving new grants in FY 2018 may use up to 35 percent of their annual grant award to pay for FDA-approved medications for the treatment of substance use disorders (*e.g.,* methadone, buprenorphine products including buprenorphine/naloxone combination formulations and buprenorphine mono-product formulations, naltrexone products including extended-release and oral formulations, disulfiram, and acamprosate calcium) when the client has no other source of funds to do so. In FY 2018, SAMHSA will fund 21 new 5-year Offender Reentry Program grants, totaling $8.8 million annually.
- *Adult Treatment Drug Courts, Adult Tribal Healing to Wellness Courts, and Family Treatment Drug Courts*—The purpose of SAMHSA's treatment drug courts is to expand and/or enhance substance use disorder treatment services in existing adult and family "problem solving" courts that use the treatment drug court model to provide substance use disorder (SUD) treatment to persons in drug courts who are identified with SUD. Grant recipients receiving new grants in FY 2018 may use up to 35 percent of the annual grant award to pay for Food and Drug Administration (FDA)-approved medications (*e.g.,* methadone, buprenorphine, naltrexone, disulfiram, acamprosate calcium,) when the client has no other source of funds to do so. Grantees must affirm that the treatment drug court(s) will not deny access to the program to any eligible client for his/her use of FDA-approved medications for SUD. In FY 2018, SAMHSA will fund 70 new 5-year Adult Treatment Drug Court grants and three Adult Healing to Wellness Court grants, totaling $32.1 million annually. In FY 2018, SAMHSA will also fund 13 new 5-year Family Treatment Drug Court grants, totaling $5.1 million annually.

Improving Access to Overdose Treatment and the Availability of Overdose-Reversing Drugs

- *Improving Access to Overdose Treatment*—This SAMHSA program, authorized by CARA, provides funds to Federally Qualified Health Centers (FQHC), Opioid Treatment Programs, or practitioners who have a waiver to prescribe buprenorphine to expand access to FDA-approved drugs or devices for emergency treatment of known or suspected opioid overdose. A new Funding Opportunity Announcement was released in April 2018 and grantees will partner with other prescribers at the community level to develop best practices for prescribing and co-prescribing FDA-approved overdose reversal drugs. After developing best practices, the recipients will train other prescribers in key community sectors as well as individuals who support persons at high risk for overdose.
- *Increasing Availability of Naloxone*—SAMHSA has a number of funding streams to expand access to naloxone: States may use their STR funds to purchase and distribute access to naloxone; the Substance Use Block Grants can be used for opioid overdose prevention activities; and SAMHSA has provided $11 million per year in grants to Prevent Prescription Drug/Opioid Overdose Related Deaths. These funds are being used to train first responders on emergency medical care to be rendered in an overdose situation and how to administer naloxone as well as to how to purchase and distribute naloxone.

Research and Development

- *NIH Opioid Research to End the Opioid Crisis*—In April 2018, NIH launched the Helping to End Addiction Long-term (HEAL) Initiative to speed scientific solutions to stem the national opioid public health crisis. The HEAL Initiative will bolster research across NIH to:
  - Prevent addiction through enhanced pain management—NIH will work with partners from the biopharmaceutical industry to develop a data sharing collaborative, new biomarkers for pain, and clinical trials network for testing new pain therapies.

- Improve treatments for opioid misuse and addiction—NIH will support research that can prevent and treat opioid misuse and addiction, and that will help people with OUDs achieve and maintain a meaningful and sustained recovery.

Moving forward, HHS will work with leadership across the Department, our sister agencies, and the White House to continue implementing a robust public health response to the opioid crisis and determine how best to incorporate the Commission's recommendations into our work.

SCREENING FOR SUBSTANCE USE DISORDERS (SUD) IN THE MEDICARE POPULATION

Question. SAMHSA has estimated that more than 1 million adults 65 or older have a *substance use disorder.* This number is only going to grow as more and more baby boomers age into Medicare. It is important that we do not ignore the Medicare population when it comes to this epidemic.

Ms. Brandt, I would like to thank you and your colleagues at CMS for your work on the Medicare Part D patient review and restriction program that Senator Toomey, Senator Portman, and I worked to get in to CARA. Now that the program is being implemented, I look forward to continuing to work with CMS to ensure that beneficiaries who are identified through this program have the right to auto-escalate their appeals.

Unfortunately, we do not do a great job when it comes to screening older Americans for substance use disorders. We don't screen often enough, and screening can be difficult: chronic conditions and other health-care issues like dementia can complicate a screening for potential substance use disorder.

As I understand it, right now individuals are screened for a variety of physical health conditions and also screened for depression during their Welcome to Medicare visit and annual Medicare wellness visits, but these visits do not currently include a screening for substance use disorder and referral to treatment, correct?

Answer. A critical part of tackling this epidemic is making sure that beneficiaries grappling with opioid use disorder have access to the most effective treatment options. Improving the way opioids are prescribed through clinical practice guidelines can ensure patients have access to safer, more effective chronic pain treatment while reducing the risk of opioid use disorder and that is why the CDC issued the CDC Guideline for Prescribing Opioids for Chronic Pain.[81] We hope that physicians are communicating with their patients about medications and medical conditions. In addition to the CDC guidelines, through its networks of health quality experts and clinicians, CMS advocates the sharing of best practices for opioid use disorder screening and treatment.

I am working with a few of my colleagues here on the Finance Committee on legislation to make sure that Medicare does a better job of screening older Americans for potential substance use disorders, both at the time they enter Medicare, and throughout their time in the program.

Question. Would CMS be willing to give us some technical assistance on the best way to make sure seniors receive these important screenings as we develop our legislation?

Answer. CMS is happy to work with members of Congress and their staff, including providing technical assistance on potential legislation. CMS is always looking for ways to improve beneficiary services across our programs, including making sure they have access to appropriate screenings.

EMERGING TECHNOLOGIES AND NEW, NON-ADDICTIVE THERAPIES AND TREATMENTS

Question. As part of the recent Bipartisan Budget Act, Congress provided new funds to both the NIH and FDA to incentivize investment in potential new non-addictive treatments and technologies to manage pain and addiction, as well as new ways to treat addiction. From new, non-addictive pain medications to new technologies in the emerging field of prescription digital therapeutics, there are many innovative products in the pipeline that could help prevent and treat addiction.

In order to ensure these new therapies and technologies get to patients as quickly as possible post-approval, it is critical CMS be ready to evaluate these innovative products and establish coverage policies as quickly as possible.

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[81] *https://www.cdc.gov/drugoverdose/prescribing/guideline.html.*

Does CMS have all the tools necessary to provide coverage for novel treatment options, such as alternative or interventional therapies for pain treatment, new technologies, and new addiction treatments, in an expedited manner as these products come on to the market?

Answer. A critical part of tackling this epidemic is making sure that beneficiaries grappling with opioid use disorder have access to the most effective treatment options. Through its networks of health quality experts and clinicians, CMS advocates the sharing of best practices for opioid use screening and treatment.

Both medicinal and non-medicinal therapeutic alternatives to opioid-based pain medications exist; although Medicare coverage and payment varies. In general, Medicare covers items and services that are "reasonable and necessary." This includes several non-pharmacologic therapies and other non-opioid pharmaceuticals. CMS uses the national and local coverage determination process to evaluate new or promising items and services with respect to Medicare Parts A and B, through well-delineated processes set forth in statute. Those items and services for which evidence demonstrates improvement in health outcomes in the Medicare population are more likely to be coverable, while those items and services for which such evidence is insufficient or lacking warrant further research. Therefore, CMS is playing an important role in expanding access to evidence-supported treatments and services while also specifying the subpopulations of patients who can benefit meaningfully from their use. CMS collaborates with research-focused HHS agencies, such as the National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ), who can concentrate research resources on these need areas.

Question. What plans does CMS have in place to ensure the agency is able to act quickly to cover and reimburse for these new technologies and treatments to ensure patient access?

Answer. Since 2010, the FDA–CMS Parallel Review program has been a collaborative effort intended to reduce the time between FDA marketing authorization and a CMS national coverage determination. This pathway is distinct because manufacturers can engage CMS before FDA approval. By the manufacturer engaging FDA and CMS together while under FDA review, a stronger evidentiary base could be developed in a more efficient manner accelerating patient access to innovative medical devices. This program is intended to ensure prompt and efficient patient access to safe and effective and appropriate medical devices for the Medicare population.

Question. What is the current policy around updating the Health Care Common Procedure Coding System (HCPCS) and the National Coverage Determination (NCD) and coverage with evidence development (CED) standards to ensure new therapies, both pharmacological and non-pharmacological? Should the standard practice for updating HCPCS and NCDs need to be updated in light of this epidemic and emerging technologies and treatments?

Answer. There are two levels of HCPCS codes. Level I of the HCPCS is comprised of Common Procedural Terminology (CPT) codes, which are maintained by the American Medical Association. The American Medical Association makes decisions regarding any updates to the CPT codes.

Level II of the HCPCS is used primarily to identify products, supplies, and services not included in the CPT codes. CMS maintains the Level II HCPCS codes, except for the dental codes in the code set, which are maintained and thus updated by the American Dental Association. CMS makes annual updates to the Level II HCPCS code set that may originate internally from CMS or from external requests made by the public. The public has an ongoing opportunity to submit requests to add codes, modify the language used to describe existing codes, or discontinue existing codes. The annual updates allow for the Level II HCPCS code set to be revised for new pharmacological and non-pharmacological therapies, if the criteria for a code set revision are met.

In addition, CMS may alter the Level II HCPCS code set in between the scheduled annual updates by establishing temporary codes. If established, temporary codes are used to address within a short time frame the national program operational needs of a particular insurance sector that are not addressed by an already existing code. As needed by Medicare or other insurers, temporary codes may allow for the Level II HCPCS code set to reflect new therapies for pain management and addiction treatment prior to an annual update, based on national program operating needs.

In terms of coverage of new therapies, Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category). National coverage determinations (NCDs) are made through an evidence-based process, with opportunities for public participation. In some cases, CMS' own research is supplemented by an outside technology assessment and/or consultation with the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC). In the absence of a national coverage policy, an item or service may be covered at the discretion of the Medicare contractors based on a local coverage determination (LCD).

Coverage with Evidence Development (CED) is a paradigm whereby Medicare covers items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data. In making coverage decisions involving CED, CMS decides after a formal review of the medical literature to cover an item or service only in the context of an approved clinical study or when additional clinical data are collected to assess the appropriateness of an item or service for use with a particular beneficiary.

CMMI

Question. What demonstration projects is CMMI currently doing that could help provide alternative models of payment/models of care for individuals struggling with substance abuse disorder or mental health issues and the affiliated provider community?

What projects does CMMI anticipate initiating that could be relevant in light of the addiction epidemic?

Answer. The CMS Center for Medicare and Medicaid Innovation (Innovation Center) maintains a growing portfolio supporting the design and testing of innovative payment and service delivery models. Last fall, we announced that we are setting a new direction for the Innovation Center and will carefully assess how models developed consistent with this new direction can complement what we are learning from the existing models. As part of setting this new direction, CMS sought public input and suggestions on innovative payment and service delivery models focused on behavioral health, including models focused on areas such as opioids and substance use disorder.[82]

CMS received over 1,000 responses to the RFI from a wide variety of individuals and organizations located across the country, including medical societies and associations, health systems, physician groups, and private businesses. The RFI was a critical step in the model design process to ensure stakeholder input was available to help shape new models. Over the coming year, CMS will use the feedback as it works to develop new models, focusing on the eight focus areas outlined in the RFI.

The President's FY 2019 budget includes a proposal for CMS to conduct a demonstration to test the effectiveness of covering comprehensive substance abuse treatment in Medicare. Through this proposal, Medicare would provide bundled reimbursement on a per-week-per-patient basis to health-care providers for methadone treatment or similar MAT and would recognize opioid treatment programs and substance abuse treatment facilities as independent health-care provider types; outpatient counseling would be billed separately as clinically necessary. The model would be allowed to target beneficiaries determined to be at-risk, as defined by the Overutilization Monitoring System, to voluntarily receive comprehensive substance abuse treatment, including MAT and SUD counseling.

TWELVE-MONTH CONTINUOUS ELIGIBILITY IN MEDICAID

Question. According to the Institute for Medicaid Innovation, "while current policymaking efforts are focused on addressing the opioid epidemic in the United States through prevention and treatment, additional efforts are needed to slow the rate of opioid misuse and overdose deaths in pregnant and postpartum women enrolled in the Medicaid program. Additionally, issues regarding churn in this population need to be addressed. Churn is defined as fluctuations in sources of eligibility (between Medicaid and private insurance) as individuals experience income-related changes. Churn leads to disruptions in care, making it difficult for Medicaid managed care plans to provide care coordination and case management when they are unable to retain Medicaid enrollees for extended periods of time. This problem is especially true for Medicaid-eligible pregnant women misusing opioids who become eligible as

[82] *https://innovation.cms.gov/Files/x/newdirection-rfi.pdf.*

a result of two different eligibility pathways: pregnancy (*i.e.,* single episode of care) and income."

States currently have the option to provide children with 12 months of continuous coverage through Medicaid/CHIP, even if the child's family experiences a change in income during the year that would otherwise make the child ineligible. This type of policy helps ensure maintenance of coverage for kids, which results in better health outcomes and continuity of care at a modest cost.

CMS should consider providing States with similar flexibility for adults in Medicaid, particularly those struggling with SUD who may churn in and out of Medicaid coverage at a rate higher than the average Medicaid population, disrupting their potential for recovery. This is especially important for post-partum women.

Does CMS acknowledge the challenges that churn creates when it comes to providing sustained, uninterrupted treatment for chronic conditions, including opioid use disorder? What are the unintended consequences for individuals receiving treatment who churn in and out of Medicaid coverage?

What policies currently exist to provide States with the flexibility to offer continuous coverage to adults, particularly those struggling with substance use disorder or mental health diagnoses, in Medicaid?

Answer. CMS is committed to making sure the right patient is getting the right treatment in the right setting. In 2017, CMS issued guidance describing additional flexibilities to help States improve access to and improve the quality of substance use disorder treatment through Medicaid section 1115 demonstrations. States need the flexibility to operate their Medicaid programs in the way that best meets their needs. CMS wants to work with States to help them share best practices and offer better guidance, and we are interested in exploring important market issues such as churn within the Medicaid program.

REEVALUATING E&M CODES

Question. As you both know, the primary care workforce plays a critical role in addressing the opioid epidemic by offering a full range of services from initial screening for substance use disorder to helping coordinate or provide addiction treatment services.

Unfortunately, primary care providers are facing a growing workforce shortage, due in part to problematic clinician reimbursement evaluation and management (E/M) codes, which do not accurately value or describe cognitive (non-procedural) services.

Does CMS currently collect data on E/M code utilization? How often is this data analyzed to reevaluate reimbursement and update the code set?

Answer. CMS previously has acknowledged the limitations of the current E/M code set. The agency expects to continue to work on the structure and valuation of the E/M code set with stakeholders in future years, although it is immediately focused on revision of the current E/M documentation guidelines in order to reduce unnecessary administrative burden. In addition, the Physician and Other Supplier Public Use File (Physician and Other Supplier PUF) provides information on services and procedures provided to Medicare beneficiaries by physicians and other health-care professionals. The Physician and Other Supplier PUF contains information on utilization, payment (allowed amount and Medicare payment), and submitted charges organized by National Provider Identifier (NPI), Health Care Common Procedure Coding System (HCPCS) code, and place of service. This PUF is based on information from CMS administrative claims data for Medicare beneficiaries enrolled in the fee-for-service program.

CMS is currently undergoing a study to redefine and revalue codes associated with global surgical packages.

Question. Does CMS have plans to reevaluate all E/M codes to ensure the physician fee schedule maintains adequate incentives and value for screening for substance use disorder in the primary care setting, and offering integrated primary and behavioral health care?

Answer. CMS previously has acknowledged the general limitations of the current E/M code set. The agency expects to continue to work on the structure and valuation of the E/M code set with stakeholders in future years, although it is immediately focused on revision of the current E/M documentation guidelines in order to reduce unnecessary administrative burden.

FAMILY FIRST PREVENTION SERVICES ACT IMPLEMENTATION

State Engagement

Question. As you are aware, Family First Prevention Services Act (FFPSA) implementation will be a large systemic change for many States, particularly States that have utilized IV–E waivers. There is understandable anxiety and numerous questions regarding the transition to FFPSA.

Ohio is a IV–E waiver State, and the State has had notable success utilizing evidence-based programs and promising prevention practices aimed at mitigating the trauma experienced by children and reducing the number of placement days in care. HHS itself has acknowledged that Ohio's targeted use of flexible funds for family preservation efforts has promoted improved outcomes. I want to be sure that HHS knows of the success Ohio has in administering prevention programs, and I feel that it is imperative that, in transitioning to FFPSA, HHS strive to help States—like Ohio—build upon successful prevention programs already operated in those States.

HHS is in the process of developing guidance on practice criteria for prevention programs under FFPSA and will issue that guidance to States by October 1st of this year. As HHS develops the guidance, I think it is important for HHS to engage with States that have been providing prevention services—particularly States like Ohio, that have had success with such programs.

How will HHS engage with States in developing guidance on practice criteria for prevention programs?

Will HHS hold any meetings with Ohio officials to discuss prevention programs that are provided in the State?

Answer. As the Secretary develops criteria that interventions must meet in order to receive funding under the title IV–E prevention services program, HHS will be opening the conversation up for public comment to allow for States and others to submit feedback. Once the criteria are established, we intend to take an equally broad approach for identifying interventions that meet the criteria. The vendor that operates the clearinghouse will assess interventions for inclusion in the clearinghouse and elevation within the levels of evidence on an ongoing basis. We intend to issue instructions to States and tribes on what must be included in plans submitted to operate a title IV–E prevention services program in conjunction with publication of the criteria for allowable interventions.

State Flexibility

Question. States have varying factors to consider in addressing child welfare, including the specific needs of the community, available resources, State laws and regulations, etc. Therefore, it is important that States have some flexibility to be able to tailor prevention programs to the specific and sometimes unique conditions present in communities.

Will HHS guidance include flexibility to allow for prevention programs to be tailored to meet local needs?

Answer. As you know, the statute requires the Secretary to develop criteria that interventions must meet in order to receive funding under the title IV–E prevention services program. Over the course of the next few months, ACF will consult broadly across HHS and the field in the development of those criteria. Once the criteria are established, ACF will take an equally broad approach for identifying interventions that meet the criteria, including interventions related to opioid use disorder.

Transition

Question. As you know, the IV–E waivers expire at the end of FY 2019 and recent projections seem to show that CBO does not view the waivers as cost neutral to the Federal Government. Therefore, their expiration will result in a loss of child welfare funds to Ohio and other States (and presumably, should Congress consider an extension, such an extension would be very costly to the Federal Government).

As Congress considers the FY 2019 and FY 2020 appropriations bills, are there steps that can be taken to ensure States like Ohio have adequate resources to adjust to the new system under Family First so that States do not face the cliff effect of an immediate loss in funding?

Answer. In the President's budget proposal, ACF proposed to create a funding option for title IV–E agencies to utilize the title IV–E foster care maintenance payments program more flexibly, including payments for associated administration, but

excluding costs for training and systems. Title IV–E agencies could use the flexible funding option for any of the purposes or services under titles IV–B and IV–E. Providing States and tribes the ability to utilize title IV–E funds for specified time-limited prevention services for a certain population through Family First, along with the flexible funding option proposed in the President's budget should provide States and tribes with the flexibility needed to better target Federal funds towards successful prevention and other services to the children and families they serve, while reducing the need for States to spend their funds complying with overly prescriptive IV–E plan requirements. This could help address State concerns about potential loss of Federal funding.

QUESTIONS SUBMITTED BY HON. MARK R. WARNER

Question. Access to timely and comprehensive substance use disorder treatment is critical in combating opioid use disorder. Unfortunately, access to qualified medical professionals can often be limited and difficult to access in areas that need it most. Recently, my colleagues and I worked on legislation to expand the use of telehealth, especially in Medicare, in our CHRONIC Care Act. I believe there is merit to expanding the use of telehealth to combat opioid use disorder as well.

If Congress were to give the Centers for Medicare and Medicaid Services (CMS) more authority to waive existing geographic and originating site restrictions—specifically for substance use disorders—could that help reduce wait times and increase access to treatment for individuals with substance use disorders?

Answer. CMS believes that telehealth can be an important tool in our efforts to fight this epidemic. Expanding the use of telehealth is a priority of CMS Administrator Verma and CMS has been looking at ways to expand the use of telehealth, particularly for rural areas. CMS looks forward to working with Congress to identify ways we can further expand access to telehealth services within Medicare.

Question. Does the Centers for Medicare and Medicaid Services (CMS) have existing plans to implement telehealth demonstration programs that could expand access to substance use disorder treatment?

Answer. CMS believes that telehealth can be an important tool in our efforts to fight this epidemic. Expanding the use of telehealth is a priority of CMS Administrator Verma and CMS has been looking at ways to expand the use of telehealth, particularly for rural areas. CMS is actively exploring potential models focused on opioids and substance use disorder.

Question. What other policy changes might Congress consider to increase access to substance use disorder treatment via telehealth?

Answer. Currently, telehealth services may be furnished to a Medicare beneficiary at an originating site meeting statutory requirements by a physician or other practitioner authorized by statute at a distant site. CMS is expanding the services that can be provided as Medicare telehealth services and reducing the administrative burden for health-care providers to bill for these services. Improving access to telehealth services reflects CMS's work to modernize Medicare payments to promote patient-centered innovations.

This administration is committed to expanding opportunities within telehealth, and CMS looks forward to working with Congress to identify ways we can further expand access to telehealth services within Medicare.

Question. Recently, the United States Surgeon General recommended that individuals taking a high dose of opioids know how to use naloxone and keep it within reach. I am aware that CMS is already trying to increase the availability of naloxone by requiring it be on Medicare Part D formularies and by working with State Medicaid programs to ensure they improve access.

Virginia has been a national leader in naloxone access. In March 2017, the Virginia Board of Medicine implemented rules that now require co-prescribing of naloxone for certain patients prescribed a high-dose opioid or where other factors may place them at a higher risk for overdose. The Department of Veterans Affairs has taken similar action.

These policy changes have increased the availability of naloxone, and initial data indicates it may actually be decreasing opioid utilization and significantly reducing opioid-related emergency room visits.

Has CMS conducted an evaluation of policies similar to the Department of Veterans Affairs or Virginia's that would require a co-prescription of an opioid overdose reversal drug when a patient receives a high-dose or high-risk opioid prescription?

If not, would CMS consider evaluating these policies and whether expanding them more broadly could save lives and help reduce opioid use disorder?

Answer. CMS is promoting improved access to the opioid overdose reversal drug naloxone. For example, we require that naloxone appear on all Medicare Part D formularies. In addition, Medicaid programs in a number of States include forms of naloxone on their Medicaid Preferred Drug Lists. CMS has also issued guidance to States on improving access to naloxone. States can offer training in overdose prevention and response for providers and members of the community, including family members and friends of opioid users.

CMS is always looking for ways to improve our programs, including increasing access to naloxone for beneficiaries at risk of an opioid overdose. We look forward to working with stakeholders to share best practices and gain valuable insight into ways we can further address the opioid epidemic.

Question. On April 1, 2017, Virginia implemented the Addiction and Recovery Treatment Services (ARTS) program, and the initial results have demonstrated success. The Commonwealth has been able to increase treatment options for individuals with substance use disorder and potentially bring down the long term costs associated with the opioid epidemic. The program did this by implementing several new rules and regulations including: enhancing reimbursement for rates for substance use disorder treatment providers and using clinically recommended criteria to increase provider qualifications and payment for evidence-based treatments.

A Virginia Commonwealth University report on the first 9 months of the program found a substantial increase in the number of providers and facilities providing addiction treatment, a 64 percent increase in treatment rates for Medicaid enrollees with a substance use disorder and a 31 percent decrease in costly emergency room visits related to opioid use disorders.

I do believe it makes sense to pay treatment providers more when we have evidence their work can save lives and save money down the road. We have to make long-term investments in this problem.

How is CMS working to take successful models like the Virginia ARTS program and either scaling them up into national programs or encouraging them as models other States should replicate?

Answer. Under the demonstration authority granted by section 1115 of the Social Security Act, CMS can waive certain Federal requirements and pay Federal matching funds for certain expenditures that otherwise would not be matchable so that States can test new or existing ways to deliver and pay for health-care services in Medicaid. Virginia's ARTS program is operating under such an 1115 demonstration project. CMS is committed to sharing best practices and encourages other States to look into whether a demonstration project would meet the needs of their residents.

We are encouraging States to apply for CMS approval of a 5-year demonstration allowing them to receive Federal financial participation for services to treat addiction to opioids or other substances for Medicaid beneficiaries residing in IMDs, including those aged 21 to 64 for whom Medicaid otherwise would not pay for services while the beneficiary is residing in an IMD, as these States work to improve access to treatment in outpatient settings as well. In addition, we are working with States that operate these demonstrations to establish strong quality of care standards, particularly for residential treatment settings.

This initiative offers a more flexible, streamlined approach to accelerate States' ability to respond to the national opioid crisis while enhancing States' monitoring and reporting of the impact of any changes implemented through these demonstrations. In addition to being budget neutral, demonstrations must include a rigorous evaluation based on goals and milestones established by CMS. States must also make available on *Medicaid.gov* information on the progress and outcomes of these demonstrations and evaluations so that other States can learn from these programs; this cycle of evaluation and reporting will be critical to informing our evolving response to the national opioid crisis. To date, we have approved these SUD demonstration projects for five States: Louisiana, New Jersey, Utah, Indiana, and Kentucky.

To further support this initiative, throughout 2018, the Medicaid Innovation Accelerator Program (IAP) will be available to States that would benefit from strategic design support related to improving their treatment delivery systems. The IAP provides States with access to national learning opportunities and technical expert resources, including strategic design support to States planning targeted addiction treatment delivery system reforms and developing 1115 proposals. In addition, CMS is available to provide technical assistance to States on how to meet Federal transparency requirements as well as to preview States' draft 1115 proposals and public notice documentation to help ensure States successfully meet Federal requirements.

Addendum: Since the time of this hearing, CMS has approved an additional demonstration project for a sixth State: Illinois.

Question. How can we better align CMS reimbursement rates to increase the number of substance use disorder treatment providers?

Answer. A critical part of tackling this epidemic is making sure that beneficiaries grappling with substance use disorder have access to the most effective treatment options. As a payer, CMS plays an important part in this plan by working to make sure providers are providing the right services to the right patients at the right time. CMS recently made changes to the Medicare Physician Fee Schedule that help support the fight against the opioid epidemic, such as establishing separate coding and payment for the insertion and removal of buprenorphine implants, a key drug used in medication-assisted treatment for opioid addiction, and improving payment for office-based behavioral health services. CMS continues to evaluate reimbursement to support opioid use disorder treatment efforts.

Question. Naloxone is critical in combating the opioid epidemic, and I believe we need to do everything we can to make sure this product is available at an affordable cost.

As I understand it, there are some manufacturers that—given the scope of this epidemic—are willing to and have been donating their products at no-cost to nonprofits, first responders and others that are on the front lines.

Has CMS been working directly with manufacturers to facilitate the affordable availability of naloxone to communities in need? If so, how?

Has CMS worked specifically with manufacturers that have been willing to donate their products for free? If not, would CMS be willing to consider such a voluntary partnership?

Answer. CMS is promoting improved access to the opioid overdose reversal drug naloxone. For example, we require that naloxone appear on all Medicare Part D formularies. In addition, Medicaid programs in a number of States include forms of naloxone on their Medicaid Preferred Drug Lists. CMS has also issued guidance to States on improving access to naloxone. States can offer training in overdose prevention and response for providers and members of the community, including family members and friends of opioid users.

CMS is always looking for ways to improve our programs, including increasing access to naloxone for beneficiaries at risk of an opioid overdose. The President's FY 2019 budget includes several proposals aimed at lowering the price of prescriptions, including a proposal that would establish a new Medicaid demonstration authority to allow up to five States more flexibility in negotiating prices with manufacturers.

Question. Existing Federal rules can often serve as a barrier to treatment providers looking to better serve their patients *and* can be dangerous to a patient in cases where, for example, a physician prescribes an opioid to an individual with an unknown existing substance use disorder. If that physician had prior access to the patient's substance use and behavioral health records they may not have prescribed an opioid.

This stands in contrast to other integrated approaches to health care that are governed under the Health Insurance Portability and Accountability Act (HIPAA) and can often lead to medical providers needing to get multiple consent forms from a patient in order to access and appropriately share their substance use records.

How can we fix this and allow medical professionals to appropriately share a patients substance use records without jeopardizing patient privacy?

Answer. Part 2, the Federal regulation governing confidentiality of substance use disorder patient information, and its governing statute, 42 U.S.C. 290dd–2 permit sharing of a patient's substance use disorder patient records during a bona fide

medical emergency when prior patient consent cannot be obtained, such as a known or suspected drug overdose. A Part 2 program also may disclose information needed by medical providers to respond to that emergency (42 CFR § 2.51—Medical emergencies). Moreover, many general medical facilities such as hospital emergency rooms treating overdoses most likely would not meet the definition of a Part 2 program and therefore would not be barred from sharing information with family members or other medical providers during an emergency, assuming such action would not conflict with other applicable confidentiality laws.

More broadly, SAMHSA encourages Part 2 programs and patients to discuss how a patient wants their information to be shared and the benefits patients may obtain from integrated care which, in turn, is facilitated by patients consenting to sharing their health-care information with their treating providers (see 42 CFR 2.33). SAMHSA revised Part 2 in January 2018 to permit additional information sharing by lawful holders, including Medicare and Medicaid entities, with contractors, subcontractors, and legal representatives for payment and health-care operations purposes consistent with HIPAA (42 CFR 2.33). SAMHSA's 2017 final rule also permits patients to consent in writing to the use of a general designation to share their Part 2 information with all of their past, current, and/or future treating providers (42 CFR 2.31).

SAMHSA continues to work to provide guidance to Part 2 programs and lawful holders on application of these provisions. Further, patients may share information with non-part 2 providers about their substance use history. This information, as recorded in the record of the non-part 2 provider, is not protected by 42 CFR part 2, but it is protected by HIPAA and is a means by which treating providers can be aware of the patient's history and vulnerabilities related to substances with abuse liability such as opioids or other prescribed medications. This only requires that clinicians ask the appropriate questions and record the patient's answers. SAMHSA will be working to educate providers and clinicians about appropriate interpretation of statutes related to privacy through guidance to the public and funding of a national technical assistance center on this topic.

Question. Should Congress consider revising HIPAA before giving medical professionals greater access to share a patients substance use records?

Answer. At HHS, we take the confidentiality of patient records seriously. It is critical that we aim to protect the rights of individuals with substance use disorders—the rights to privacy, but also the rights to high quality care in a way no different than for others without substance use disorders seeking treatment. While patient privacy is a critical concern, equally important is the need for individuals with substance use disorders to get the safest and most effective treatment possible when they experience medical illnesses. This requires that health-care providers be able to share information and for care to be provided in a coordinated and integrated manner. HHS supports Congress's further consideration of the benefits of aligning part 2 and its governing statute with HIPAA.

Question. I've heard from providers in Virginia that when it comes to reimbursement policies—more often than not—it's in the financial interest of patients and physicians to simply use an opioid as their course of treatment for pain management. This commonly occurs even when another non-opioid alternative might be readily available and clinically appropriate.

How can we do a better job of reviewing and realigning CMS reimbursement rates in a way that provides patients equally affordable opportunities to access non-opioid pain management treatments?

Answer. The opioid crisis cannot be tackled by CMS alone, and that is why we are collaborating with other HHS agencies, such as the FDA, CDC, and NIH, to identify services that need more evidence to support coverage by Medicare and other health plans.

Both medicinal and non-medicinal therapeutic alternatives to opioid-based pain medications exist; although Medicare coverage and payment varies. In general, Medicare covers items and services that are "reasonable and necessary." This includes several non-pharmacologic therapies and other non-opioid pharmaceuticals. CMS uses the national and local coverage determination process to evaluate new or promising items and services with respect to Medicare Parts A and B, through well-delineated processes set forth in statute. Those items and services for which evidence demonstrates improvement in health outcomes in the Medicare population are more likely to be coverable, while those items and services for which such evidence is insufficient or lacking warrant further research.

CMS has partnered with the CDC to develop the Opioid Safety Commitment poster campaign,[83] which promotes the most effective pain management treatments and strategies. This campaign emphasizes patient engagement, clinician counseling regarding opioid alternative pain management strategies, and discussion with patients of the risks and benefits of opioids when opioids are prescribed.

CMS has a number of initiatives underway to increase the use of recommended evidence-based practices for pain management. In addition to the work of the Quality Innovation Network Quality Improvement Organization program, described above, CMS provides outreach regarding best practices and technical assistance through the Transforming Clinical Practice Initiative's (TCPI's) Practice Transformation Networks.[84] TCPI is designed to use peer-based learning networks for information sharing, outreach, and dissemination of evidence-based practices to educate prescribers on safe and appropriate methods of pain treatment. For example, the TCPI Medication Management and Opioid Initiative is mobilizing the existing network of more than 100,000 clinicians into action to address the opioid crisis, generating collaborations with other CMS quality improvement projects, showcasing successful strategies in engaging providers and patients on proper opioid utilization and spreading the successful strategies throughout all CMS communities.

CMS also promotes free educational materials for health-care professionals on CMS programs, policies, and initiatives through the Medicare Learning Network (MLN).[85] The "CDC Guidelines for Prescribing Opioids for Chronic Pain" is featured in the January 12, 2017 [86] MLN Connects newsletter.

Question. Would CMS consider opportunities to test new pilots at the Center's for Medicare and Medicaid Innovation Institute (CMMI)?

Answer. The CMS Center for Medicare and Medicaid Innovation (Innovation Center) maintains a growing portfolio supporting the design and testing of innovative payment and service delivery models. Last fall, we announced that we are setting a new direction for the Innovation Center and will carefully assess how models developed consistent with this new direction can complement what we are learning from the existing models. As part of setting this new direction, CMS sought public input and suggestions on innovative payment and service delivery models focused on behavioral health, including models focused on areas such as opioids and substance use disorder.[87]

CMS received over 1,000 responses to the RFI from a wide variety of individuals and organizations located across the country, including medical societies and associations, health systems, physician groups, and private businesses. The RFI was a critical step in the model design process to ensure stakeholder input was available to help shape new models. Over the coming year CMS will use the feedback as it works to develop new models, focusing on the eight focus areas outlined in the RFI.

The President's FY 2019 budget includes a proposal for CMS to conduct a demonstration to test the effectiveness of covering comprehensive substance abuse treatment in Medicare. Through this proposal, Medicare would provide bundled reimbursement on a per-week-per-patient basis to health-care providers for methadone treatment or similar MAT and would recognize opioid treatment programs and substance abuse treatment facilities as independent health-care provider types; outpatient counseling would be billed separately as clinically necessary. The model would be allowed to target beneficiaries determined to be at-risk, as defined by the Overutilization Monitoring System, to voluntarily receive comprehensive substance abuse treatment, including MAT and SUD counseling.

Question. Medication-Assisted Treatment (MAT) is a clinically recommended treatment course for individuals suffering from opioid use disorder and has proven effective in saving lives and ensuring individuals undergoing treatment for substance use disorder successfully complete their treatment.

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[83] *https://www.cdc.gov/drugoverdose/prescribing/posters.html.*

[84] *https://innovation.cms.gov/initiatives/Transforming-Clinical-Practices/.*

[85] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNGenInfo/Index.html.*

[86] *https://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Provider-Partnership-Email-Archive-Items/2017-01-12-eNews.html?DLPage=7&DLEntries=10&DLSort=0&DLSortDir=descending#_Toc471878721.*

[87] *https://innovation.cms.gov/Files/x/newdirection-rfi.pdf.*

There are significant barriers in place that make it difficult for many individuals to access MAT—including availability of prescribing physicians, burden on physicians to obtain additional training and more.

These barriers are even more prevalent among the young adult and adolescent populations where pediatricians haven't traditionally administered MAT.

What is the existing strategy for ensuring Medication Assisted Treatment is available to young adults and adolescents that are struggling with opioid use disorder?

Answer. Medication-Assisted Therapy (MAT) is a valuable intervention that has been proven to be the most effective treatment for OUD, particularly because it sustains long-term recovery and has been shown to reduce opioid-related morbidity and mortality.[88] To increase access to MAT, CMS requires that Medicare Part D formularies include covered Medicare Part D drugs used for MAT and mandates Medicare Part C coverage of the behavioral health element of MAT services. In addition, CMS issued guidance on best practices in Medicaid for covering MAT in a joint informational bulletin with the Substance Abuse and Mental Health Services Administration (SAMHSA), the CDC, and the National Institute on Drug Abuse.[89] CMS also released an informational bulletin with SAMHSA on coverage of treatment services for youth with SUD.[90]

While Medicaid programs vary greatly by State, all 50 States currently offer some form of MAT. In addition, the President's FY 2019 budget includes a proposal that would require State Medicaid programs to cover all FDA-approved MAT for OUD, including associated counseling and other costs. These up-front investments in expanded MAT treatment are expected to reduce total Medicaid expenditures over time as more individuals recover from OUD; this provision would result in an estimated $865 million is savings over 10 years.

Under an additional proposal in the President's FY 2019 budget, CMS would conduct a demonstration to test the effectiveness of covering comprehensive substance abuse treatment in Medicare. This demonstration could be expanded nation-wide if successful in key metrics, such as reducing opioid-related deaths among beneficiaries, reducing hospitalization for opioid poisoning, and reducing emergency room utilization for opioid-related issues. Through this proposal, Medicare would provide bundled reimbursement on a per-week-per-patient basis to health-care providers for methadone treatment or similar MAT and would recognize opioid treatment programs and substance abuse treatment facilities as independent health-care provider types; outpatient counseling would be billed separately as clinically necessary. The model would be allowed to target beneficiaries determined to be at-risk, as defined by the Overutilization Monitoring System, to voluntarily receive comprehensive substance abuse treatment, including MAT and SUD counseling.

There are three approved medications for the treatment of OUD in adults. Buprenorphine is approved for use starting at age 16, while methadone can be used within certified opioid treatment programs in anyone under age 18, providing that there have been two prior unsuccessful treatments without using any OUD medication in a 12-month period and that there is parental informed consent. Injectable naltrexone is approved for OUD for people age 18 and up.

In addition to the ability to use SAMHSA funds from the State Targeted Response, State Opioid Response, and Tribal Opioid Response grant programs for adolescents and youth in clinical need of MAT, there are other programs relevant to this age group. SAMHSA is funding the provision of MAT for adolescents and young adults with OUD in fiscal year 2018 funding opportunity announcement, TI–18–010, Enhancement and Expansion of Treatment and Recovery Services for Adolescents, Transitional Aged Youth, and their Families. The purpose of this grant program is to enhance and expand comprehensive treatment, early intervention, and recovery support services for adolescents (ages 12–18), transitional aged youth (ages 16–25), and their families/primary caregivers with substance use disorders (SUD) and/or co-occurring substance use and mental disorders.

SAMHSA anticipates making 27 new awards to public and non-profit entities at up to $541,350 per award annually for 5 years. Grant recipients can provide medication as part of their SUD, specifically alcohol use disorder (AUD) and OUD, as part of a comprehensive treatment approach. Up to 10 percent of annual grant funds

[88] *https://www.ncbi.nlm.nih.gov/pubmed/24500948.*
[89] *https://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-07-11-2014.pdf.*
[90] *https://www.medicaid.gov/federal-policy-guidance/downloads/cib-01-26-2015.pdf.*

may be used to pay for Food and Drug Administration (FDA)-approved medications for the treatment of SUDs and/or co-occurring disorders.

QUESTIONS SUBMITTED BY HON. SHELDON WHITEHOUSE

Question. The Ensuring Patient Access and Effective Drug Enforcement Act of 2016 (Pub. L. 114–145) required the Secretary of Health and Human Services to report to Congress on a number of issues, including issues with diversion of controlled substances, how collaboration between law enforcement agencies and the pharmaceutical industry can prevent diversion and abuse of controlled substances, and steps to improve reporting requirements regarding opioid prescriptions. Under the law, HHS was required to produce this report no later than April 19, 2017, over 1 year ago. This report is particularly critical as Congress reevaluates Pub. L. 114–145 and considers changes to make the law more effective.

What is the status of this report?

When can Congress expect the report?

Why is the report over 1 year late?

Answer. The HHS Behavioral Health Coordinating Council Subcommittee on Opioids and Controlled Substances is currently working to finalize the Report required under the Ensuring Patient Access and Effective Drug Enforcement Act of 2016. The Subcommittee has been working with interagency partners such as the Drug Enforcement Administration and the HHS Office of the Inspector General to compile the report. The last phase of the development of the Report is engaging with medical and pharmacy providers and patients, as required in the Act. HHS staff will incorporate the feedback provided by these stakeholders into the Report. The Report will then undergo final review by HHS before being transmitted to the committees of jurisdiction as required in the Act.

Question. As we discussed at the Opioid Listening Session with Senior Counselor Conway and other administration officials, I am interested in an update on the implementation of each provision of the Comprehensive Addiction and Recovery Act of 2016 (Pub. L. 114–198). Please provide an update on which provisions have been fully implemented, and the status of any remaining items that have not yet been fully implemented.

Answer. The Comprehensive Addiction and Recovery Act (CARA) of 2016 provided HHS with a variety of new authorities to continue the Department's implementation of a robust public health response to the opioid crisis. As you are aware, in April 2017, HHS outlined its five-point strategy, which provides the overarching strategy and framework to leverage the expertise and resources of the HHS agencies in a strategic and coordinated effort. The Opioid Strategy is well-aligned with the provisions in CARA, and, to date, HHS has taken significant steps to implement programs that are responsive to the intent of the law. Following are HHS-related provisions that have been implemented within each title.

Title 1 Prevention and Education—

- *Task Force on Pain Management:* On August 25, 2017, HHS established the Pain Management Best Practices Inter-Agency Task Force on Pain Management ("The Task Force"). The first meeting of the Task Force was held on May 31, 2018.
- *Public Awareness Campaign:* On June 7th, the White House launched the first phase of its anti-opioid media campaign, a part of the administration's efforts to address the opioid crisis. The first ads target young adults, warning them of the dangers of opioid addiction, and it includes four television and digital ads featuring true stories of young people who have struggled with addiction. The goal of the campaign is to show the dangers of misusing opioids and how quickly one can become addicted. The effort is a partnership among the White House and the Ad Council, the organization behind many of the government's public service announcements, including the Truth Initiative, a national anti-tobacco campaign. The campaign is funded largely from donations, including free media time from NBC Universal, Turner Broadcasting, Facebook, YouTube, Google and the Ad Council. ONDCP is providing $380,000 to the campaign. In addition, CDC launched its RxAwareness campaign on September 25, 2018. RxAwareness has had a total of 141-million digital impressions and 5.9 million digital interactions since the campaign

went live. All campaign digital assets performed at or above government benchmark for interaction rate, which has remained at or above government benchmark for interaction rate, which has remained steady.

- *Community-Based Coalition Enhancement Grants:* SAMHSA released a funding opportunity announcement (FOA) for awards in FY 2018.
- *FDA Opioid Action Plan:* FDA has consulted with advisory committees on new opioids, including on pediatric issues. In addition, FDA announced its intention to expand its Risk Evaluation and Mitigation Strategies (REMS) to incorporate all opioid analgesics that are intended for use in outpatient settings, including immediate-release formulations. And, FDA revised the associated Blueprint[91] for how providers should be educated about pain management in general, and prescribing opioid analgesics specifically.
- *Improving Access to Opioid Treatment:* In FY 2017, SAMHSA awarded one multi-year grant in the amount of $1 million for 5 years.
- *NIH Opioid Research With Respect to Pain:* NIH launched HEAL, Helping to End Addiction Long-term, to provide scientific solutions to the national opioid crisis and offer new hope for individuals, families, and communities affected by this devastating crisis. NIH has put "all hands on deck" to identify a set of research priorities reflecting urgent unmet needs, areas of promising scientific opportunity, and concrete strategies capable of providing rapid and durable solutions to the opioid crisis.
- *Opioid Overdose Reversal Medication Access:* SAMHSA provides a number of funding streams that can be used to expand access to naloxone. States are able to use State Targeted Response (STR) Opioid Crisis Grants to purchase and distribute naloxone, and some States are also using a portion of their Substance Abuse Prevention and Treatment Block Grants (SABG) funds for opioid overdose prevention activities. SAMHSA is currently providing $11 million per year in Grants to Prevent Prescription Drug/Opioid Overdose Related Deaths to 12 States. These grants are also being used to train first responders on emergency medical care to be rendered in an overdose situation and how to administer naloxone as well as how to purchase and distribute naloxone.

Title II—Law Enforcement and Treatment

- *First Responder Training:* In September 2017, SAMHSA awarded funding for grants authorized by CARA, including almost $45 million over 5 years to grantees in 22 States to provide resources to first responders and treatment providers who work directly with the populations at highest risk for opioid overdose.

Title III—Treatment and Recovery

- *Evidence-Based Prescription Opioid and Heroin Treatment and Interventions:* SAMHSA has several initiatives aimed specifically at advancing the utilization of medication assisted treatment (MAT), which is proven effective but is highly underutilized. SAMHSA's Medication Assisted Treatment for Prescription Drug and Opioid Addiction (MAT–PDOA) program expands MAT access by providing grants to States with the highest rates of treatment admissions for opioid addiction. Twenty-eight States are currently funded by MAT–PDOA, and in September 2017, SAMHSA awarded $35 million dollars over 3 years in additional MAT–PDOA grants to six States.
- *Building Communities of Recovery:* In March 2018, SAMHSA awarded $4.6 million over 3 to 8 years in Building Communities of Recovery (BCOR) program grants. An additional 13 awards are expected to be made in September 2018 for an additional $11.7 million over 3 years.
- *Medication-Assisted Treatment for Recovery From Addiction:* Prior to the passage of CARA, HHS already had the ability to change the maximum patient limit and finalized a rule to allow physicians to prescribe buprenorphine for up to 275 patients if they met the requirements of the regulation. Subsequent to the hearing date, As of July 21, 2018, there are 4,272 physicians that have a waiver to treat up to 275 patients. In addition, the passage of CARA, extended the privilege of prescribing buprenorphine to qualifying nurse practitioners (NPs) and physician assistants (PAs) until October 1, 2021. CARA re-

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

quires that NPs and PAs complete 24 hours of training to be eligible for a prescribing waiver. NPs and PAs who have completed the required training and obtained the DATA-waiver are allowed to treat up to 30 patients during the first year. After 1 year, they can apply to increase their patient limit to 100. As of July 21, 2018, 6,465 NPs (5,825 at the 30-patient limit and 640 at the 100 patient limit) and 1,735 PAs (1,513 at the 30-patient limit and 222 at the 100 patient limit) have received waivers.

Title IV—NA to HHS

Title V—Addiction and Treatment Services for Women, Families, and Veterans

- *Improving Treatment for Pregnant and Postpartum Women:* Under SAMHSA's Pregnant and Postpartum Women's Program (PPW), which serves women with opioid or other substance use disorders who are pregnant and/or newly parenting, grantees are encouraged to ensure access to MAT for opioid addiction. In FY 2018, SAMHSA will fund 18 new 5-year residential PPW grants totaling $9.5 million annually and 19 continuing PPW 5-year residential grants totaling $10.7 million annually. Additionally, SAMHSA will fund three new 3-year PPW Pilot grants totaling $3.2 million annually. The PPW Pilot Program was created under the Comprehensive Addiction and Recovery Act (CARA) of 2016 with the first three grants funded in FY 2017 totaling $3.2 million annually. PPW Pilot grants are awarded to State substance abuse agencies to increase outpatient treatment and recovery support services for substance use disorder, including opioid use disorder, across the continuum of care and promote new approaches and models of service delivery. In FY 2017, SAMHSA began a 3-year PPW cross site evaluation to examine the effectiveness of the PPW Pilot Program. The evaluation results will be used broadly to improve the collective understanding about effective components of the continuum of care for pregnant and postpartum women with a primary diagnosis of a substance use disorder, including whether the PPW Pilot Program is an effective approach to increase access to the use of medication-assisted treatment.
- *Infant Plan of Safe Care:* Since the passage of CARA, the Children's Bureau in the Administration for Children and Families (ACF) has taken a number of steps to inform States of steps they must take to comply with the updated Child Abuse Prevention Treatment Act (CAPTA) requirements and to share best practices to guide their implementation of the updated requirement. Steps included an Informational Memorandum (IM) (ACF–CB–IM–16–05) to inform States of amendments to CAPTA; a Program Instruction (PI) (ACYF–CB–PI–17–02) to provide guidance to States on implementing new CAPTA provisions added by CARA relating to infants affected by substance abuse; and another Program Instruction (ACYF–CB–PI–17–05). The SAMHSA–ACF funded National Center on Substance Abuse and Child Welfare (NCSACW) is providing technical assistance to States on development and implementation of the Plans of Safe Care.

Title VI—Incentivizing State Comprehensive Initiatives to Address Prescription Opioid Abuse

- *State Demonstration Grants for Comprehensive Abuse Response:* This provision required HHS to award grants to States to establish and implement a comprehensive State and local response including education, PDMP, treatment and overdose death prevention. This provision is similar to the Opioid State Targeted Response grant program authorized by the 21st Century Cures Act and Congress appropriated funding for that program at $500 million in both FY 2017 and FY 2018. States can use the funds to focus on areas of greatest need, including increasing access to treatment, supporting prevention and recovery services, and paying for naloxone. SAMHSA issued a supplemental STR grant FOA targeted to the hardest hit States and in March 2018, SAMHSA awarded grants totaling $1 million to New Hampshire, Massachusetts, and West Virginia. The 2018 omnibus provides for an additional $1 billion for a new State Opioid Response Grant. Subsequent to the hearing date, SAMHSA released funding opportunity announcements (FOA) that include the required 15 percent set aside for hardest hit States and $50 million for tribes.

Title VII—Miscellaneous

- *Grant Accountability and Evaluations:* This provision requires DOJ and HHS to enter into an agreement with the National Academy of Sciences—or another non-governmental entity with expertise in conducting and evaluating research pertaining to opioid use and drawing conclusions about overall opioid use and misuse on the basis of that research—to identify outcomes to be achieved, the metrics by which the performance will be evaluated, and the evaluation of the Comprehensive Opioid Abuse Grant Program. HHS is working actively to meet the intent of the law with respect to working with the National Academy of Sciences.
- *Programs to Prevent Prescription Drug Abuse Under Medicare Parts C and D:* In response to the requirements under section 704 of CARA. CMS issued a report to Congress (July 2017) on ways to improve the appeals process for Medicare prescription drug coverage under Part D, including an analysis comparing appeals processes under parts C and D. In developing such report, the Secretary was required to solicit feedback on the current appeals process from stakeholders, such as beneficiaries, consumer advocates, plan sponsors, pharmacy benefit managers (PBMs), pharmacists, providers, independent review entity (IRE) evaluators, and pharmaceutical manufacturers. CMS held a special Open Door Forum (ODF) telephone conference on December 20, 2016, to solicit stakeholder feedback on how to make the Part D coverage determination, appeal, and grievance processes more understandable and accessible for Medicare beneficiaries. CMS also collected feedback from stakeholders via email until December 29, 2016. CMS also held a stakeholder listening session on November 14, 2016, to solicit input regarding CMS's implementation of section 704 of CARA.

HHS will continue to work with Congress on any CARA provisions that have not been implemented due to the lack of an appropriation for the specific authorization.

Question. This year, Senator Portman and I introduced the CARA 2.0 Act (S. 2456), which would build on the successes of CARA (Pub. L. 114–198).

Does the administration support CARA 2.0?

Answer. While the administration has not taken a position on this bill, the Department looks forward to working with congressional members on ways to address the opioid crisis and is always available to provide technical assistance, as requested, on pending legislation.

Question. What is the administration's position on increasing funding for the Building Communities of Recovery Program (section 6)?

Answer. The administration supports the Building Communities of Recovery (BCOR) program and increased funding for these activities. The purpose of this program is to mobilize resources within and outside of the recovery community to increase the prevalence and quality of long-term recovery support from substance abuse and addiction. The grants support the development, enhancement, expansion, and delivery of recovery support services as well as promotion of and education about recovery. The BCOR program also supports all pathways to recovery, including abstinence attained with FDA-approved medications. Through participation in BCOR, participants benefit from peer-to-peer services and much needed recovery supports such as assistance with housing, education, employment, parenting, life skills and other supports and services. In addition to the eight BCOR grants funded in FY17, 13 additional BCOR grants will be funded in FY18.

Question. What is the administration's position on the bill's proposed policy changes related to prescription drug monitoring programs (section 13)?

Answer. The use of PDMPs among all providers is a promising State-level intervention to improve opioid prescribing, inform clinical practice, and protect patients at heightened risk of opioid misuse, abuse, and overdose. PDMP data can also provide public health authorities with timely information about prescribing and patient behaviors that contribute to the epidemic. For example, States can use PDMP data to determine "hot spots" or geographic areas within a State with disproportionately higher rates of opioid prescribing and dispensing and therefore target interventions. While PDMPs vary in operation across States, there are system components that can improve PDMP functionality as a public health tool. Those include: universal use among providers and/or their delegates (for example, nurse practitioners or physician assistants) within a State; more timely or real-time data contained within a PDMP; actively managing the PDMP in part by sending proactive reports to pro-

viders to inform prescribing; and ensuring that PDMPs are easy to use and accessible by providers.

The Department is supportive of the use of PDMPs in this manner, as both a public health surveillance and a clinical decision support tool.

From a public health standpoint, data sharing with law enforcement is helpful when done at the aggregate level and with the aim of helping law enforcement partners allocate resources accordingly. For instance, PDMP data can inform where prescribing (and overdose) rates are highest within a given State and therefore in most need of enhanced public health and public safety efforts to reduce risk of overdose.

When PDMP data are shared with licensing boards, best practices indicate that the underlying purpose in doing so should be to engage in increasing awareness, educating, and providing additional trainings to prescribers to share with them the most updated science and data on prescribing, as opposed to for punitive purposes. It often is the case that prescribers may not realize that they are prescribing opioids for pain management at rates disproportionately higher than their peers. Therefore, making providers aware of this reality, through provider outreach, academic detailing, or unsolicited reporting through the PDMP, is often the precipitating event that encourages them to align their prescribing with clinical best practices.

Question. As you know, the $6 billion for opioid response activities appropriated in the bipartisan budget agreement will flow through multiple departments and multiple agencies within those departments. Who is the best point of contact in the administration to help State and local agencies and other organizations understand and take advantage of new grant funding opportunities arising from the bipartisan budget agreement?

Answer. State and local agencies and other organizations that want information on current and new grant funding opportunities related to the opioid crisis may contact the HHS Office of the Assistant Secretary for Legislation (ASL) at 202–690–7627. ASL staff will connect the State or local agency or organization with the appropriate HHS agency, depending on their interest. Here are a links to several agency websites where grant information is posted and updated regularly.

- Substance Abuse and Mental Health Services Administration (SAMHSA): *https://www.samhsa.gov/grants.*
- National Institutes of Health (NIH): *https://www.nih.gov/grants-funding.*
- NIH National Institute on Drug Abuse: *https://www.drugabuse.gov/drugs-abuse/opioids.*
- Food and Drug Administration (FDA): *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm609188.htm.*
- Centers for Disease Control and Prevention (CDC): *https://www.cdc.gov/funding/resources/index.html.*
- Health Resources and Services Administration: *https://www.hrsa.gov/grants/index.html.*
- *Grants.gov* is a central source for information on over 1,000 grant programs and provides access to information on awards: *https://www.grants.gov/.*

Question. The 21st Century Cures Act included $1 billion for States to combat the opioid crisis, but the formula used to allocate that funding accounted for the number of opioid overdose deaths, rather than the rate, disadvantaging small States like Rhode Island. Would the Department consider using the local intensity of the opioid crisis as a criterion for competitive grant proposals, to ensure funds are directed at States that are hit the hardest by this epidemic?

Answer. As you know, Congress has incorporated a 15 percent set-aside for those States who have been hardest hit by the crisis as evidenced by mortality data. And subsequent to the hearing on June 14, 2018, SAMHSA issued a funding opportunity announcement announcing it is accepting applications for FY 2018 State Opioid Response Grants. This program also includes a 15 percent set-aside for the 10 States with the highest mortality rate related to drug overdose deaths.

Question. In March, I sent the attached letter to Chairman Hatch and Ranking Member Wyden describing policies I am interested in as the Finance Committee explores opportunities to improve the Federal response to the opioid crisis. Please summarize CMS's efforts in the following areas, and opportunities CMS has identified that may require legislative action.

Authorizing the CMS Innovation Center to test new care delivery and payment models for behavioral health that include incentive payments to behavioral health providers for adopting electronic health record technology, as outlined in the Improve Access to Behavioral Health Information Technology Act (S. 1732).

Answer. The CMS Center for Medicare and Medicaid Innovation (Innovation Center) maintains a growing portfolio supporting the design and testing of innovative payment and service delivery models. Last fall, we announced that we are setting a new direction for the Innovation Center and will carefully assess how models developed consistent with this new direction can complement what we are learning from the existing models. As part of setting this new direction, CMS sought public input and suggestions on innovative payment and service delivery models focused on behavioral health, including models focused on areas such as opioids and substance use disorder.[92]

CMS received over 1,000 responses to the RFI from a wide variety of individuals and organizations located across the country, including medical societies and associations, health systems, physician groups, and private businesses. The RFI was a critical step in the model design process to ensure stakeholder input was available to help shape new models. Over the coming year CMS will use the feedback as it works to develop new models, focusing on the eight focus areas outlined in the RFI.

In addition, as part of the government-wide MyHealthEData initiative, led by the White House Office of American Innovation, CMS intends to overhaul its Electronic Health Record (EHR) Incentive Programs, since renamed the Promoting Interoperability Programs, to refocus the programs on interoperability and to reduce the time and cost required of providers to comply with the programs' requirements. CMS will continue to collaborate with the Office of the National Coordinator for Health Information Technology (ONC) to improve the clinician experience with their EHRs. The MyHealthEData initiative will work to make clear that patients deserve to not only electronically receive a copy of their entire health record, but also be able to share their data with whomever they want, making the patient the center of the healthcare system. Patients can use their information to actively seek out providers and services that meet their unique health-care needs, have a better understanding of their overall health, prevent disease, and make more informed decisions about their care.

Question. Improving Medicare and Medicaid coverage for medication-assisted treatment, including coverage for methadone under Medicare and requiring coverage of all FDA-approved forms of medication-assisted treatment under Medicaid.

Answer. Medication-Assisted Therapy (MAT) is a valuable intervention that has been proven to be the most effective treatment for OUD, particularly because it sustains long-term recovery and has been shown to reduce opioid-related morbidity and mortality.[93] To increase access to MAT, CMS requires that Medicare Part D formularies include covered Medicare Part D drugs used for MAT and mandates Medicare Part C coverage of the behavioral health element of MAT services. In addition, CMS issued guidance on best practices in Medicaid for covering MAT in a joint informational bulletin with the Substance Abuse and Mental Health Services Administration (SAMHSA), the CDC, and the National Institute on Drug Abuse.[94] CMS also released an informational bulletin with SAMHSA on coverage of treatment services for youth with SUD.[95]

While Medicaid programs vary greatly by State, all 50 States currently offer some form of MAT. In addition, the President's FY 2019 budget includes a proposal that would require State Medicaid programs to cover all FDA-approved MAT for OUD, including associated counseling and other costs. These up-front investments in expanded MAT treatment are expected to reduce total Medicaid expenditures over time as more individuals recover from OUD; this provision would result in an estimated $865 million is savings over 10 years.

Under an additional proposal in the President's FY 2019 budget, CMS would conduct a demonstration to test the effectiveness of covering comprehensive substance abuse treatment in Medicare. Through this proposal, Medicare would provide bundled reimbursement on a per-week-per-patient basis to health-care providers for methadone treatment or similar MAT and would recognize opioid treatment pro-

[92] *https://innovation.cms.gov/Files/x/newdirection-rfi.pdf.*
[93] *https://www.ncbi.nlm.nih.gov/pubmed/24500948.*
[94] *https://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-07-11-2014.pdf.*
[95] *https://www.medicaid.gov/federal-policy-guidance/downloads/cib-01-26-2015.pdf.*

grams and substance abuse treatment facilities as independent health-care provider types; outpatient counseling would be billed separately as clinically necessary. The model would be allowed to target beneficiaries determined to be at-risk, as defined by the Overutilization Monitoring System, to voluntarily receive comprehensive substance abuse treatment, including MAT and SUD counseling.

Question. Ensuring continuity of care for individuals with substance use disorders, including incarcerated individuals.

Answer. CMS is committed to making sure patients get the right care, in the right setting. We are also committed to working with States to find innovative and efficient ways to provide care to those eligible for Medicaid coverage. States need the flexibility to operate their Medicaid programs in the way that best meets their needs. CMS wants to work with States to help them share best practices and offer better guidance around these issues, and look forward to continuing to work with you and the committee on possible solutions.

Question. Supporting certified peer recovery coaches under Medicare, including through alternative payment models.

Answer. CMS is committed to making sure that all Medicare beneficiaries receive the right care in the right setting, and understand that peer recovery coaches can be an important part of the care team. Certified peer recovery coaches are not enrolled as Medicare providers. The Center for Medicare and Medicaid Innovation (Innovation Center) maintains an expanding portfolio supporting the development and testing of innovative health-care payment and service delivery models that can include different types of providers, for example, the Health Care Innovation Awards tested funding for community health workers, another provider not typically enrolled in Medicare. In addition, CMS recently sought public input and suggestions on innovative payment system models that will help promote effective substance abuse treatment programs, including models focused on opioids and substance use disorder.[96]

Question. Loosening restrictions on Medicaid reimbursement for residential substance use treatment facilities.

Answer. Under the demonstration authority granted by section 1115 of the Social Security Act, CMS can waive certain Federal requirements and pay Federal matching funds certain expenditures that otherwise would not be matchable so that States can test new or existing ways to deliver and pay for health-care services in Medicaid. Last November, we announced that we were using this authority to provide for a streamlined process for States interested in designing demonstration projects that increase access to treatment for OUDs and other SUDs by permitting services to be covered in an institution for mental diseases (IMD) as part of a State's comprehensive OUD/SUD strategy. Current law prohibits Medicaid from making payments to IMDs for services rendered to Medicaid beneficiaries ages 21 to 64. Previously, States seeking to cover services otherwise subject to the exclusion of coverage for IMD patients had been required to meet rigid CMS standards concerning operational details for implementation before Medicaid demonstration approvals could be granted. The new policy will allow States to begin to provide better treatment options more quickly while improving the continuum of care over time.

We are encouraging States to apply for CMS approval of a 5-year demonstration allowing them to receive Federal financial participation for services to treat addiction to opioids or other substances for Medicaid beneficiaries residing in IMDs, including those aged 21 to 64 for whom Medicaid otherwise would not pay for services while the beneficiary is residing in an IMD, as these States work to improve access to treatment in outpatient settings as well. In addition, we are working with States that operate these demonstrations to establish strong quality of care standards, particularly for residential treatment settings.

This initiative offers a more flexible, streamlined approach to accelerate States' ability to respond to the national opioid crisis while enhancing States' monitoring and reporting of the impact of any changes implemented through these demonstrations. In addition to being budget neutral, demonstrations must include a rigorous evaluation based on goals and milestones established by CMS. States must also make available on *Medicaid.gov* information on the progress and outcomes of these demonstrations and evaluations so that other States can learn from these programs; this cycle of evaluation and reporting will be critical to informing our evolving re-

[96] *https://innovation.cms.gov/Files/x/newdirection-rfi.pdf.*

sponse to the national opioid crisis. To date, we have approved these SUD demonstration projects for five States: Louisiana, New Jersey, Utah, Indiana, and Kentucky.

To further support this initiative, throughout 2018, the Medicaid Innovation Accelerator Program (IAP) will be available to States that would benefit from strategic design support related to improving their treatment delivery systems. The IAP provides States with access to national learning opportunities and technical expert resources, including strategic design support to States planning targeted addiction treatment delivery system reforms and developing 1115 proposals. In addition, CMS is available to provide technical assistance to States on how to meet Federal transparency requirements as well as to preview States' draft 1115 proposals and public notice documentation to help ensure States successfully meet Federal requirements.

Addendum: Since the time of this hearing, CMS has approved a demonstration project for a sixth State: Illinois.

PREPARED STATEMENT OF HON. ORRIN G. HATCH,
A U.S. SENATOR FROM UTAH

WASHINGTON—Senate Finance Committee Chairman Orrin Hatch (R–Utah) today delivered the following opening statement at the Senate Finance Committee hearing to address opioid and substance-abuse disorders in Medicare, Medicaid, and human services programs.

I'd like to welcome everyone to today's hearing on tackling opioid and substance use disorders in Medicare, Medicaid, and human services programs.

I feel compelled to start with news that we all wish was untrue: more than 60,000 Americans died from a drug overdose in 2016. The majority of these overdoses involved prescription opioids or illicit opioids like heroin or fentanyl. These numbers are more than mere statistics. They represent our constituents, our friends, and our loved ones.

My home State of Utah continues to be hard hit. An alarming number of Utahans have undergone hospital stays and emergency room visits due to opioid overdoses. In 2016 alone, over 450 Utahans died from an opioid overdose.

Americans across the country recognize the challenges posed by the epidemic and are fighting against it. President Trump and Secretary of Health and Human Services Alex Azar have made tackling the opioid epidemic a top priority, and I look forward to working with them to advance policy solutions.

Congress continues to support States and communities in their efforts, and has a record of working in a bipartisan manner to identify solutions that can have a meaningful impact for struggling individuals and families. I was proud to work with Ranking Member Wyden and other members of this committee to lead an effort that makes significant strides to address the opioid epidemic: the Family First Prevention Services Act, enacted in February.

This bill will provide States with access to funds to help families with substance abuse disorders and allow more children to stay safely with their families instead of being placed in foster care.

I'm also pleased that Congress wisely opted to build on the foundation of the Family First Prevention Services Act in the March omnibus law by providing States with additional funds to ramp up these services immediately. This will allow States to develop more evidence-based services that will make a real difference in the lives of families affected by substance use disorders.

The Federal Government cannot solve this crisis alone, but my hope is that we can work together to ensure that our Federal programs, such as Medicare, Medicaid, and human services programs are innovative and responsive to the needs of Americans with chronic pain or opioid use disorders.

Ranking Member Wyden and I have successfully partnered to make numerous recent improvements in health care. We worked together to realize a 10-year extension of the Children's Health Insurance Program. We pushed through a package of policies, known as the CHRONIC Care Act, that improve Medicare for beneficiaries with chronic conditions.

I'd be remiss if I didn't point out that none of these accomplishments would have been possible without the bipartisan engagement of members on this committee.

Identifying policies to evaluate and improve the Federal response to the opioid epidemic will be no different, and the success of these efforts will depend upon bipartisan, committee-wide support.

Today, members will have an opportunity to speak with two of the administration's leading experts on opioid-related policies about how Medicare, Medicaid, and human services programs can adapt and be improved to address the crisis, and what this administration and Congress can do to save lives together.

It is my hope that members take advantage of this hearing and the expertise of our two witnesses to drill down into policies that are likely to garner bipartisan support to help this committee advance its long record of working together collaboratively. Anything less would be a missed opportunity to help individuals, families, and communities across the Nation.

In fact, through outreach to stakeholders and soliciting input from each member of the committee, we've already identified areas of potential bipartisan support. These include the need to evaluate access to and utilization of non-opioid treatment options for managing pain; enhancing data-sharing to promote appropriate health-care interventions and strengthen program integrity; and ensuring evidence-based care is available for patients to identify and treat opioid use disorders.

In closing, my view is that the committee must do all it can to prevent and relieve opioid-related suffering by implementing effective policies in Medicare, Medicaid, and human services programs. We have a unique opportunity to do so in the near term.

We'll hear the ranking member's thoughts on this momentarily, but I do hope that he agrees on the need to work toward bipartisan solutions that would add to the committee's long list of bipartisan health-care accomplishments.

The witnesses will get a proper introduction shortly, but I would like to briefly say a few words before I have to attend a Judiciary Committee markup.

First, I'd like to welcome Dr. Brett P. Giroir. His recent appointment as Secretary Azar's point-person on opioid policy speaks highly of his capabilities. I am grateful that the Finance Committee will be the first congressional committee to hear from him in this capacity.

I am also delighted to have CMS's Kim Brandt appear before the committee today.

Ms. Brandt likely needs no introduction to my fellow committee members, as she served as a senior member of my staff for 6 years before assuming the role of Principal Deputy Administrator for Operations at CMS last year.

I would like to quickly say that, while I certainly gave my blessing to Ms. Brandt before she moved on to a CMS leadership role, it was difficult for me to see Kim go.

I ask that you all indulge a point of personal privilege to allow me to explain why. I no longer get those uplifting visits from her puppy, Sherlock.

And those incredible cookies and other goodies she frequently provided to members and staff are now much harder to come by.

But I am glad to know that Kim is helping to steer the ship at CMS. Truly, it could not be in better hands. As we all know, Kim served me and the other members of this committee—on both sides of the aisle—with great distinction. And I'm glad to have her here today.

SUBMITTED BY HON. DEAN HELLER,
A U.S. SENATOR FROM NEVADA

April 19, 2018

The Honorable Michael Bennet
U.S. Senate
261 Russell Senate Office Building
Washington, DC 20510

The Honorable Dean Heller
U.S. Senate
324 Hart Senate Office Building
Washington, DC 20510

Dear Senators,

We write to thank you for your leadership on the Every Prescription Conveyed Securely Act and urge your colleagues in Congress to support this vital legislation. The

opioid crisis is devastating families and communities from coast to coast. In 2016, more than 42,000 people died as a result of the crisis, more than any year on record according to the Centers for Disease Control and Prevention (CDC).[1]

A number of approaches have been summoned to attack this epidemic, but we believe that the use of already-existing electronic prescribing of controlled substances (EPCS) technology is going underutilized. EPCS reduces opportunities for diversion, as the DEA-approved electronic prescribing process provides more protection from diversion than the current system of paper and oral prescriptions. EPCS prescriptions cannot be altered, cannot be copied, and are electronically trackable. Furthermore, the federal DEA rules for EPCS establish strict security measures, such as two-factor authentication, that reduce the likelihood of fraudulent prescribing. Additionally, electronic prescribing offers new dimensions of safety and security for controlled substance prescriptions.

Over the past few years, the private sector has dramatically improved its use of e-prescribing. Data from self-reported drug abusers suggest that between 3 percent and 9 percent of diverted opioid prescriptions are tied to forged prescriptions.[2] While in 2013, 1 billion prescriptions were e-prescribed, in 2016, 1.6 billion prescriptions were e-prescribed. Yet, despite this vast growth, EPCS is lagging behind broader e-prescribing trends. According to health information network Surescripts, while approximately 90 percent of non-controlled substance prescriptions are e-prescribed, only 15 percent of prescriptions for controlled substances were submitted electronically in 2017.[3]

The Every Prescription Conveyed Securely Act promotes the use of EPCS to help address the opioid crisis by requiring that controlled substances for Medicare beneficiaries are prescribed electronically. This connection will encourage wider adoption of EPCS and help curtail "doctor shopping."

FDA Commissioner, Scott Gottlieb, has indicated that a national e-prescribing system would allow his agency to think more strategically about controlled substances and their REMS program. EPCS could be used to strengthen the tools at the disposal of prescribers and pharmacists and even present a solution to a problem recognized by the Commissioner, interoperability across state lines.[4]

Seven states (New York, Maine, Virginia, Connecticut, North Carolina, Rhode Island, and Arizona) have already passed legislation to mandate EPCS. These states now have a significantly more secure process in place or in the works. The system provides security and convenience from start to finish: from the doctors' electronic prescription-writing process to the pharmacy dispensing medications to the patient.

A national bill such as the one you have proposed would make available the promise of EPCS to the entire country and mark a significant step forward in the fight against the opioid crisis. Your bill would help fill a critical gap in the current prescription drug distribution chain.

The time to act on this common-sense policy is now. EPCS is a bi-partisan solution that the President's Commission on Combating Drug Addiction and the Opioid Epidemic endorsed as a part of its November 2017 recommendations. In the same 2017 report the Commission states that each day 175 deaths are attributed to the opioid epidemic. We can no longer afford to delay the advancement of policies, such as electronic prescribing, that will help curb diversion and abuse rates and inform appropriate interventions.[5]

Thank you for your critical leadership with the Every Prescription Conveyed Securely Act. We encourage your colleagues to cosponsor the bill and ensure its speedy passage in both chambers of Congress.

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[1] Centers for Disease Control and Prevention, "Drug Overdose Death Data, 2016 Deaths," available at: *https://www.cdc.gov/drugoverdose/index.html.*

[2] Rosenblum, Andrew, et al., "Prescription opioid abuse among enrollees into methadone maintenance treatment," *Drug and Alcohol Dependence* 90.1 (2007): 64–71; and Inciardi, James A., et al., "The 'black box' of prescription drug diversion," *Journal of Addictive Diseases* 28.4 (2009): 332–347.

[3] Surescripts, Data Brief, January 2018.

[4] Michael Mezher, "Gottlieb: FDA Looking Beyond Opioids in Overdose Epidemic," Regulatory Affairs Professionals Society, Regulatory Focus™, February 2018, available at: *https://www.raps.org/news-and-articles/news-articles/2018/2/gottlieb-fda-looking-beyond-opioids-in-overdose-e.*

[5] The President's Commission on Combating Drug Addiction and the Opioid Crisis, "Recommendations on Drug Addiction and the Opioid Crisis," November 1, 2017.

Sincerely,

Albertsons Companies
America's Health Insurance Plans
AmerisourceBergen
Association for Accessible Medicines
College of Healthcare Information Management Executives
CVS Health
Express Scripts
Healthcare Information and Management Systems Society
Health IT Now
Imprivata
Magellan Health
National Coalition on Health Care
National Consumers League
National Association of Chain Drug Stores
National Community Pharmacists Association
Prime Therapeutics
Pharmaceutical Care Management Association
Rite Aid
Surescripts
Walgreens

cc:
The Honorable Elizabeth Warren
The Honorable Patrick Toomey

Freedom Caucus

Mark Meadows of North Carolina
Joe Barton of Texas
Rod Blum of Iowa
Jim Bridenstine of Oklahoma
Ken Buck of Colorado
Warren Davidson of Ohio
Scott DesJarlais of Tennessee
Matt Gaetz of Florida
Louie Gohmert of Texas
Morgan Griffith of Virginia
Jody Hice of Georgia
Raúl Labrador of Idaho
Gary Palmer of Alabama
Scott Perry of Pennsylvania
Mark Sanford of South Carolina
Randy Weber of Texas
Justin Amash of Michigan
Andy Biggs of Arizona
Dave Brat of Virginia
Mo Brooks of Alabama
Ted Budd of North Carolina
Ron DeSantis of Florida
Jeff Duncan of South Carolina
Tom Garrett Jr. of Virginia
Paul Gosar of Arizona
Andy Harris of Maryland
Jim Jordan of Ohio
Alex Mooney of West Virginia
Steve Pearce of New Mexico
Bill Posey of Florida
David Schweikert of Arizona
Ted Yoho of Florida

SUBMITTED BY HON. CLAIRE MCCASKILL,
A U.S. SENATOR FROM MISSOURI

United States Senate

Homeland Security and Governmental Affairs Committee, Ranking Member's Office
MINORITY STAFF REPORT

Fueling an Epidemic

Insys Therapeutics and the Systemic Manipulation of Prior Authorization

The opioid epidemic has exacted a staggering human and financial cost in the United States over the past 20 years. Approximately 183,000 Americans died from prescription opioid overdoses between 1999 and 2015, with more than 15,000 Americans dying in 2015 alone.[1] According to the Centers for Disease Control and Prevention (CDC), in 2015 "[t]he age-adjusted rate of drug overdose deaths in the United

[1] Centers for Disease Control and Prevention, "Prescription Opioid Overdose Data" (August 1, 2017) *(www.cdc.gov/drugoverdose/data/overdose.html).*

States in 2015 . . . was more than 2.5 times the rate in 1999."[2] Provisional 2016 statistics from the CDC also show that "[d]rug deaths involving fentanyl more than doubled from 2015 to 2016," and "deaths involving synthetic opioids, mostly fentanyls, have risen to more than 20,000 from 3,000 in just 3 years."[3] In Missouri, the rate of prescription opioid-related inpatient hospitalizations and emergency room visits more than doubled from 187 per 100,000 to 424 per 100,000 between 2005 and 2014.[4] Similarly, Medicare Part D spending on commonly abused opioids increased 165 percent between 2006 and 2015, and one out of three Part D recipients received at least one prescription opioid in 2016 at a cost of $4.1 billion.[5]

In response to this crisis, Senator McCaskill issued wide-ranging requests for documents related to opioid sales and marketing efforts to five major opioid manufacturers.[6] These requests focused on internal estimates concerning the risk of opioid addiction, compliance audits and reports concerning sales and marketing policies, marketing and business plans, materials related to manufacturer payments to physicians and manufacturer-created physician presentations, funding of educational materials targeted to opioid-prescribing physicians, and funding for major pain advocacy groups and other groups. In response, the minority staff has received thousands of pages of internal company documents, including extensive materials from Insys Therapeutics.

Drawing on these documents and other materials, this report provides new information regarding the significant efforts Insys has undertaken to reduce barriers to the prescription of Subsys, its powerful fentanyl product. These efforts include actions to mislead pharmacy benefit managers (PBMs) about the role of Insys in the prior authorization process and the presence of breakthrough cancer pain in potential Subsys patients. An internal Insys document suggests Insys apparently lacked even basic measures to prevent its employees from manipulating the prior authorization process and received clear notice of these deficiencies. In the case of Subsys patient Sarah Fuller, an audio recording reveals that an Insys employee repeatedly misled representatives of Envision Pharmaceutical Services to obtain approval for her prescription. The result, in the case of Ms. Fuller, was death due to allegedly improper and excessive Subsys use.

BACKGROUND ON Insys THERAPEUTICS AND Subsys

Insys Therapeutics was co-founded in 2002 by Dr. John Kapoor, a serial pharmaceutical industry entrepreneur "known for applying aggressive marketing tactics and sharp price increases on older drugs."[7] In 2012, Insys received U.S. Food and Drug Administration (FDA) approval for Subsys, a fentanyl sublingual spray product designed to treat breakthrough cancer pain, and the drug proved incredibly successful financially.[8] Insys had "the best-performing initial public offering in 2013," and, over the next 2 years, revenues tripled and profits rose 45 percent.[9] The value of company stock increased 296 percent between 2013 and 2016.[10]

To prevent the overprescription and abuse of powerful and expensive drugs like Subsys, insurers—often using PBMs—employ a process known as prior authorization. As noted in a Permanent Subcommittee on Investigations report Senator McCaskill and Senator Rob Portman issued on October 4, 2016, the prior authoriza-

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[2] Centers for Disease Control and Prevention, "Drug Overdose Deaths in the United States, 1999–2015" (February 24, 2017) *(www.cdc.gov/nchs/products/databriefs/db273.htm).*

[3] "The First Count of Fentanyl Deaths in 2016: Up 540 Percent in Three Years," *New York Times* (September 2, 2017) *(www.nytimes.com/interactive/2017/09/02/upshot/fentanyldrug-overdose-deaths.html).*

[4] Hospital Industry Data Institute, "Alarming Trends in Hospital Utilization for Opioid Overuse in Missouri" (October 2015) *(www.mhanet.com/mhaimages/HIDIHealthStats/ Opioids_HealthStats_1015.pdf).*

[5] Department of Health and Human Services Office of Inspector General, "High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns" (OEI–02–16–00290) (June 21, 2016); Department of Health and Human Services Office of Inspector General, "Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing" (OEI–02–17–00250) (July 13, 2017).

[6] Letter from Senator Claire McCaskill to Santosh Vetticaden, Interim Chief Executive Officer of Therapeutics, Inc. (March 28, 2017).

[7] "Fentanyl Billionaire Comes Under Fire as Death Toll Mounts From Prescription Opioids," *Wall Street Journal* (November 22, 2016) *(www.wsj.com/articles/fentanylbillionaire-comes-under-fire-as-death-toll-mounts-from-prescription-opioids-1479830968).*

[8] *Id.*

[9] *Id.*

[10] "An Opioid Spray Showered Billionaire John Kapoor in Riches. Now He's Feeling the Pain," *Forbes* (October 4, 2016) *(www.forbes.com/sites/matthewherper/2016/10/04/death-kickbacks-and-a-billionaire-the-story-of-a-dangerous-opioid/).*

tion process "requires additional approval from an insurer or its pharmacy benefit manager before dispensing. . . . Prior authorization policies can also impose 'step therapy,' which requires beneficiaries to first use less expensive medications before moving on to a more expensive approach." [11]

With regard to Insys specifically, recent court filings explain that insurers have "required that a prior authorization be obtained before a claim [can] be submitted for a Subsys® prescription." [12] This process includes "confirmation that the patient had an active cancer diagnosis, was being treated by an opioid (and, thus, was opioid tolerant), and was being prescribed Subsys® to treat breakthrough pain that the other opioid could not eliminate. If any one of those factors was not present, the prior authorization would be denied . . . meaning no reimbursement would be due." [13]

These screening processes reportedly raised significant obstacles to Subsys prescriptions shortly after Insys introduced the drug. According to a criminal indictment filed against former Insys CEO Michael Babich and five other Insys executives, an internal company analysis in November 2012 revealed that insurers and PBMs approved reimbursements for Subsys in only approximately 30 percent of cases.[14]

In response to these challenges, Insys allegedly created a prior authorization unit, known at one point as the Insys Reimbursement Center (IRC), to intervene with PBMs and secure reimbursements between January 2013 and October 2016.[15] Led by an Insys employee named Elizabeth Gurrieri, IRC employees reportedly received significant financial incentives and management pressure—including quotas and group and individual bonuses—to boost the rate of Subsys authorizations.[16] According to Patty Nixon, a former Insys employee, Ms. Gurrieri personally pressured IRC employees to improve the rate of prescription approvals, noting that "Dr. Kapoor's not happy; we have to get these approvals up." [17]

IRC employees allegedly met this demand through a number of techniques. Employees, for example, reportedly falsified medical histories for prospective Subsys patients, "fraudulently assert[ing] that a patient had a cancer diagnosis regardless of the patient's history and regardless of whether the prescriber had prescribed Subsys® for a different diagnosis." [18] In response to increased scrutiny from PBMs and the U.S. Department of Health and Human Services, Insys allegedly developed a canned response to questions concerning whether a potential Subsys patient suffered from breakthrough cancer pain. In this response, Insys employees stated that "[t]he physician is aware that the medication is intended for the management of breakthrough pain in cancer patients [and] [t]he physician is treating the patient for their pain (or breakthrough pain, whichever is applicable)." [19] According to an affidavit filed in support of criminal charges against Ms. Gurrieri, the script "deliberately omitted the word 'cancer' in order to mislead agents of insurers and PBMs." [20]

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[11] Senate Permanent Subcommittee on Investigations, "Combatting the Opioid Epidemic: A Review of Anti-Abuse Efforts in Medicare and Private Health Insurance Systems" (October 4, 2016); *see also* Department of Health and Human Services, Centers for Medicare and Medicaid Services, "How Medicare Prescription Drug Plans and Medicare Advantage Plans With Prescription Drug Coverage (MA–PDs) Use Pharmacies, Formularies, and Common Coverage Rules" (October 2015).

[12] Complaint (July 12, 2017), *Blue Cross of California, Inc., et al. v. Insys Therapeutics, Inc.,* D. Ariz. (No. 2:17 CV 02286).

[13] *Id.*

[14] Indictment (December 6, 2016), *United States v. Babich, et al.,* D. Mass. (No. 1:16 CR 10343).

[15] *See* Complaint (July 12, 2017), *Blue Cross of California, Inc., et al. v. Insys Therapeutics, Inc.,* D. Ariz. (No. 2:17 CV 02286).

[16] "Murder Incorporated: Insys Therapeutics, Part I," Southern Investigative Reporting Foundation (December 3, 2015) *(sirf-online.org/2015/12/03/murder-incorporatedthe-insys-therapeutics-story/); see also* Indictment (December 6, 2016), *United States v. Babich, et al.,* D. Mass. (No. 1:16 CR 10343).

[17] "Fentanyl Billionaire Comes Under Fire as Death Toll Mounts From Prescription Opioids," *Wall Street Journal* (November 22, 2016).

[18] Complaint (July 12, 2017), *Blue Cross of California, Inc., et al. v. Insys Therapeutics, Inc.,* D. Ariz. (No. 2:17 CV 02286).

[19] Indictment (December 6, 2016), *United States v. Babich, et al.,* D. Mass. (No. 1:16 CR 10343).

[20] Affidavit of Special Agent Paul S. Baumrind, Federal Bureau of Investigation, in Support of a Criminal Complaint and Arrest Warrant (October 12, 2016), *United States v. Gurrieri,* D. Mass. (No. 1:17 CR 10083); *see also* Complaint (July 12, 2017), *Blue Cross of California, Inc., et al. v. Insys Therapeutics, Inc.,* D. Ariz. (No. 2:17 CV 02286).

The IRC also allegedly misled PBMs and insurers about the unit's role in facilitating approvals for Subsys.[21] To prevent PBMs from tracing calls back to Insys, for example, the IRC obscured its outgoing phone number on caller ID.[22] When PBMs required a phone number for a return call, Insys employees reportedly provided a 1–800 number manned by another Insys representative—instead of contact information for the prescribing physician.[23] Insys executives also allegedly told IRC employees to claim they were calling "from" a physician's office; later, "employees were instructed to tell agents of insurers and pharmacy benefit managers that they were calling 'on behalf' of a specific doctor, and were 'with' a specific doctor's office."[24]

According to a class action lawsuit, Insys management "was aware that only about 10 percent of prescriptions approved through the Prior Authorization Department were for cancer patients," and an Oregon Department of Justice investigation found that 78 percent of preauthorization forms submitted by Insys on behalf of Oregon patients were for off-label uses.[25] In just one example, an Anthem review of Subsys claims "revealed that 54 percent of members with Subsys® prescriptions that had been reimbursed by Anthem did not actually have an underlying cancer diagnosis," and "[f]or an additional 6 percent of members with reimbursed Subsys® prescriptions, it was unclear whether Subsys® was properly prescribed."[26] Anthem estimates that it "paid over $19 million in reimbursements for Subsys® prescriptions that were not covered by Anthem's plans."[27]

INSYS KNEW ABOUT PROBLEMATIC PRIOR AUTHORIZATION PRACTICES AND FAILED TO TAKE CORRECTIVE ACTION

Internal Insys documents suggest the company knew—more than a year before the events involving Sarah Fuller, described below—that the IRC lacked formal policies or monitoring procedures to ensure proper communication between Insys employees and health-care professionals. Insys, in other words, lacked even basic measures to prevent its employees from manipulating the prior authorization process and received clear notice of these deficiencies.

In an internal presentation dated 2012 and entitled, "2013 Subsys Brand Plan," Insys identified one of six "key strategic imperatives" as "Mitigate Prior Authorization barriers."[28] On a later slide, the company identified several tasks associated with this effort, including "Build internal [prior authorization] assistance infrastructure," "Establish an internal 1–800 reimbursement assistance hotline," and "Educate field force on [prior authorization] process and facilitation."[29]

Additional materials produced by Insys to the minority staff suggest, however, that Insys did not match these efforts with sufficient compliance processes to prevent fraud and was internally aware of the danger of problematic practices. Specifically, on February 18, 2014, Compliance Implementation Services (CIS)—a health-care consultant—issued a draft report to Insys titled, "Insys Call Note, Email, and IRC Verbatim Data Audit Report."[30] The introduction to the report explained that "CIS was approached by Insys's legal representative . . . on behalf of the Board of Directors for Insys to request that CIS support in review of certain communications with Health Care Professionals (HCPs) and Insys employees, and report how they were being documented."[31] Insys had expressed concerns "with respect to communica-

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[21] Indictment (December 6, 2016), *United States v. Babich, et al.,* D. Mass. (No. 1:16 CR 10343).

[22] "Murder Incorporated: Insys Therapeutics, Part I," Southern Investigative Reporting Foundation (December 3, 2015); *see also* Indictment (December 6, 2016), *United States v. Babich, et al.,* D. Mass. (No. 1:16 CR 10343).

[23] "Murder Incorporated: Insys Therapeutics, Part I," Southern Investigative Reporting Foundation (December 3, 2015).

[24] Indictment (December 6, 2016), *United States v. Babich, et al.,* D. Mass. (No. 1:16 CR 10343).

[25] "The Pain Killer: A Drug Company Putting Profits Above Patients," *CNBC* (November 4, 2015) *(www.cnbc.com/2015/11/04/the-deadly-drug-appeal-of-insys-pharmaceuticals.html).*

[26] Complaint (July 12, 2017), *Blue Cross of California, Inc., et al. v. Insys Therapeutics, Inc.,* D. Ariz. (No. 2:17 CV 02286).

[27] *Id.*

[28] Insys Therapeutics, Inc., "2013 Subsys Brand Plan, 2012 Assessment" (2012) (INSYS_HSGAC_00007472) (selected slides attached as Exhibit A).

[29] *Id.* at INSYS_HSGAC_00007473.

[30] Compliance Implementation Services, "Insys Call Note, Email and IRC Verbatim Data Audit Report" (February 18, 2014) (INSYS_HSGAC_00007763) (attached as Exhibit B).

[31] *Id.* at INSYS_HSGAC_00007765.

tions with HCPs by Insys employees being professional in nature and in alignment with Insys approved topics regarding off or on-label promotion of an Insys product, and general adherence to Insys documentation requirements."[32] An additional concern "stemmed from the lack of monitoring of commercial activities where these types of interactions could occur."[33]

Given these issues, Insys requested that CIS review—in part—"the general communications from the Insys Reimbursement Center (IRC) to HCPs, their office staff or representatives, as well as health insurance carriers . . . to ensure they were appropriate in nature with respect to specific uses of Subsys, Insys's commercially marketed product."[34]

According to the findings CIS issued, Insys lacked formal policies governing the actions of its prior authorization unit. For example, "[n]o formal and approved policy on appropriate communications between IRC employees and HCPs, their staff, [health care insurers (HCIs)], or patients exists . . . that governs the support function of obtaining a prior authorization for the use of Subsys."[35] In addition, the report noted that "there were also gaps in formally approved foundational policies, procedures, and [standard operating procedures] with respect to required processes specifically within the IRC."[36] In fact, "[t]he majority of managerial directives, changes to controlled documents or templates, as well as updates or revisions to processes were not formally approved, documented, and disseminated for use, and were sent informally via email blast."[37] Although four informal standard operating procedures existed with regard to IRC functions, these documents "lacked a formal review and approval" and failed to "outline appropriately the actions performed within the IRC."[38]

The report also explains that Insys lacked procedures for auditing interactions between IRC employees and outside entities. According to CIS, "no formal, documented, or detailed processes by which IRC representatives' calls via telephone were audited for proper communication with HCPs or HCIs in any fashion [existed] other than random physical review of a call in a very informal and sporadic manner."[39] More broadly, the report notes that "no formal and documented auditing and monitoring or quality control policy, process, or function exists between IRC employee communications and HCPs, HCP staff, HCIs, or patients."[40]

At the end of the report, CIS provided a number of recommendations concerning IRC activities. First, CIS suggested that IRC management "formally draft and obtain proper review and approval of an IRC specific policy detailing the appropriate communications that should occur while performing the IRC associate job functions and interacting with HCPs."[41] Similarly, IRC management was urged to formally draft IRC-specific standard operating procedures "specific to each job function within the IRC," accompanied by "adequate training and understanding of these processes."[42] To ensure compliance with IRC standards, Insys was also directed to create an electronic system to allow management "to monitor both live and anonymously IRC employee communications both incoming and outgoing."[43] Finally, CIS recommended that Insys institute a formal process for revising and updating "IRC documentation used for patient and HCP data."[44]

The CIS report concluded by noting, in part, that a review of 10 conversations between IRC employees and health-care providers, office staff, and insurance carriers revealed "that all IRC staff was professional in communication, and in no instance was inaccurate or off-label usage of Subsys communicated."[45] Yet within a year of this conclusion, according to the recording transcribed below, an Insys IRC employee appears to have misled a PBM representative regarding the IRC employee's affili-

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[32] *Id.*
[33] *Id.*
[34] *Id.*
[35] *Id.* at INSYS_HSGAC_00007770.
[36] *Id.* at INSYS_HSGAC_00007768.
[37] *Id.* at INSYS_HSGAC_00007771.
[38] *Id.* at INSYS_HSGAC_00007770.
[39] *Id.* at INSYS_HSGAC_00007769.
[40] *Id.* at INSYS_HSGAC_00007771.
[41] *Id.* at INSYS_HSGAC_00007770.
[42] *Id.* at INSYS_HSGAC_00007771.
[43] *Id.*
[44] *Id.*
[45] *Id.* at INSYS_HSGAC_00007772.

ation and the diagnosis applicable to Sarah Fuller. The alleged result, in that case, was death due to inappropriate and excessive Subsys prescriptions.

INSYS REPRESENTATIVE SOUGHT AUTHORIZATION FOR PATIENT SARAH FULLER

As part of its investigation, the minority staff received an audio recording of conversations between an Insys employee and PBM representatives related to a Subsys prescription for Sarah Fuller, who later died from an alleged fentanyl overdose. This recording suggests the IRC employee in question repeatedly misled Envision Pharmaceutical Services to obtain approval for Subsys treatment for Ms. Fuller.

The recording reveals that the Insys employee identified herself as being "with" the office of Ms. Fuller's doctor; in the second conversation, the employee confirms she is "calling from the doctor's office." The Insys employee also states that Subsys is "intended for the management of breakthrough cancer pain" without explicitly claiming that Ms. Fuller suffers from this type of pain. She then states that Ms. Fuller suffers from breakthrough pain—pointedly dropping "cancer" from the description. Later, when asked whether the Subsys prescription will treat "breakthrough cancer pain or not," the Insys employee sidesteps the question by merely stating there is "no code for breakthrough cancer pain." She then reaffirms that the prescription is "for breakthrough pain, yeah."

Background About Sarah Fuller

According to a March 23, 2017, complaint filed in the Superior Court of Middlesex County, NJ, Sarah A. Fuller died from a Subsys overdose on March 25, 2016.[46] In 2014, Ms. Fuller allegedly sought treatment under the care of Dr. Vivienne Matalon of Cherry Hill to manage the medications she took for various health conditions, including fibromyalgia and back pain.[47] During this initial consultation, Ms. Fuller's parents indicated she had previously overcome an addiction to narcotic pain medication; despite this information, Dr. Matalon prescribed OxyContin and Percocet to Ms. Fuller over the next few months.[48] In January 2015, Dr. Matalon, Ms. Fuller, and her father allegedly met with an Insys representative to discuss Subsys as a remedy for Ms. Fuller's neck and back pain.[49] According to the complaint, "[n]either the Insys sales representative nor Dr. Matalon informed Sarah or her father that Subsys was fentanyl and that it was only approved and indicated for patients that were experiencing breakthrough cancer pain from malignant cancer."[50]

Over the next several months, Ms. Fuller received increasing amounts of Subsys on a monthly basis until she was admitted, on October 28, 2015, to a local hospital suffering from "hyper-sedation with hypoxia secondary to narcotics and sedatives."[51] Despite instructions to discontinue Subsys—included in medical records provided to Dr. Matalon—Ms. Fuller received additional Subsys prescriptions, along with prescriptions for Percocet, OxyContin, and Alprazolam, over the next 5 months.[52] On March 25, 2016, Ms. Fuller died "due to an adverse reaction to prescription medications."[53] During the 14-month period in which Ms. Fuller received Subsys treatment, Medicare paid as much as $24,000 per month for the prescriptions.[54]

According to the Centers for Medicare and Medicaid Services (CMS) Open Payments database, Dr. Matalon received almost $600 in payments from Insys in 2015.[55] Although this amount pales in comparison to other payments physicians have received from the company, a clear link exists between even minimal manufacturer payments and physician prescribing practices. A 2016 study published in *JAMA Internal Medicine,* for example, found "a significant association between [a physician] attending a single meal promoting a specific drug, with a mean value of less than $20, and the prescribing of the promoted drug over

[46] Complaint (March 23, 2017), *Fuller v. Matalon, et al.,* Middlesex Cty. Sup. Ct. (No. L1859–17).
[47] *Id.*
[48] *Id.*
[49] *Id.*
[50] *Id.*
[51] *Id.*
[52] *Id.*
[53] *Id.*
[54] *Id.*
[55] Open Payments Data, Centers for Medicare and Medicaid Services, Physician Profile for Vivienne I. Matalon *(https://openpaymentsdata.cms.gov/physician/153888/payment-information)* (accessed July 18, 2017).

therapeutic alternatives."[56] In addition, "additional meals and costlier meals [were] associated with greater increases in prescribing of the promoted drug."[57] ProPublica has similarly found that "doctors who received industry payments were two to three times as likely to prescribe brand-name drugs at exceptionally high rates as others in their specialty."[58]

Insys Representative Misleads PBM to Obtain Prior Authorization

The minority staff has obtained an audio recording of a conversation between an Insys employee and the PBM Envision, which provided prior authorization services in connection with the Subsys prescription for Ms. Fuller. During this January 2015 conversation, an IRC employee discussed prior authorization for Subsys with a representative from Convey Health Solutions, a call center support vendor for Envision Pharmaceutical Services, as well as a member of the clinical department of EnvisionRx Plus.

In the first portion of this recording, the Insys employee begins her conversation with a PBM representative by misleadingly identifying herself as "with the doctor's office." At no point does the employee identify herself as working for Insys or explain she is calling from an Insys office. After being transferred to the Envision clinical department for further questioning, the Insys employee confirms she is calling "from" a doctor's office and claims the prior authorization request is "urgent."

Insys Representative: Hi, my name is [XXXX], and I'm with the doctor's office. I never heard an option for me to choose to . . . I need to see if a certain medication requires authorization.

Representative from Convey Health Solutions: Okay, can I . . . for security purposes, can I have your NPI number?

I: It's [XXXX].

R: You say [XXXXX]?

I: Yes.

R: Okay, and which doctor is that?

I: It's Dr. Matalon.

R: Okay, and for security purposes can you verify the member ID number?

I: Yes, it's . . . well, you know what, I have . . . I only have their Medicare ID number.

R: Okay, you can go ahead with that number.

I: It's [XXXX].

[. . .]

* * *

R: Hi [XXXX], thank you so much for holding. Yeah, I'm going to have to connect you to our clinical department so that they can go ahead and try to do that override for you.

[. . .]

* * *

Envision Clinical Department Representative: Clinical Department, this is [XXXX]. How can I help you?

I: Hi [XXXX], you guys must be very busy people.

E: We are, and I apologize for the long wait, but how can I help you now?

I: I need to know if a certain medication requires authorization, and if it does, can I do it over the phone. It's urgent.

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[56] Colette DeJong, et al., "Pharmaceutical Industry-Sponsored Meals and Physician Prescribing Patterns for Medicare Beneficiaries," *JAMA Internal Medicine* (June 20, 2016).

[57] *Id.*

[58] "Now There's Proof: Docs Who Get Company Cash Tend to Prescribe More Brand-Name Meds," *ProPublica* (March 17, 2016) *(www.propublica.org/article/doctors-who-take-company-cash-tend-to-prescribe-more-brand-name-drugs).*

E: Oh, okay. You're calling from the doctor's office then, correct?

I: Yeah, Dr. Matalon's office.

[. . .]

As the conversation with the Envision clinical department representative proceeds, the Insys employee correctly notes that Subsys is "intended for the management of breakthrough cancer pain," but then states only that Dr. Matalon is treating Ms. Fuller for "breakthrough pain." When questioned as to whether Ms. Fuller does, in fact, suffer from breakthrough cancer pain, the Insys employee avoids responding directly and instead explains "there's no code for breakthrough cancer pain." She then states again that the Subsys prescription is "for breakthrough pain, yeah," and the Envision representative discontinues this line of questioning. Toward the end of the call, the Insys employee states that Ms. Fuller is anticipated to remain on Subsys indefinitely.

E: Okay, and what is the diagnosis for the patient?

I: Let me look through here [inaudible] . . . medication is intended for the management of breakthrough cancer pain. The doctor is treating the patient for breakthrough pain, with a diagnosis code of 338.29—

[. . .]

E: Thank you. Is it also for the breakthrough cancer pain or not?

I: Well, there's no code for breakthrough cancer pain.

E: Yeah, and that's fine. I typed out the description; I just want to make sure that I heard you correctly.

I: It's for breakthrough pain, yeah.

E: Good. Okay.

[. . .]

E: And what is the anticipated duration of therapy?

I: Well, there's no end date. I mean, we just try to give her a year and go from there.

E: Okay. And is this a brand or a generic? This is single-source, no generic, so the brand is required. . . . What other medications in the same therapeutic class have been tried?

I: Okay, they've tried morphine, morphine sulfate. . . . Let me know if you need me to spell something or go slow, okay?

E: You're doing fine at the pace you're at right now. Morphine sulfate, okay.

I: Oxycodone, OxyContin, and I think that's all I can tell from the notes.

E: Okay, were those ineffective?

I: Yeah, let me see what the note says. It says it had an inadequate analgesic effect. Patient is opioid-tolerant.

E: Thank you. And are there any alternatives that are contraindicated, that are not appropriate for the patient? You know, aside from not being effective.

I: That's all that I have.

E: Okay. And this is a spray. Okay.

I: Yeah, it's 200 micrograms, 120 units, for 30 days.

E: And it doesn't look like it's going to have a problem with the quantity limitation. So is there any other clinical information you'd like to provide at this time?

I: No, just that patient will remain on a long-acting opioid and patient is opioid-tolerant. Other than that, I think we've covered everything.

[. . .]

RESPONSE FROM INSYS

The minority staff requested that Insys officials address whether the company implemented the recommendations in the CIS report or took any other action to ad-

dress deficiencies in prior authorization policies. In response, Insys President and CEO Saeed Motahari provided a letter explaining that the company had "completely transformed its employee base over the last several years," including in "key management positions," and has "actively taken the appropriate steps to place ethical standards of conduct and patient interests at the heart of [its] business decisions."[59] Specifically, Mr. Motahari noted that Insys had "invested significant resources in establishing an effective compliance program with protocols designed to ensure compliant and ethical behavior"; the company also engaged an independent "gap assessment into [its] compliance protocols."[60] In closing, Mr. Motahari pledged "to play a positive and productive role in helping our Nation overcome the opioid epidemic."[61]

As part of its ongoing investigation, the minority staff will continue to evaluate whether these efforts have resulted in a true transformation of the Insys corporate culture.

CONCLUSION

According to public reporting, lawsuits from Subsys patients, and criminal indictments, Insys Therapeutics has repeatedly employed aggressive and likely illegal techniques to boost prescriptions for its fentanyl product Subsys. An audio recording and other materials the minority staff have reviewed suggest these efforts have included actions to undermine critical safeguards in the prior authorization process—with Insys officials aware, at the very least, of the serious danger of these acts occurring. The high stakes of opioid overprescription—including patient death—demand close attention to these practices by law enforcement officials, policymakers, and the PBMs charged with approving or rejecting fentanyl treatment.

The PBM Express Scripts excluded Subsys from its list of covered drugs in 2015, and UnitedHealth Group, which owns the PBM OptumRx, did the same in 2016.[62] In December 2016, Federal prosecutors indicted Mr. Babich and five other former Insys executives on racketeering charges, alleging that these individuals "approved and fostered" fraudulent prior authorization practices.[63] In June 2017, Ms. Gurrieri, the former head of the IRC, pled guilty "to having conspired to defraud insurers."[64]

On July 17, 2017, shortly after the filing of a complaint by Anthem insurance plans, Insys released a statement explaining that the company has "taken, and will continue to take, appropriate steps to learn from the past and to ensure that appropriate protocols and policies are in place at our Company."[65] As part of its ongoing investigation, the minority staff will continue to evaluate whether these efforts have resulted in a true transformation of the Insys corporate culture.

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[59] Letter from Saeed Motahari, Insys President and CEO, to Senator Claire McCaskill (September 1, 2017) (attached as Exhibit C).

[60] *Id.*

[61] *Id.*

[62] "The Pain Killer: A Drug Company Putting Profits Above Patients," *CNBC* (November 4, 2015).

[63] Indictment (December 6, 2016), *United States v. Babich, et al.,* D. Mass. (No. 1:16 CR 10343).

[64] "Ex-Insys Employee Pleads Guilty in U.S. Opioid Drug Probe," *Reuters* (June 19, 2017) *(www.reuters.com/article/us-insys-court-idUSKBN19A2MB).*

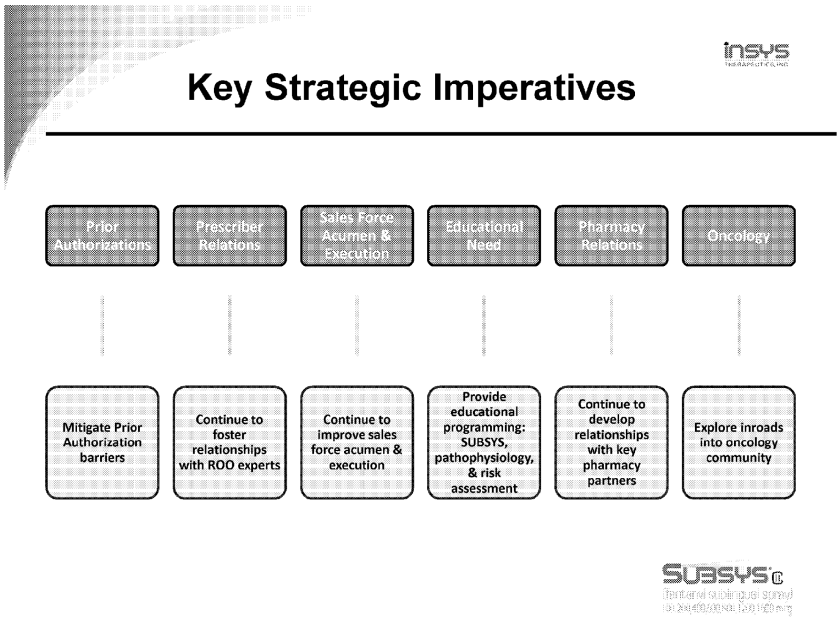
[65] Insys Therapeutics, Inc.: Insys Therapeutics, Inc. Releases Statement on Payor Interactions (July 17, 2017) *(www.globenewswire.com/news-release/2017/07/17/1047299/ 0/en/Insys -Therapeutics-Inc-Releases-Statement-on-Payor-Interactions.html).*

EXHIBIT A

2013 Subsys Brand Plan

2012 Assessment

For Planning Purposes Only: Not for Promotion



KSI 1: Prior Authorizations

- Mitigate prior authorization barrier
  - Build internal PA assistance infrastructure
  - Track all PAs via a comprehensive database
  - Establish an internal 1–800 reimbursement assistance hotline
  - Educate field force on PA process and facilitation
  - Partner with PA specialists in key provider offices via best practice ad boards and educational programming
  - Partner with private pharmacies to orchestrate PA logistics
  - Continue to provide Super Voucher during PA navigation

EXHIBIT B

Insys Call Note, Email, and IRC Verbatim Data Audit Report

Presented to

Insys
THERAPEUTICS, INC.

February 18, 2014

By

Compliance Implementation Services
Ellis Preserve
3809 West Chester Pike, Suite 100
Newtown Square, PA 19073

Introduction

In mid-2013, CIS was approached by Insys's legal representative (at that time Leslie Zacks) on behalf of the Board of Directors for Insys to request that CIS support in the review of certain communications with Health Care Professionals (HCPs) and Insys employees, and report how they were being documented. It was communicated at that time to CIS that there was concern with respect to communications with HCPs by Insys employees being professional in nature and in alignment with Insys approved topics regarding off or on-label promotion of an Insys product, and general adherence to Insys documentation requirements of these types of communications. It was also communicated to CIS that while there were no documented examples of this type of interaction to date, the concern stemmed from the lack of monitoring of commercial activities where these types of interactions could occur. This was to more specifically include a review of email communications that had occurred (if any) with HCPs by Insys employees and the documentation process and quality of the call notes recorded after in office meetings with HCPs by Insys employees had occurred. All of this was to be reviewed against existing Insys policy and procedure that governed the above discussed activities (if any), interviews with senior leadership to understand more fully any directive given with respect to communications with HPCs, and verifying compliance to them.

It was further requested that a review of the general communications from the Insys Reimbursement Center (IRC) to HCPs, their office staff or representatives, as well as health insurance carriers occur to ensure they were appropriate in nature with respect to specific uses of Subsys, Insys's commercially marketed product. All requests ultimately came together to provide a thorough review of internal Insys email communications with the top twenty (20) Subsys prescribing physicians, the call notes that were recorded post an Insys employee visit with these specific twenty (20) HCPs, as well as an onsite review of IRB operations that included interviews, live monitoring, and a review of existing policies and procedures (if any) governing the actions of those working within the IRC.

CIS is pleased to present the following observations and recommendations found within this report.

Project Objective and Scope

Objective:

The objective of this audit was to evaluate and assess the existence, adequacy, and comprehensiveness of Insys's existing policy and procedural documentation to determine whether adequate controls were in place to effectively ensure compliance and adherence to said documents, Insys guidance and industry best practices related to all forms of communication from Insys employees to HCPs.

Specifically, the objective of this audit was to review sales representative call notes and other communications ad documentation to ensure oversight of day-to-day promotional activities and to ensure prospective compliance with the Insys policies, procedures, and communicated controls (if any). Further, the objective of this review was to ensure that the IRC's communications were in alignment with Insys and IRC specific policies, procedures, and communicated controls (if any) regarding interactions with HCPs, as well as on label with respect to product indication.

HCP and IRC Scope:

The project sponsors both Leslie Zacks and Desiree Hollandsworth at the request of the Insys Board of Directors and in conjunction with the CIS team, narrowed the scope of the engagement to specifically target all communications, interactions, and documentation with the top twenty (20) prescribing HCPs for Insys's commercially marketed product, Subsys. Further, the scope of data and document review of the IRC interactions with HCPs was to be narrowed to a random sampling of live phone calls, interviews with employees and management, and review of existing policy, procedure, and SOPs (if any) governing the actions of the IRC and its employees.

Documentation, Interview, and Live Monitoring Scope:

CIS reviewed the following policies and procedures that Insys provided related to their internal requirements governing interactions with HCPs, the documentation of HCP visits within the Insys Sales Force 360 platform (call note repository), and the IRC. CIS also collected functional data for the audit which is listed below. Finally, CIS scheduled interviews with the below listed Insys employees to obtain a better understanding of processes and requirements as they related to HCP communication and documentation both in the field and the IRC. It should be noted that during the onsite IRC visit there were employees on vacation and or out of the office, so multiple calls were monitored for the same employee. CIS would like to note that the recording and transcripts of the live monitoring session was not possible to obtain, as currently Insys does not have the ability to do so with its current phone system.

Document Type	Title
Governance	Insys Code of Business Conduct
Governance	Compliance Program and Certification of Compliance
Governance	Insys Employee Handbook
SOP #4	Insurance Reimbursement Center Communication Process
SOP #3	Insys Reimbursement Center Line
SOP #2	Insys Reimbursement Center
SOP #1	30 Units Free and Super-Vouchers
PPT-Training	Overview of IRC Impact
Document	IRC At-A-Glance
PPT-Training	Prescription Process Flow Chart
PPT-Training	PA Workshop (New Hire Training and Refresher Training)
PPT-Training	IRC Sales Force Training
Internal Document	New Opt-In Form
Internal Document	IRC Flow Chart—Appeal Process
Internal Document	IRC Flow Chart—PA Process
Corporate Email	Multiple Internal IRC Emails with directives from management on numerous topics
PPT-Training	Revised Core Speaker Deck
PPT-Training	Supplemental Speaker Deck Slides
PPT-Training	New Sales Force Training Curriculum
HCP Data	Top Twenty (20) HCP Prescriber data excel files (2)

Document Type	Title
Call Notes Data	All call notes associated with the top twenty (20) HCP Prescibers for 2013
Corporate Email Data	Email communications associated with the top twenty (20) HCP Prescibers—2013

Insys Employee Interview	Date
Desiree Hollandsworth—Marketing/Communication	October 27, 2013, November 15, 2013, December 19, 2013
Leslie Zacks—Legal	October 27, 2013
Maury Rice—IT	December 19, 2013
Mike Gurry—Managed Markets (IRC)	December 18, 2013
Liz Gurrieri—Managed Markets (IRC)	December 18, 2013
Darin Fila—Sales Training	December 19, 2013

Insys IRC Employee—Live Monitor	Date
Allyson Fulton	December 18, 2013
Sam Renzetti	December 18, 2013
Traci Giles	December 18, 2013
Allyson Fulton	December 18, 2013
Patricia Ray Nixon	December 19, 2013
Patricia Ray Nixon	December 19, 2013
Sam Renzetti	December 19, 2013
Traci Giles	December 19, 2013
Allison Fulton	December 19, 2013
Traci Giles	December 19, 2013

Project Methodology

The audit focused on evaluating any existing written documentation that governs appropriate communication with HCPs as an Insys employee and whether or not there are adequate controls in place that effectively ensure compliance and adherence with said documentation, Insys guidance, and industry best practices related to HCP communication and interactions.

The methodology outlined below was used for the Call Notes, Email, and IRC Verbatim Audit Report:

FIELD WORK AND GENERAL OBSERVATIONS

- **Document Collection, Review, and Interviews**

  CIS collected and reviewed various documents provided by Insys as well as carried out interviews with key stakeholders to better understand specific processes in place with respect to HCP interactions and communication. These documents and interviews are listed in the Documentation and Interview scope section above and include, but are not limited to:

  I. *Policies and Procedures*

  Insys has various policies and procedures in place that provide certain instruction for compliance and governance related to appropriate interactions and communications with HPCs. The documentation listed

above was reviewed and covered both organization wide requirements as well as business unit specific; specifically those governing the IRC and its employees.

II. *Call Notes Repository (Salesforce 360), Corporate email account platform*

Insys provided CIS with one (1) year worth of call notes associated with the top twenty (20) Subsys prescribing HCPs to assess whether the calls were recorded in a manner consistent with Insys communicated guidance, policies, and procedures. Insys also provided CIS with one (1) year worth of corporate email data associated in some way to the top twenty (20) HCP prescribers of Subsys listed by Insys, to review and ensure appropriate communication with HCPs via email per Insys communicated guidance, policy, and procedures.

III. *IRC Specific Work Instructions and Governance Documentation*

Insys provided CIS with all existing documentation that governs the work processes, templates, SOPs, and expectations on how to appropriately engage HPCs or their staff, Health Care Insurers, and other third party entities that may be part of a conversation regarding IRC support and proper documentation of those engagements with the ultimate goal of supporting patients in obtaining a Prior Authorization (PA) for an Insys marketed product.

IV. *IRC Interviews, Live Monitoring, and Walkthroughs of current requirements*

CIS met with Mike Gurry, Vice President Managed Markets, and Liz Gurrieri Manager Managed Markets, on December 18, 2013 to review the IRC support process and gain a more in depth understanding of the specific roles and responsibilities of the IRC staff, as well as the general procedures which occur daily with respect to HCP and Health Care Insurer (HCI) interactions and how specific support to gain a PA is obtained. CIS also was present for the live monitoring of ten (10) calls made by IRC representatives, both incoming and outgoing in support of obtaining a PA for patients. After each call, CIS asked the IRC representative to walk them through the process flow of the particular type of call, and the expected documentation to be on file with it. Further, the CIS monitor spoke with Liz regarding the current auditing and monitoring of IRC associate calls, and what processes were in place to ensure adherence to Insys and IRC communicated guidance, policy, and procedures regarding HCP interaction and communication. It was apparent to the CIS monitor during the live telephone interactions that the IRC staff was adequately trained with respect to HCP, HCI, and IRC employee communication standards. All employees conducted themselves in a professional manner and no deviance from Insys or IRC controls was observed.

- ***Identified Existing Key Document Controls***
  CIS identified that some key controls related to the appropriate communication and interaction with HCPs were in place through the documentation review process. Additionally, CIS determined that some of the submitted IRC communications, procedures, and governance documentation supported in the training and adherence of IRC personnel to Insys and IRC communicated guidance and industry best practices related to the specific HCP and HCI interactions that occur. CIS also noted upon review of the call notes provided for the audit, that all HCP interactions were filled out completely using the required drop down descriptions, and incomplete or partial entries were not found.
- ***Identified the Lack of Formal and Approved Governance Documentation, Policy, Procedures, and SOPs***
  CIS identified that while documentation with respect to communication and interactions with HCPs existed, there were also gaps in formally approved foundational policies, procedures, and SOPs with respect to required processes specifically within the IRC. CIS also identified the lack of a formal policy with respect to email communication from a sales representative to an HCP and the appropriate and approved methods by which they are to occur.
- ***Identified the Absence of an Auditing and Monitoring Function Within Multiple Business Units as Well as Through Interviews With Key Insys Stake Holders***

During the interviews held with Insys employees, it was apparent that no quality assurance processes were in place to monitor or audit the actions of sales representatives with respect to a timely call note record creation of an HCP visit within the SalesForce 360 platform. Further, there were no plans communicated to CIS with respect to implementing an auditing and monitoring function to ensure adherence to communications with this action. Further, through interviews it was apparent that no specific email monitoring process was in place and documented with respect to corporate email communication and HCPs in general, and specifically those that may occur from a field sales representative to an HCP. Finally, through interviews with the IRC management, there was no formal, documented, or detailed process by which IRC representatives' calls via telephone were audited for proper communication with HCPs or HCIs in any fashion other than random physical review of a call in a very informal and sporadic manner.

Specific Observations and Recommendations

Based on the audit procedures performed that related to the Verbatim Data Audit Process, CIS is providing the following specific observations and recommendations identified as a result of the review and audit performed.

All observations and recommendations are based on compliance coverage for adherence to Insys communicated guidance, policies, and SOPs, as well as benchmarking against industry best practices.

Observation #1: Upon reviewing the training curriculum with respect to sales representatives entering in call notes post an HCP visit, as well as any associated written requirements, interviews with Insys Marketing Communication and Sales Training employees, the following observations were made:

- *Observation 1–1:* While sales representatives are required to record a call note for each visit made to an HCP, governance documentation and training generally lack specificity on the time frame a representative has to input the call note by.
- *Recommendation 1–1:* The requirement to input a call note for an HCP visit within an Insys approved time frame should be pronounced during trainings, and specifically called out within procedural guidance for inputting HCP call notes. It is recommended that a "Documentation of HCP Communication" SOP be created, approved, and disseminated.
- *Observation 1–2:* No formal auditing and monitoring process currently exists to ensure that sales representatives are inputting call notes within a specified time frame post and HCP visit.
- *Recommendation 1–2:* CIS recommends that a job description and requirement be added to District Managers and above to periodically review the call note input date within the Salesforce 360 platform to ensure that they are in alignment with Insys requirements for call note creation post an HCP visit. These audits to be retained for performance review issues, further training when deemed necessary, and in some cases disciplinary action.

Observation #2: Upon initiating the corporate email review and assessing how to query any communication from Insys employees with the top twenty (20) HPC prescribers of Subsys, it became apparent that due to the extremely high volume of email search hits that came back under keyword queries, (all of which consisted of internal emails discussing HCP engagements or mention of the HCP's name) a random sampling of each of the twenty (20) top HCP Subsys prescribers would serve as a more realistic sample. The randomly sampled emails were reviewed for adherence to Insys communication and interactions with HCPs documentation, as well as specific Insys communicated guidance with respect to email communication and HCPs. Many multiple thousands of emails were produced over a year's time frame, which presented a challenge for the IT department when searching and categorizing them. For the size and scope of this particular review, CIS chose to randomly sample one hundred (100) emails from each of the top twenty (20) HCP Subsys prescribers to ensure all communication was in alignment with Insys policy, procedure, and appropriate in nature.

Out of the two thousand (2,000) randomly selected emails (100 for each of the top twenty (20) HCP prescribers of Subsys); no direct email was found between a sales or field representative and an HCP. Any direct email communication with the HCP was engaged by a member of the Marketing, Executive, or Senior Management team and found appropriate in nature. CIS would like to note that the majority of re-

viewed emails consisted of internal Insys discussions with respect to that particular HCP and all appropriate in nature.

Recommendation: Although no inappropriate communication or violation of Insys policy around HCP communication was found, CIS does recommend that a corporate compliance auditing and monitoring function be created and implemented to ensure periodic reviews of HCP email communication as on ongoing monitoring activity. This will ensure a much more up to date picture of communications between HCPs and Insys employees in general, and also serve to satisfy the Office of Inspector General's specified element of an effective compliance program, by having this function ongoing. CIS also recommends that while sections of the Insys Employee Handbook and Code of Ethics do discuss appropriate interactions with HCPs, a separate and distinct "Interactions With Health Care Professionals" policy should be drafted and disseminated company wide.

- *Observation 2–1:* During the interview process CIS learned that Insys field sales representatives are prohibited from emailing HCPs, and communication was to be restricted to in-person, telephone, or text messaging only. There was no policy found to support this requirement.
- *Recommendation 2–1:* A separate and distinct policy should be created that outlines the approved methods of communication with HCPs as they relate to Insys employees, and specifically the sales representatives to ensure accountability and establish a baseline standard of communication that can be measured.

- *Observation 2–2:* No formal auditing and monitoring process currently exists to ensure that email communications between HCPs and Insys employees are both appropriate and professional in nature, as well as being initiated and sent solely by an authorized Insys employee.
- *Recommendation 2–2:* CIS recommends that Insys incorporate an auditing and monitoring function, as well as system controls within the corporate email server that can notify appropriate levels of management when a key word on HCP name is scanned. This will serve as a monitoring tool for compliance to communication standards as they relate to HCP interactions.

Observation #3: CIS observed that there was a specific lack of formal and approved policies, procedures, and SOPs that govern the actions of the IRC. Upon review of submitted IRC documentation and interviews held with IRC representatives, the following observations were made:

- *Observation 3–1:* No formal and approved policy on appropriate communications between IRC employees and HCPs, their staff, HCIs, or patients exists (or wasn't supplied to CIS for review) that governs the support function of obtaining a prior authorization for the use of Subsys.
- *Recommendation 3–1:* Insys IRC management to formally draft and obtain proper review and approval of an IRC specific policy detailing the appropriate communications that should occur while performing the IRC associate job functions and interacting with HCPs.

- *Observation 3–2:* CIS observed that four (4) informal SOPs existed (see document scope section) but lacked a formal review and approval, as well as specificity with respect to the referenced topic. CIS noted that the documents were most likely white papers or narrative flow charts of processes, but no formal and approved SOPs exist (or weren't supplied to CIS for review) that outline appropriately the actions performed within the IRC.
- *Recommendation 3–2:* Insys IRC management to formally draft and obtain proper review and approval of IRC specific SOPs that in a detailed and action specific manner will govern all processes engaged within the IRC. Insys IRC management should ensure these SOPs are specific to each job function within the IRC and that once formally reviewed and approved, adequate training and understanding of these processes exists.

- *Observation 3–3:* While a quality control function does exist with respect to IRC documentation regarding the Opt-in program and patient file information, no formal and documented auditing and monitoring or quality control policy, process, or function exists between IRC employee communications and HCPs, HCP staff, HCIs, or patients.
- *Recommendation 3–3:* Insys IRC management to formally draft and obtain proper review and approval of an IRC Auditing and Monitoring specific policy and SOP. Further a specific schedule to monitor both live and anonymously IRC employee communications both incoming and outgoing and at any given time should be created and adhered to. This function will serve to ensure adherence

to IRC communication standards and serve as supporting documentation for training, annual reviews, and if necessary disciplinary action. It is recommended that the Insys IRC implement an electronic system that will allow management to listen to calls in real time to ensure total anonymity.

Observation #4: Upon review of submitted IRC documentation (CIS requested all governance documentation in general that could be reviewed), CIS noted the following:

- *Observation 4–1:* The majority of managerial directives, changes to controlled documents or templates, as well as updates or revisions to processes were not formally approved, documented, and disseminated for use, and were sent informally via email blast, and in some reviewed document submissions, updates or changes to existing templates and documents were copy and pasted into the body of emails and disseminated for immediate use.
- *Recommendation 4–1:* Insys IRC management formally implement a change control process by which standardized documents, templates, and IRC documentation used for patient and HCP data may be revised or updated in a formal, approved method that is in alignment with existing Insys change control and documentation creation and revision policies and guidelines. This is industry best practice and will allow for periodic review of file audits to ensure the most up to date templates are in use.

Conclusion

This audit report supports an ongoing acknowledgement by Insys of the need to conduct continual monitoring activities to ensure Policies, Standard Operating Procedures, and industry best practices exist and are adhered to within the organization and throughout various business units. Insys recognizes its responsibility in monitoring company activities and as such requested this specific audit as a means to assist in its ongoing monitoring of communication and interactions between HCPs, HCIs, and other affiliated entities and Insys employees from both the corporate side, as well as the commercial or field force side of the business.

Throughout the review of Insys wide email communications with specific HCPs and the documentation of interactions with specific HCPs via call note creation and entry by sales representatives, CIS concluded that while there lacks specific policies as well as auditing and monitoring procedures, (see recommendations section) very few adverse observations were noted, and no major violation of Insys communicated guidance or governance documentation existed. The following points were also noted:

- There is sound compliance to documenting appropriately interactions with an HCP via a call note within the SalesForce 360 platform. There were no instances of non-compliance or incomplete entries found upon review, and the Insys sales force should be commended for their dedication to this requirement.
- Out of 2,000 reviewed emails that all referenced a specific subset of high Subsys prescribing HCPs, there were no instances of inappropriate communication or discussion found as they related to off-label promotion of a product or use, and no violation of Insys policy with respect to email communication with HCPs and specific job titles namely sales representatives.
- Upon monitoring ten (10) IRC associate conversations with HCPs, their office staff, and insurance carriers with respect to the authorization and use of Subsys, CIS noted that all IRC staff was professional in communication, and in no instance was inaccurate or off-label usage of Subsys communicated.

Despite changes in original scope of this engagement, and specific review requests such as not being able to record IRC employee conversations while on the phone anonymously due to the lack of technology, and the unexpected volume of emails referencing a specific subset of high Subsys prescribing HCPs, the Call Notes, Email, and IRC Verbatim Data Audit was completed and found to be exemplary in the minimal amount of specific findings and recommendations noted. In conclusion, CIS recommends that all types of communication, interaction, and documentation between HCPs and Insys employees be associated with a governing policy and SOP, to ensure compliance to clear and concise Insys communicated guidance and standards. CIS also recommends that an auditing and monitoring function across the reviewed areas be implemented immediately to ensure a constant and ongoing review of interactions and communications between HCPs and Insys employees, and that they are in compliance with formally drafted and approved governance documentation.

EXHIBIT C

September 1, 2017

The Honorable Claire McCaskill
U.S. Senate
Committee on Homeland Security and Governmental Affairs
Washington, DC 20510

Re: Insys Therapeutics, Inc.

Dear Senator McCaskill:

As you and your staff continue to review certain aspects of the commercial practices of Insys Therapeutics, Inc. ("Insys"), I would like to assure you that I stand with you and share the desire to address the serious national challenge related to the misuse and abuse of opioids that has led to addiction and unnecessary deaths and has caused so much pain to families and communities around the country.

Four months ago, I joined Insys after undergoing my own due diligence process and coming to the understanding that this company has great potential to assist patients in unmet medical needs. Like you and your staff, I was concerned about certain mistakes and unacceptable actions of former Insys employees that have been disclosed and discussed in public forums over the past several years. These mistakes and actions are not indicative of the people that are currently employed at Insys and I share your belief that the "vast majority of the employees, executives, sales representatives, scientists, and doctors involved with this industry are good people and responsible actors" including our employees. In this regard, Insys has completely transformed its employee base over the last several years. Notably, over 90 percent of the 250 field-based sales staff employed prior to 2014 are no longer with the organization. Even in the limited time since I joined the company, we have hired over 50 new employees and replaced key management positions including the following leaders:

- President and Chief Executive Officer
- Chief Financial Officer
- Vice President of Sales
- Regional Director of Sales
- Vice President of Marketing and Managed Care
- Senior Director of Commercial Operations
- Vice President of Medical Affairs
- Senior Director, Clinical Development Medical Affairs (a pain and addiction specialist)

Over the past several years, Insys has actively taken the appropriate steps to place ethical standards of conduct and patient interests at the heart of our business decisions. Our compliance program has been under significant scrutiny for several years from both governmental authorities but also as a result of internal reviews conducted with the assistance of external experts and counsel. During this period, we have invested significant resources in establishing an effective compliance program with protocols designed to ensure compliant and ethical behavior. We recently completed a successful gap assessment into our compliance protocols and processes by an independent, global consulting firm. This assessment was voluntarily conducted with oversight from our Compliance Committee of the Board of Directors. We passionately believe that the company has taken necessary steps to ensure that we will not repeat the mistakes of the past.

Notwithstanding these transformative changes, as the Chief Executive Officer of Insys and a member of its board of directors, I believe that it is imperative that we take responsibility for the actions of our former employees. This belief is strongly shared by our board of directors. Insys continues to strive to do that where the facts and circumstances dictate that we do so.

I write to you today on behalf of over 400 employees, across three facilities including a research and development laboratory and a fully functional manufacturing facility who have worked tirelessly to develop and manufacture our two FDA-approved products approved for the conditions of breakthrough pain in cancer patients, nausea and vomiting associated with chemotherapy and weight loss in AIDS patients. These products fulfill a significant unmet need for patients requiring supportive or palliative care as they fight their battle with cancer or AIDS. These employees, many of whom have advanced and doctorate level degrees in the technical and health sciences are working diligently every day to develop new medicines and

therapies to treat severe catastrophic diseases such as intractable pediatric epilepsy, rare genetic diseases such as Prader-Willi Syndrome, life-threatening anaphylaxis reactions, opioid overdose, opioid addiction and dependence, agitation in Alzheimer's Disease and anorexia in cancer patients. It is worth noting that since 2012, Insys has invested over $170 million in research and development to advance our pipeline and make a positive impact in the lives of patients and caregivers.

Like so many stakeholders in health care and government, we hear the call to action to address the Nation's opioid crisis. The opioid epidemic is a highly complex and multi-faceted issue requiring a solutions based approach. We stand ready to help address this public health crisis collaboratively through educational initiatives and drug monitoring programs centered around patients, caregivers, health-care providers and the overall community. We feel strongly that to develop a solution we must first understand and correct the drivers of the problem.

Subsys® is one of six pharmaceutical products in a class called Transmucosal Immediate Release Fentanyl (TIRF). A doctor is not permitted to prescribe, a pharmacy is not permitted to dispense, and a patient is not permitted to receive any TIRF product, including Subsys®, unless each of them is enrolled in the Food and Drug Administration ("FDA") mandatory TIRF Risk Evaluation and Mitigation Strategy ("REMS") program. The TIRF–REMS program strives to limit the risk of abuse and misuse by restricting prescriptions to appropriate patients, preventing inappropriate conversions between medicines and educating patients, pharmacists, and prescribers about potential for abuse, addiction, and overdose of TIRFs, as well as the label for these products.

In 2016, there were 215 million opioid prescriptions written in the United States. Subsys® accounted for approximately 34,000 (less than 0.02 percent) of these prescriptions nationally. These 2016 prescription numbers for Subsys® place Insys below the top 50 manufacturers of opioids in the United States. When considering fentanyl's role in the current opioid crisis, it is important to note that in the National Heroin Threat Assessment Summary issued in June 2016, the Drug Enforcement Administration concluded that "pharmaceutical fentanyl is diverted for abuse in the United States at small levels" and recent overdose deaths from fentanyl are "largely due to clandestinely-produced fentanyl, not diverted pharmaceutical fentanyl."

From a personal perspective, we all have been touched or been affected by cancer-as a patient, caregiver, friend, family member, or loved one. An aspect of cancer that can be easily overlooked and greatly underappreciated is the excruciating pain that often accompanies the disease as it progresses and is associated with surgical, radiation, and chemotherapy treatment. For some patients, the breakthrough cancer pain or cancer related pain can be debilitating and devastating. We would be willing to share with you some of the experiences of patients who have benefited from Subsys®. Their experiences illustrate the importance of addressing and treating breakthrough cancer pain appropriately.

I sincerely welcome an opportunity to engage in a meaningful dialogue and partner with key stakeholders such as yourself, other Senators and professional consortiums to play a positive and productive role in helping our Nation overcome the opioid epidemic.

Respectfully,

Saeed Motahari
President and Chief Executive Officer
Insys Therapeutics, Inc.

United States Senate

Homeland Security and Governmental Affairs Committee, Ranking Member's Office
MINORITY STAFF REPORT

Fueling an Epidemic

Report Two

Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups

EXECUTIVE SUMMARY

This report provides the first comprehensive snapshot of the financial connections between opioid manufacturers and advocacy groups and professional societies operating in the area of opioids policy. Drawing on disclosures from Purdue Pharma L.P., Janssen Pharmaceuticals, Inc., Mylan N.V., Depomed, Inc., and Insys Therapeutics, Inc., in response to requests from Ranking Member McCaskill, the sections below describe nearly $9 million in payments from these manufacturers to 14 outside groups working on chronic pain and other opioid-related issues between 2012 and 2017. In addition, physicians affiliated with these groups accepted more than $1.6 million in payments from the five manufacturers between 2013 and the present. In total, the five manufacturers have made more than $10 million in payments to these groups and affiliated individuals since January 2012.

Payments from Purdue totaling $4,153,554.33 account for roughly half of the nearly $9 million in funding to groups, and the company provided donations to the most diverse array of groups—a significant majority of the organizations profiled below. Primarily due to large payments to the National Pain Foundation and the U.S. Pain Foundation, Insys had the second-highest contribution total from 2012 to 2017, with $3,146,265 in payments. Depomed contributed the third-highest total—$1,071,116.95—during this period, and Janssen contributed $465,152.85. At the other end of the spectrum, Mylan reported only $20,250 in payments during the same period.

Initiatives from the groups in this report often echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of opioid manufacturers. These groups have issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain, lobbied to change laws directed at curbing opioid use, and argued against accountability for physicians and industry executives responsible for overprescription and misbranding. Notably, a majority of these groups also strongly criticized 2016 guidelines from the Centers for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain—the first national standards for prescription opioids and a key Federal response to the ongoing epidemic.

The fact that these same manufacturers provided millions of dollars to the groups described below suggests, at the very least, a direct link between corporate donations and the advancement of opioids-friendly messaging. By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic.

INTRODUCTION AND METHODOLOGY

More than 42,000 Americans died from opioid overdoses in 2016, with deaths from natural and semisynthetic opioid painkillers like hydrocodone and oxycodone rising roughly 14 percent compared to 2015.[1] In Missouri, around 60 percent of the more than 1,300 drug overdose deaths in 2016 involved opioids,[2] and the epidemic cost

[1] Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, NCHS Data Brief No. 294, "Drug Overdose Deaths in the United States, 1999–2016" (December 21, 2017) *(www.cdc.gov/nchs/products/databriefs/db294.htm);* "CDC Releases Grim New Opioid Overdose Figures: 'We're Talking About More Than an Exponential Increase,'" *Washington Post* (December 21, 2017) *(www.washingtonpost.com/news/ wonk/wp/2017/12/21/cdc-releases-grim-new-opioid-overdose-figures-were-talking-about-more-than-an-exponential-increase/?utm_term=.79af03095271).*

[2] "Opioid Crisis Drives Declines in U.S., Missouri Life Expectancy," *Columbia Missourian* (January 10, 2018) *(www.columbiamissourian.com/news/local/opioid-crisis-drives-declines-in-u-*

Continued

the State $12.6 billion the same year, according to the Missouri Hospital Association.[3] Alarmingly, fatal overdoses from fentanyl and other synthetic opioids more than doubled in the United States between 2015 and 2016—"more than an exponential increase," according to the chief of the mortality statistics branch at the National Center for Health Statistics.[4] This surge in overdose deaths resulted in the first 2-year drop in average U.S. life expectancy since the early 1960s.[5]

The necessary conditions for this crisis may have arisen, in part, due to the financial relationships between opioid manufacturers and patient advocacy groups and medical professional societies—the precise terms of which parties to these transactions rarely disclose. Patient advocacy organizations and professional societies play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public. Even small organizations—with "their large numbers and credibility with policymakers and the public"—have "extensive influence in specific disease areas."[6] Larger organizations with extensive funding and outreach capabilities "likely have a substantial effect on policies relevant to their industry sponsors."[7]

Nearly all health advocacy groups accept funding from the pharmaceutical industry. According to a recent study from PharmedOut—a Georgetown University Medical Center project focused on pharmaceutical marketing practices—only "a handful of 7,865 health advocacy groups in the United States are completely independent of pharmaceutical industry money."[8] As a result, "[t]he voices of independent groups that truly represent patients and consumers are drowned out by the thousands of groups that take money from industry and push industry viewpoints."[9]

Moreover, neither pharmaceutical manufacturers nor advocacy groups fully or routinely disclose the extent of their financial relationships. In a special report published in *The New England Journal of Medicine* in March 2017, for example, researchers found that out of 104 organizations, "at least 83 percent received financial support from drug, device, and biotechnologies companies, and at least 39 percent have a current or former industry executive on the governing board."[10] Full disclosure of these payments was limited, with only 57 percent of organizations disclosing amounts of donations; even then, this disclosure "was typically done with the use of broad ranges rather than exact figures."[11] Moreover, only 12 percent of the organizations researchers examined "have published policies in place for managing institutional conflicts of interest."[12]

A January 2017 article in *JAMA Internal Medicine* similarly examined relationships between patient advocacy organizations and the pharmaceutical industry. According to the study, more than 67 percent of 245 examined organizations received industry funding within the last fiscal year, with almost 12 percent receiving more than half of their funding from industry sources.[13] Only 65 percent of organizations that provided information on their funding from for-profit sources "provided a detailed breakdown" of this funding, and a similar percentage (63.9 percent) of 274 responsive organizations "reported having a written organizational conflict of interest policy."[14]

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s-missouri-life-expectancy/article_cd71e66e-f488-11e7-ac3f-d77b751b7c73.html); see also Department of Health and Human Services, Centers for Disease Control and Prevention, "Drug Overdose Mortality by State" (January 10, 2018) *(www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm).*

[3] "Opioid Crisis Cost Missouri $12.6 Billion in 2016, Report Says," *St. Louis Business Journal* (January 17, 2018).

[4] "CDC Releases Grim New Opioid Overdose Figures: 'We're Talking About More Than an Exponential Increase,'" *Washington Post* (December 21, 2017).

[5] "Opioid Crisis Trims U.S. Life Expectancy, Boosts Hepatitis C: CDC," *Reuters* (December 21, 2017) *(www.reuters.com/article/ususa-healthcare-cdc/opioid-crisis-trims-u-s-life-expectancy-boosts-hepatitis-c-cdc-idUSKBN1EF1TF).*

[6] Susannah L. Rose et al., "Patient Advocacy Organizations, Industry Funding, and Conflicts of Interest," *JAMA Internal Medicine* (March 2017).

[7] *Id.*

[8] "Very Few Patient Groups Don't Take Pharma Money," *Bloomberg BNA* (October 20, 2017) *(www.bna.com/few-patient-groups-b73014471175/).*

[9] PharmedOut, Pharma-Free Advocacy Groups *(www.pharmedout.org/pharma-free-groups.html)* (accessed December 7, 2017).

[10] Matthew S. McCoy et al., "Conflicts of Interest for Patient-Advocacy Organizations," *New England Journal of Medicine* (March 2, 2017).

[11] *Id.*

[12] *Id.*

[13] Susannah L. Rose et al., "Patient Advocacy Organizations, Industry Funding, and Conflicts of Interest," *JAMA Internal Medicine* (March 2017).

[14] *Id.*

These financial relationships—and the lack of transparency surrounding them—have raised concerns regarding the information and initiatives patient advocacy organizations promote. In the *JAMA* study discussed above, 8 percent of respondents in the study "reported [that] pressure to conform their organizations' positions to the interests of industry funders is of concern."[15] Without additional disclosure, according to David Mitchell of Patients for Affordable Drugs, "policy makers or patients are unable to make informed judgments about the motives of the information being given, and the credibility of the information."[16]

On March 28, 2017, Ranking Member McCaskill issued wide-ranging requests for documents related to opioid sales and marketing efforts to five major opioid manufacturers: Purdue Pharma L.P., Janssen Pharmaceuticals, Inc., Mylan N.V., Depomed, Inc., and Insys Therapeutics, Inc.[17] As the requests explain, these companies manufactured the top five opioid products as measured by worldwide 2015 sales.[18] Among other items, the requests required manufacturers to produce records of payments to certain advocacy groups and professional societies since 2012, including the date, amount, and purpose of each payment.[19] (Many of the groups at issue appeared in a previous congressional request from 2012 and feature prominently in nationwide litigation against the opioids manufacturing industry.[20]) In response, manufacturers produced information on payments flowing to many—but not all—of the groups listed in the March 2017 requests. To verify this information, Ranking Member McCaskill issued additional requests directly to 15 of the organizations at issue on October 5, 2017.[21]

The information produced to the committee demonstrates that many patient advocacy organizations and professional societies focusing on opioids policy have promoted messages and policies favorable to opioid use while receiving millions of dollars in payments from opioid manufacturers. Through criticism of government prescribing guidelines, minimization of opioid addiction risk, and other efforts, ostensibly neutral advocacy organizations have often supported industry interests at the expense of their own constituencies.

PAYMENTS BY OPIOID MANUFACTURERS TO PATIENT ADVOCACY ORGANIZATIONS AND PROFESSIONAL SOCIETIES

Between January 2012 and March 2017, the five opioid manufacturers featured in this report contributed nearly $9 million to leading patient advocacy organizations and professional societies operating in the opioids policy area. For some groups, contributions from these manufacturers—alone—constituted significant portions of their total annual contributions and grants.

In addition, the five manufacturers specifically at issue in this report also made substantial payments to individual group executives, staff members, board members, and advisory board members. Physicians affiliated with these groups accepted more than $1.6 million in payments from the five manufacturers between 2013 and the present. These same individuals received payments totaling over $10 million from all opioid manufacturers during this time period.

Opioid Manufacturers Contributed Millions to Patient Advocacy Organizations and Professional Societies

Purdue, Janssen, Mylan, Depomed, and Insys provided at least $8,856,339.13 in funding to 14 outside groups working on chronic pain and other opioid-related issues between January 2012 and March 2017. Detailed information on these payments, including payment totals for each manufacturer and group and the contributions applicable to each relationship, appears below in Figure 1.

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[15] *Id.*

[16] "More Than 80 Percent of Patient Groups Accept Drug Industry Funds, Study Shows," *New York Times* (March 1, 2017) *(www.nytimes.com/2017/03/01/health/patient-groups-drug-industry-money.html).*

[17] *See, e.g.,* Letter from Senator Claire McCaskill to Santosh Vetticaden, Interim Chief Executive Officer of Insys Therapeutics, Inc. (March 28, 2017).

[18] *Id.*

[19] *Id.*

[20] *See, e.g.,* Letter from Senator Baucus and Senator Grassley to Catherine Underwood, Executive Director, American Pain Society (May 8, 2012); Third Amended Complaint (October 25, 2016), *City of Chicago v. Purdue Pharma L.P., et al.,* N.D. III. (No. 1:14 CV 04361).

[21] *See, e.g.,* Letter from Senator Claire McCaskill to Steven P. Stanos, President, American Academy of Pain Medicine (October 5, 2017).

FIGURE 1: Manufacturer Payments to Selected Groups, 2012–2017

	Purdue [22]	Janssen [23]	Depomed	Insys	Mylan	Total
Academy of Integrative Pain Management	$1,091,024.86	$128,000.00	$43,491.95	$3,050.00 [24]	$0.00	**$1,265,566.81**
American Academy of Pain Medicine	$725,584.95	$83,975.00	$332,100.00	$57,750.00	$0.00	**$1,199,409.95**
AAPM Foundation	$0.00	$0.00	$304,605.00	$0.00	$0.00	**$304,605.00**
ACS Cancer Action Network	$168,500.00 [25]	$0.00	$0.00	$0.00	$0.00	**$168,500.00**
American Chronic Pain Association	$312,470.00	$50,000.00	$54,670.00	$0.00	$0.00	**$417,140.00**
American Geriatrics Society	$11,785.00 [26]	$0.00	$0.00	$0.00	$0.00	**$11,785.00**
American Pain Foundation	$25,000.00	$0.00	$0.00	$0.00	$0.00	**$25,000.00**
American Pain Society	$542,259.52	$88,500.00	$288,750.00	$22,965.00	$20,250.00	**$962,724.52**
American Society of Pain Educators	$30,000.00	$0.00	$0.00	$0.00	$0.00	**$30,000.00**
American Society of Pain Management Nursing	$242,535.00	$55,177.85 [27]	$25,500.00 [28]	$0.00	$0.00	**$323,212.85**
The Center for Practical Bioethics	$145,095.00	$18,000.00	$0.00	$0.00	$0.00	**$163,095.00**
The National Pain Foundation [29]	$0.00	$0.00	$0.00	$562,500.00	$0.00	**$562,500.00**
U.S. Pain Foundation	$359,300.00	$41,500.00	$22,000.00	$2,500,000.00 [30]	$0.00	**$2,922,800.00**
Washington Legal Foundation	$500,000.00	$0.00	$0.00	$0.00	$0.00	**$500,000.00**
	$4,153,554.33	**$465,152.85**	**$1,071,116.95**	**$3,146,265.00**	**$20,250.00**	**$8,856,339.13**

[22] Purdue also reported $91,449 in payments to entities with incomplete names like "American Academy of Pain" and "American Society of." Production from Purdue Pharma to the Senate Homeland Security and Governmental Affairs Committee (November 13, 2017).

[23] Payments from Janssen include payments from Johnson & Johnson Health Care Systems, Inc. Letter from Daniel F. Donovan, Counsel for Janssen, to Senator Claire McCaskill (November 10, 2017).

[24] Insys was unable to account for $12,500 in payments to the Academy of Integrative Pain Management for expenses related to the organization's 2014 and 2015 annual meetings. Brian D. Smith, Counsel for Insys Therapeutics, briefing with Senate Committee on Homeland Security and Governmental Affairs minority staff (November 28, 2017).

[25] Payments from Purdue to the American Cancer Society Cancer Action Network include payments to the American Cancer Society that could potentially have applied to the Cancer Action Network. Production from Purdue Pharma to the Senate Homeland Security and Governmental Affairs Committee (November 13, 2017).

[26] The American Geriatrics Society reported that Purdue also provided $40,000 in "corporate roundtable dues" to its AGS Health in Aging Foundation, a 501(c)(3) organization affiliated with the group, between 2012 and 2015. Letter from Nancy E. Lundebjerg, chief executive officer, American Geriatrics Society, to Senator Claire McCaskill (October 11, 2017).

[27] Payments from Janssen to the American Society of Pain Management Nursing include two payments to Rockpointe Corporation for an educational grant with signatories including the American Society of Pain Management Nursing. Production from Johnson & Johnson to the Senate Homeland Security and Governmental Affairs Committee (November 10, 2017).

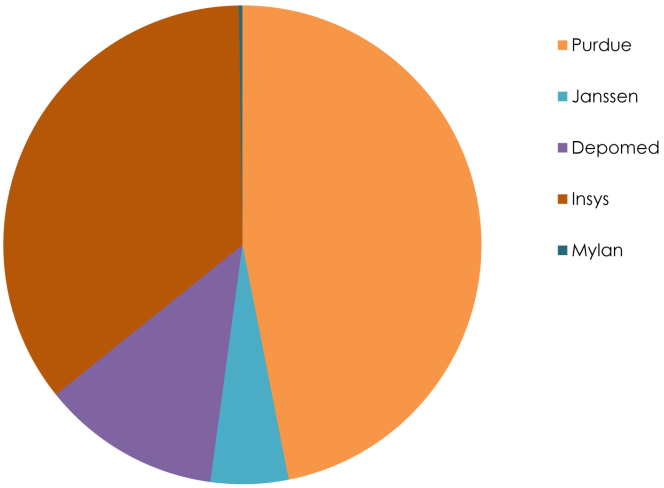
[28] This total includes $4,500 in reported payments from Depomed to the "American Society of Pain Management Nurses." Production from Depomed to the Senate Homeland Security and Governmental Affairs Committee (April 25, 2017).

[29] The National Pain Foundation changed its name to the Global Pain Initiative in mid-2017. Email from Dr. Daniel Bennett, chairman, board of directors, Global Pain Initiative, to Committee on Homeland Security and Governmental Affairs minority staff (January 10, 2018). According to Dr. Bennett, the Global Pain Initiative board decided in the fourth quarter of 2016 not to accept contributions from pharmaceutical or device manufacturers. This decision "permits an academic 'hands off' approach, which is crucial to [the Global Pain Initiative's] public credibility and mission." *Id.*

[30] An additional payment from Insys to the U.S. Pain Foundation of $250,000—on April 7, 2017—fell outside the scope of the March 28, 2017, requests and is not included in this total.

As shown in Figure 2, payments from Purdue account for roughly half of this funding, and the company provided donations to the most diverse array of groups—a significant majority of the organizations profiled below. Primarily due to large payments to the National Pain Foundation and the U.S. Pain Foundation, Insys had the second-highest contribution total from 2012 to 2017. At the other end of the spectrum, Mylan reported only $20,250 in payments during the same period; in correspondence with the committee, the company has claimed a "very limited role in the opioid-containing products marketplace."[31]

FIGURE 2: Percentages of Total Payments by Manufacturer, 2012-2017



As shown in Figure 3 below, trends based on yearly payment totals varied between manufacturers from 2012 to 2017. Payments from Purdue, for example, fell dramatically in 2016 after remaining in the $800,000–$1,000,000 range between 2012 and 2015. Conversely, payments from Insys to advocacy groups rose significantly between 2012—when the company received U.S. Food and Drug Administration approval for its fentanyl drug Subsys—and 2017. As Ranking Member McCaskill noted in a recent report entitled, "Fueling an Epidemic: Insys Therapeutics and the Systemic Manipulation of Prior Authorization," Insys revenues tripled and profits rose 45 percent between 2013 and 2015, and the value of company stock increased 296 percent between 2013 and 2016.[32]

Payments from Janssen to the groups listed above dropped sharply to $0 in 2015 from $126,000 in 2014 (and $99,250 and $239,902.85 in 2013 and 2012, respectively) and remained at $0 for 2016 and 2017. In April 2015, Janssen sold U.S. licensing rights for its major Nucynta opioid product line to Depomed for $1.05 billion.[33] For its part, Depomed more than tripled payments to the advocacy groups featured in this report in 2015 relative to 2014, and the payments total for 2016—$318,257.47—remained steady compared to the 2015 total.

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[31] Letter from Jonathan C. Su, Counsel for Mylan, to Senator Claire McCaskill (September 15, 2017).

[32] "Fentanyl Billionaire Comes Under Fire as Death Toll Mounts From Prescription Opioids," *Wall Street Journal* (November 22, 2016) *(www.wsj.com/articles/fentanyl-billionaire-comes-under-fire-as-death-toll-mounts-from-prescription-opioids-1479830968);* "An Opioid Spray Showered Billionaire John Kapoor in Riches. Now He's Feeling the Pain," *Forbes* (October 4, 2016) *(www.forbes.com/sites/matthewherper/2016/10/04/death-kickbacks-and-a-billionaire-the-story-of-adangerous-opioid/).*

[33] Janssen Pharmaceuticals, Inc.: "Janssen Pharmaceuticals, Inc. Completes Divestiture of U.S. License Rights to Nucynta® (tapentadol), Nucynta® ER (tapentadol) extended-release tablets and Nucynta® (tapentadol) Oral Solution to Depomed, Inc." (April 2, 2015); "DepoMed to Buy U.S. Rights to Nucynta From J&J Unit," *Wall Street Journal* (January 16, 2015) *(www.wsj.com/articles/depomed-to-buy-u-s-rights-to-nucynta-from-j-j-unit-1421357503).*

Mylan made a single $15,000 payment to the American Pain Society in March 2015—its first payment to the groups in this report—before making significantly smaller payments to the same group in 2016 and 2017. Also in March 2015, Mylan announced the launch of intermediate dosage strengths for its fentanyl transdermal system.[34] In connection with this launch, according to the company, Mylan "engaged in marketing efforts to educate doctors about the availability of the intermediate strengths."[35]

Purpose of Manufacturer Contributions

Based on the descriptions manufacturers submitted in connection with each specific reported payment, the minority staff designated broad payment categories. Payments directed to special projects and restricted grants comprise the largest category of contributions, totaling $2,617,899 and constituting roughly 30 percent of total contributions between 2012 and 2017. For these types of restricted grants, donors specify a use for their contribution beyond the broad parameters resulting from the nature of the non-profit entity at issue, the environment in which it operates, or the purposes specified in its organizing documents.[37]

Following closely behind the total for special projects and restricted grants is the amount manufacturers contributed in the form of non-education grants, which totaled $2,269,765 and constituted roughly 26 percent of all contributions. According to a publicly available overview from Purdue, non-education grants provide support for health-care related organizations or initiatives focused on patient and public education, scientific research, and other programs.[38]

Payments for advertising and sponsorship related to group events and dues occupy the next tier of categories, with $1,564,215.86 and $1,253,988 in payments and roughly 18 percent and 14 percent of the total contributions, respectively. Finally, national grants and education grants occupy the third tier of categories, with similar payments totals of $413,154 and $413,128, respectively, and percentages of roughly 5 percent. According to Purdue, an education grant "[p]rovides for health-care professional continuing education (CE) activities designed to foster improved understanding of scientific, clinical, and other health-care issues that help to improve patient care."[39] *See* Figure 4.

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[34] Mylan N.V.: "Mylan Launches First and Only Available Intermediate Dosage Strengths of Fentanyl Transdermal System 37.5, 62.5 and 87.5 mcg/hr" (March 11, 2015).

[35] Letter from Jonathan C. Su, Counsel for Mylan, to Senator Claire McCaskill (September 15, 2017).

[37] Financial Accounting Standards Board, "Not-for-Profit Entities" (Topic 958) (August 2016) *(https://asc.fasb.org/imageRoot/56/92564756.pdf)*.

[38] Purdue Pharma L.P., "Grants and Giving Frequently Asked Questions" (July 11, 2014).

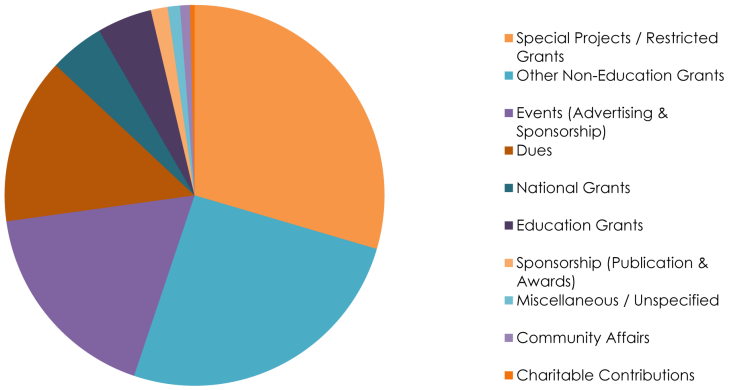
[39] *Id.*

FIGURE 3: Manufacturer Yearly Payment Totals, 2012–2017

	2012	2013	2014	2015	2016	2017	Total
Purdue	$824,227.86	$973,328.00	$812,451.95	$935,344.00	$558,067.52	$50,135.00	**$4,153,554.33**
Janssen	$239,902.85[36]	$99,250.00	$126,000.00				**$465,152.85**
Depomed	$73,080.00	$135,300.00	$113,600.00	$350,000.00	$318,257.47	$80,879.48	**$1,071,116.95**
Insys	$14,040.00	$68,000.00	$34,200.00	$530,025.00		$2,500,000.00	**$3,146,265.00**
Mylan				$15,000.00	$2,500.00	$2,750.00	**$20,250.00**
Total	**$1,151,250.71**	**$1,275,878.00**	**$1,086,251.95**	**$1,830,369.00**	**$878,824.99**	**$2,633,764.48**	**$8,856,339.13**

[36] Although Janssen representatives confirmed the company made a $60,000 payment to the American Pain Society and $75,975 in payments to the American Academy of Pain Medicine via a third party during the 2012–2017 time period, it could not provide the exact day and month associated with these payments. *See* Daniel F. Donovan, counsel for Janssen, briefing with Senate Committee on Homeland Security and Governmental Affairs minority staff (January 17, 2018). According to information the minority staff received from Janssen, the American Pain Society, and the American Academy of Pain Medicine, all these payments occurred in 2012. *See* email from Daniel F. Donovan, counsel for Janssen, to Committee on Homeland Security and Governmental Affairs minority staff (January 31, 2018); production from the American Pain Society to the Senate Homeland Security and Governmental Affairs Committee (October 9, 2017); production from the American Academy of Pain Medicine (October 16, 2017). Janssen representatives later reported an additional $8,500 payment to the American Pain Society and an additional $500 payment to the American Academy of Pain Medicine—both via a third party in 2012. Email from Daniel F. Donovan, counsel for Janssen, to Committee on Homeland Security and Governmental Affairs minority staff (January 31, 2018).

FIGURE 4: Payment Categories as Percentages of Total Payments, 2012-2017



Payments by Organization

The U.S. Pain Foundation received the largest amount of payments during the 2012–2017 period—almost $3 million—which includes $2,500,000 in payments from Insys . The Academy of Integrative Pain Management, formerly the American Academy of Pain Management, received $1,265,566.81 in donations—the second-highest total—followed closely by the American Academy of Pain Medicine with $1,199,409.95 in payments. (The American Academy of Pain Medicine Foundation also received $304,605 in payments from Depomed during the same period.)

FIGURE 5: Group Rankings by Manufacturer Payments, 2012–2017

U.S. Pain Foundation	$2,922,800.00
Academy of Integrative Pain Management	$1,265,566.81
American Academy of Pain Medicine	$1,199,409.95
American Pain Society	$962,724.52
The National Pain Foundation	$562,500.00
Washington Legal Foundation	$500,000.00
American Chronic Pain Association	$417,140.00
American Society of Pain Management Nursing	$323,212.85
AAPM Foundation	$304,605.00
ACS Cancer Action Network	$168,500.00
The Center for Practical Bioethics	$163,095.00
American Society of Pain Educators	$30,000.00
American Pain Foundation	$25,000.00
American Geriatrics Society	$11,785.00

Contributions by Selected Manufacturers as a Percentage of Overall Contributions

Based on comparisons between manufacturer contributions to groups and group reporting on contributions and grants in IRS filings between 2013 and 2015, the percentage of total contributions attributable to the five manufacturers discussed in this report vary significantly. Insys contributions to the National Pain Foundation in 2015, for example, actually *exceeded* total contributions the group reported on its Form 990 by $154,800. In a less extreme example, the American Society of Pain Management Nursing received approximately 76 percent of its funding from Depomed, Janssen, and Purdue in 2013, although this percentage declined for 2014 and 2015. For other groups, the percentages of contributions attributable to the five manufacturers remained consistent during 2013–2015. The Academy of Integrative Pain Management and the American Academy of Pain Medicine, for example, received between 13 percent and 20 percent of their contributions from at least one of the five manufacturers during this 3-year period. At the other end of the spectrum, the American Cancer Society Cancer Action Network received less than 1 percent of its contributions from Purdue between 2013 and 2015.

FIGURE 6: Comparison of Contributions From Selected Manufacturers and Total Contributions and Grants, 2013–2015 [40]

2013 Information	Contributions From Selected Manufacturers	Contributions and Grants	Percent of Selected Contributions
Academy of Integrative Pain Management	$319,929	$1,624,115	19.70%
American Academy of Pain Medicine	$201,944	$1,071,992	18.84%
AAPM Foundation	$50,000	$381,738	13.10%
ACS Cancer Action Network	$28,500	$35,409,632	0.08%
American Chronic Pain Association	$100,970	$564,004	17.90%
American Geriatrics Society	$0	$2,709,179	0.00%
American Pain Foundation	Unavailable	Unavailable	Unavailable
American Pain Society	$161,585	$1,271,537	12.71%
American Society of Pain Educators	$5,000	Unavailable	Unavailable
American Society of Pain Management Nursing	$97,950	$129,167	75.83%
The Center for Practical Bioethics	$101,000	$1,276,473	7.91%
The National Pain Foundation	$50,000	$50,100	99.80%
U.S. Pain Foundation	$84,000	$467,040	17.99%
Washington Legal Foundation	$75,000	$4,113,151	1.82%

[40] Data on contributions and grants are taken from line 8 of Form 990 for each group. The American Pain Foundation ended its operations in 2012.

FIGURE 6: Comparison of Contributions From Selected Manufacturers and Total Contributions and Grants, 2013–2015

2014 Information	Contributions From Selected Manufacturers	Contributions and Grants	Percent of Selected Contributions
Academy of Integrative Pain Management	$269,980	$1,929,818	13.99%

FIGURE 6: Comparison of Contributions From Selected Manufacturers and Total Contributions and Grants, 2013–2015—Continued

2014 Information	Contributions From Selected Manufacturers	Contributions and Grants	Percent of Selected Contributions
American Academy of Pain Medicine	$255,087	$1,346,712	18.94%
AAPM Foundation	$0	$533,776	0.00%
ACS Cancer Action Network	$40,000	$35,288,961	0.11%
American Chronic Pain Association	$85,000	$558,510	15.22%
American Geriatrics Society	$0	$3,197,135	0.00%
American Pain Foundation	Unavailable	Unavailable	Unavailable
American Pain Society	$161,190	$949,867	16.97%
American Society of Pain Educators	$5,000	Unavailable	Unavailable
American Society of Pain Management Nursing	$68,100	$229,732	29.64%
The Center for Practical Bioethics	$30,095	$1,232,768	2.44%
The National Pain Foundation	$0	$3,100	0.00%
U.S. Pain Foundation	$121,800	$791,657	15.39%
Washington Legal Foundation	$50,000	$4,213,431	1.19%

FIGURE 6: Comparison of Contributions From Selected Manufacturers and Total Contributions and Grants, 2013–2015

2015 Information	Contributions From Selected Manufacturers	Contributions and Grants	Percent of Selected Contributions
Academy of Integrative Pain Management	$275,098	$1,465,067	18.78%
American Academy of Pain Medicine	$239,941	$1,482,707	16.18%
AAPM Foundation	$100,000	$451,835	22.13%
ACS Cancer Action Network	$100,000	$37,925,236	0.26%
American Chronic Pain Association	$30,000	$382,671	7.84%
American Geriatrics Society	$0	$4,041,760	0.00%
American Pain Foundation	Unavailable	Unavailable	Unavailable
American Pain Society	$266,020	$660,894	40.25%
American Society of Pain Educators	$10,000	Unavailable	Unavailable
American Society of Pain Management Nursing	$63,810	$171,256	37.26%
The Center for Practical Bioethics	$3,500	$857,788	0.41%
The National Pain Foundation	$512,500	$357,700	143.28%

FIGURE 6: Comparison of Contributions From Selected Manufacturers and Total Contributions and Grants, 2013–2015—Continued

2015 Information	Contributions From Selected Manufacturers	Contributions and Grants	Percent of Selected Contributions
U.S. Pain Foundation	$129,500	Unavailable	Unavailable
Washington Legal Foundation	$100,000	$4,583,620	2.18%

Manufacturers Also Provided Payments to Group-Affiliated Individuals

The five manufacturers specifically at issue in this report also made substantial payments to individual group executives, staff members, board members, and advisory board members. Figure 7 below lists totals for these payments between August 2013 and the present, as well as the sum of these payments and the amounts manufacturers contributed to the groups directly. In terms of total contributions, the U.S. Pain Foundation ranks first among the groups despite minimal payments to affiliated individuals, and the National Pain Foundation assumes the second-place ranking due to payments to individual physicians of over $800,000. Notably, the nearly $300,000 in payments to individuals affiliated with the American Society of Pain Educators significantly outweighs the relatively minor amount the group received from Purdue directly. In contrast, manufacturer payments to groups like the Academy of Integrative Pain Management, the American Academy of Pain Medicine, the American Pain Society, and the American Chronic Pain Association far exceeded payments to physicians affiliated with these organizations.

FIGURE 7: Purdue, Janssen, Insys, Depomed, and Mylan Payments to Groups and Group-Affiliated Individuals, 2012–Present [41]

	Payments to Group	Payments to Group-Affiliated Individuals	Total
U.S. Pain Foundation	$2,922,800.00	$126.20	$2,922,926.20
The National Pain Foundation	$562,500.00	$839,848.84	$1,402,348.84
Academy of Integrative Pain Management	$1,265,566.81	$30,223.42	$1,295,790.23
American Academy of Pain Medicine	$1,199,409.95	$16,462.42	$1,215,872.37
American Pain Society	$962,724.52	$95,474.56	$1,058,199.08
AAPM Foundation	$304,605.00	$314,175.58	$618,780.58
Washington Legal Foundation	$500,000.00	N/A	$500,000.00
American Chronic Pain Association	$417,140.00	$31,265.87	$448,405.87
American Society of Pain Management Nursing	$323,212.85	N/A	$323,212.85
American Society of Pain Educators	$30,000.00	$280,765.92	$310,765.92
The Center for Practical Bioethics	$163,095.00	$7,116.86	$170,211.86
ACS Cancer Action Network	$168,500.00	N/A	$168,500.00
American Pain Foundation	$25,000.00	N/A	$25,000.00
American Geriatrics Society	$11,785.00	$194.13	$11,979.13

FIGURE 7: Purdue, Janssen, Insys, Depomed, and Mylan Payments to Groups and Group-Affiliated Individuals, 2012–Present[41]—Continued

	Payments to Group	Payments to Group-Affiliated Individuals	Total
Total	$8,856,339.13	$1,615,653.80	**$10,471,992.93**

[41] These totals consist of payments in the Open Payments database from the five opioid manufacturers at issue to physician board members, advisory board members, advisory council members, staff members, and officers and executives of the advocacy groups listed. The totals only include payments from manufacturers to physicians since August 2013, when the first reporting period for the CMS Open Payments database began. *See* Centers for Medicare and Medicaid Services, "How Open Payments Works" (September 2, 2015), *(www.cms.gov/OpenPayments/About/How-Open-Payments-Works.html)*. The listed payments from manufacturers to the groups occurred between January 2012 and March 2017.

As shown in Figure 8 below, individuals affiliated with these groups have significant financial ties not only with the five companies at issue in this report, but also with all other opioid manufacturers. According to CMS Open Payments data, for example, the current President of the American Academy of Pain Medicine, Dr. Steven Stanos, received over $90,000 in payments from opioid manufacturers between 2013 and 2016.[42] Additional searches of Open Payments data also show that multiple American Academy of Pain Medicine Corporate Relations Council members made payments directly to at least one American Academy of Pain Medicine board member between 2013 and 2016.[43] In total, between 2013 and 2016, American Academy of Pain Medicine board members received more than $200,000 in payments from opioid manufacturers.[44] In addition, Dr. Charles Argoff, current president of the American Academy of Pain Medicine Foundation, received over $600,000 in payments from opioid manufacturers between 2013 and 2016.[45]

Similarly, Open Payments data indicates that between 2013 and 2016, ten members of the American Chronic Pain Association Advisory Board received more than $140,000 from opioid manufacturers, including Endo, Purdue, Mallinckrodt, Pfizer, Teva, and Depomed.[46] In another prominent example, National Pain Foundation

[42] Centers for Medicare and Medicaid Services, Steven Stanos, Open Payments Data *(https://openpaymentsdata.cms.gov/physician/138667/summary)* (accessed December 22, 2017). *See also* American Academy of Pain Medicine, AAPM Fact Sheet *(www.painmed.org/files/aapm-fact-sheet.pdf)* (accessed December 22, 2017).

[43] Centers for Medicare and Medicaid Services, Steven Stanos, Open Payments Data *(https://openpaymentsdata.cms.gov/physician/138667/summary)* (accessed December 22, 2017); Centers for Medicare and Medicaid Services, Jianguo Cheng, Open Payments Data *(http://openpaymentsdata.cms.gov/physician/163794/summary)* (accessed December 22, 2017); Centers for Medicare and Medicaid Services, Ajay Wasan, Open Payments Data *(https://openpaymentsdata.cms.gov/physician/1272772/summary)* (accessed December 22, 2017); Centers for Medicare and Medicaid Services, Daniel B. Carr, Open Payments Data *(https://openpaymentsdata.cms.gov/physician/202832/summary)* (accessed December 22, 2017); Centers for Medicare and Medicaid Services, Robert Hurley, Open Payments Data *(https://openpaymentsdata.cms.gov/physician/299398/summary)* (accessed December 22, 2017); Centers for Medicare and Medicaid Services, Robert Wailes, Open Payments Data *(https://openpaymentsdata.cms.gov/physician/233305/summary)* (accessed December 22, 2017); Centers for Medicare and Medicaid Services, Chester Church Buckenmaier III, Open Payments Data *(https://openpaymentsdata.cms.gov/physician/1035447/summary)* (accessed December 22, 2017). *See also* American Academy of Pain Medicine, AAPM Fact Sheet *(www.painmed.org/files/aapm-fact-sheet.pdf)* (accessed December 22, 2017).

[44] *Id.*

[45] Centers for Medicare and Medicaid Services, Charles Argoff, Open Payments Data *(https://openpaymentsdata.cms.gov/physician/93628/summary)* (accessed December 22, 2017). *See also* American Academy of Pain Medicine Foundation, AAPM Foundation Leadership *(https://aapmfoundation.org/leadership)* (accessed December 22, 2017).

[46] Centers for Medicare and Medicaid Services, Daniel B. Carr, Open Payments Data, *(https://openpaymentsdata.cms.gov/physician/202832/summary)* (accessed December 22, 2017); Centers for Medicare and Medicaid Services, Edward C. Covington, Open Payments Data, *(https://openpaymentsdata.cms.gov/physician/1008604/summary)* (accessed December 22, 2017); Centers for Medicare and Medicaid Services, Steven Feinberg, Open Payments Data, *(https://openpaymentsdata.cms.gov/physician/308924/payment-information)* (accessed December 22, 2017); Centers for Medicare and Medicaid Services, Gary W. Jay, Open Payments Data *(https://openpaymentsdata.cms.gov/physician/1134064/payment-information)* (accessed December 22, 2017); Centers for Medicare and Medicaid Services, John D. Loeser, Open Payments Data *(https://openpaymentsdata.cms.gov/physician/555855/payment-information)* (accessed December 22, 2017); Centers for Medicare and Medicaid Services, Sean Mackey, Open Payments Data *(https://openpaymentsdata.cms.gov/physician/406055/summary)* (accessed December 22,

Continued

chairman and founder Dr. Daniel Bennett[47] received over $170,000 from Insys Therapeutics, manufacturer of the powerful fentanyl drug Subsys, between 2013 and 2016.[48] Members of the National Pain Foundation Board of Directors, which include Dr. Bennett, received more than $950,000 from opioid manufacturers, including more than $250,000 from Insys Therapeutics, during the same period.[49] In addition, at least half of the members of the National Pain Foundation Clinical and Scientific Advisory Council[50] have received general payments—totaling more than $7,900,000—from opioid manufacturers between 2013 and 2016.[51] Manufacturer payments to all individuals affiliated with the National Pain Foundation total more than $8,000,000 since 2013—by far the largest total for the groups profiled in this report.

FIGURE 8: Payments From All Opioid Manufacturers to Group-Affiliated Individuals, 2013–Present[52]

	Manufacturer Payments to Affiliated Individuals
The National Pain Foundation	$8,307,243.47
AAPM Foundation	$798,051.22
American Society of Pain Educators	$749,564.78
American Academy of Pain Medicine	$204,631.53

2017); Centers for Medicare and Medicaid Services, Srinivasa Raja, Open Payments Data *(https://openpaymentsdata.cms.gov/physician/72208/payment-information)* (accessed December 22, 2017); Centers for Medicare and Medicaid Services, Steven Stanos, Open Payments Data *(https://openpaymentsdata.cms.gov/physician/138667/summary)* (accessed December 22, 2017); Centers for Medicare and Medicaid Services, Knox Todd, Open Payments Data *(https://openpaymentsdata.cms.gov/physician/1052955/payment-information)* (accessed December 22, 2017); Centers for Medicare and Medicaid Services, Debra Weiner, Open Payments Data *(https://openpaymentsdata.cms.gov/physician/591428/payment-information)* (accessed December 22, 2017). *See also* American Chronic Pain Association, Advisory Board *(https://theacpa.org/Advisory-Board)* (accessed December 22, 2017).

[47] Global Pain Initiative, board of directors *(www.globalpaininitiative.org/board-of-directors/)* (accessed January 2, 2018).

[48] Centers for Medicare and Medicaid Services, Daniel S. Bennett, Open Payments Data *(https://openpaymentsdata.cms.gov/physician/329225/summary)* (accessed January 2, 2018). *See also* Global Pain Initiative, board of directors *(https://globalpaininitiative.org/board-of-directors/)* (accessed January 2, 2018).

[49] Centers for Medicare and Medicaid Services, Daniel S. Bennett, Open Payments Data *(https://openpaymentsdata.cms.gov/physician/329225/summary)* (accessed January 2, 2018); Centers for Medicare and Medicaid Services, Dmitry M. Arbuck, Open Payments Data *(http://openpaymentsdata.cms.gov/physician/213597/summary)* (accessed January 2, 2018); Centers for Medicare and Medicaid Services, Joseph V. Pergolizzi, Jr., Open Payments Data *(https://openpaymentsdata.cms.gov/physician/223423/summary)* (accessed January 2, 2018). *See also* Global Pain Initiative, board of directors *(https://globalpaininitiative.org/board-of-directors/)* (accessed January 2, 2018).

[50] Global Pain Initiative, Clinical and Scientific Advisory Council *(www.globalpaininitiative.org/clinical-scientific-council/)* (accessed October 3, 2017).

[51] Centers for Medicare and Medicaid Services, Kenny Chantasi, Open Payments Data *(https://openpaymentsdata.cms.gov/physician/64321/summary)* (accessed January 2, 2018); Centers for Medicare and Medicaid Services, Leonard A. Farber, Open Payments Data *(https://openpaymentsdata.cms.gov/physician/300520/summary)* (accessed January 2, 2018); Centers for Medicare and Medicaid Services, Perry G. Fine, Open Payments Data *(https://openpaymentsdata.cms.gov/physician/672854/summary)* (accessed January 2, 2018); Centers for Medicare and Medicaid Services, Joseph Pergolizzi, Jr., Open Payments Data *(https://openpaymentsdata.cms.gov/physician/223423/summary)* (accessed January 2, 2018); Centers for Medicare and Medicaid Services, Steven M. Simon, Open Payments Data *(https://openpaymentsdata.cms.gov/physician/386520/summary)* (accessed January 2, 2018); Centers for Medicare and Medicaid Services, Lisa Jo Stearns, Open Payments Data *(https://openpaymentsdata.cms.gov/physician/41530/summary)* (accessed January 2, 2018); Centers for Medicare and Medicaid Services, Andrea Trescot, Open Payments Data *(https://openpaymentsdata.cms.gov/physician/231857/summary)* (accessed January 2, 2018); Centers for Medicare and Medicaid Services, Lynn R. Webster, Open Payments Data *(https://openpaymentsdata.cms.gov/physician/1136720/summary)* (accessed January 2, 2018). *See also* Global Pain Initiative, Clinical and Scientific Advisory Council *(https://globalpaininitiative.org/clinical-scientific-council/)* (accessed January 2, 2018).

FIGURE 8: Payments From All Opioid Manufacturers to Group-Affiliated Individuals, 2013–Present [52]—Continued

	Manufacturer Payments to Affiliated Individuals
American Pain Society	$187,699.34
ACS Cancer Action Network	$154,578.09
American Chronic Pain Association	$145,861.30
Academy of Integrative Pain Management	$82,596.98
The Center for Practical Bioethics	$16,945.88
American Geriatrics Society	$7,548.35
U.S. Pain Foundation	$138.91
American Pain Foundation	N/A
American Society of Pain Management Nursing	N/A
Washington Legal Foundation	N/A
Total	$10,654,859.85

[52] As with the previous figure, these totals only include payments to group-affiliated physicians since August 2013.

GROUPS FAIL TO ADEQUATELY DISCLOSE MANUFACTURER CONTRIBUTIONS

Due to their classification under the U.S. tax code, the groups profiled in this report have no obligation to disclose their donors publicly; as a result, each group maintains different levels of transparency regarding its financial connections to the pharmaceutical industry. Specifically, as either 501(c)(3), 501(c)(4), or 501(c)(6) public charities, the groups discussed below have no obligation to publicly disclose the list of donors they provide to the Internal Revenue Service with their annual Form 990 filing.[53] Instead, these organizations have the ability to selectively disclose donors, donations, and other support—or no information at all. Importantly, no organization profiled in this report provides an online list linking donors, their specific donations, and the projects or events benefiting from each donation for each of the years between 2012 and 2017.

The minority staff reviewed disclosure policies available online for each of the groups listed in the March 28, 2017, requests. Several groups—the American Society of Pain Educators, the National Pain Foundation, and the Academy of Integrative Pain Management—provided no information concerning their policies for disclosing donors and donations. Other groups stated explicitly that they do not disclose any information concerning donor relationships. The Washington Legal Foundation, for example, states in its 2016 Annual Report: "All contributions to WLF are strictly confidential. WLF does not disclose, publish, or trade the names of its donors."[54]

Other groups simply list donors, "corporate members," or "corporate partners" without indicating specific donation amounts or even the range of donations for each category of contributor. The website for the American Geriatrics Society, for example, states that "AGS corporate arrangements will be disclosed regularly as part of the organization's financial reporting to the Board of Directors," but for the public, the organization simply lists three "corporate partners" without details of the amounts donated or any related arrangements.[55] The U.S. Pain Foundation similarly lists

[53] *See* 26 U.S.C. § 6104(d)(3)(A).

[54] Washington Legal Foundation, "2016 Annual Report (2016)" *(www.wlf.org/pdf/WLF2016AnnualReport.pdf).*

[55] American Geriatrics Society Health in Aging Foundation, "Guidelines for Corporate Relationships" *(www.healthinagingfoundation.org/support-us/become-a-corporate-partner/guidelines-for-corporate-relationships/)* (accessed October 18, 2017); American Geriatrics Society

Continued

"Platinum," "Gold," and "Basic" corporate members—including opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, and Mallinckrodt—without indicating the level of donations required for each classification.[56] The American Chronic Pain Association lists many of the same corporations as "Partners and Contributors" at the "Champion," "Ambassador," "Educator," and "Builder" levels without specifying the applicable ranges of contributions.[57] Both the American Cancer Society Cancer Action Network and the Center for Practical Bioethics also list corporate or individual donors without including donation amounts.[58] Finally, the American Academy of Pain Medicine website lists donors between January 1, 2017, and October 31, 2017, and describes the list as including "matching gifts from companies," but no companies appear on the list.[59]

A handful of groups disclose both their donors and list the ranges of donations applicable to each category of contributor. The American Pain Society, for example, specifies that "Corporate Council" contributors donated at least $25,000, "Executive" donors provided at least $15,000, and "Associate" contributors donated at least $7,500.[60] Opioid manufacturers, including Pfizer, Teva, Depomed, Purdue, and Mallinckrodt, appear at all three donor levels.[61] The website of the American Society of Pain Management Nursing similarly specifies that all listed corporations contributed more than $5,000.[62]

GROUP ACTIVITIES CONTRIBUTING TO OPIOID OVERPRESCRIPTION AND OVERUSE

Many of the groups discussed in this report have amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain. Several groups have also lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for overprescription and misbranding.

Minimizing the Risk of Addiction

Many of the groups have issued guidelines to physicians and other health practitioners that minimize the risk of opioid addiction or emphasize the long-term use of opioids to treat chronic pain. According to a complaint from the city of Chicago, for example, the American Academy of Pain Medicine and the American Pain Society issued a consensus statement in 1997 "which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low."[63] Dr. J. David Haddox, then a paid speaker for Purdue and now the Vice President of Health Policy at the company, co-authored the statement.[64] The American Academy of Pain Medicine and the American Pain Society also allegedly issued guidelines in 2009 that "promote[d] opioids as 'safe and effective' for treating chronic pain, despite acknowledging limited

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Health in Aging Foundation, "Meet Our Partners" *(www.healthinagingfoundation.org/support-us/become-a-corporate-partner/meet-our-partners/)* (accessed January 2, 2018).

[56] U.S. Pain Foundation, "Transparency" *(www.uspainfoundation.org/transparency/)* (accessed October 18, 2017).

[57] American Chronic Pain Association, "Partners and Contributors" *(www.theacpa.org/Partners-Contributors)* (accessed October 18, 2017).

[58] American Cancer Society Cancer Action Network, "Our Partners" *(www.cancer.org/our-partners.html)* (accessed October 18, 2017); Center for Practical Bioethics, "Community Supporters" *(www.practicalbioethics.org/support-our-mission/community-supporters.html)* (accessed October 18, 2017). The website for the Center for Practical Bioethics also provides a link to the organization's annual audits and Form 990 filings, which list total amounts of contributions and grants per year. See "Ways to Help," Center for Practical Bioethics *(www.practicalbioethics.org/support-our-mission/ways-to-help.html)* (accessed February 13, 2018).

[59] American Academy of Pain Medicine Foundation, AAPM Foundation Donors *(www.aapmfoundation.org/donors)* (accessed Oct. 18, 2017).

[60] American Pain Society, "Corporate Council Members" *(www.americanpainsociety.org/get-involved/corporate-council/overview)* (accessed Oct. 18, 2017).

[61] *Id.*

[62] American Society for Pain Management Nursing, "Corporate Membership" *(www.aspmn.org/Pages/corporatemembership.aspx)* (accessed October 18, 2017); American Society for Pain Management Nursing, "ASPMN Corporate Membership Categories" *(www.aspmn.org/Documents/Membership/Corporate%20membership%20information_17.pdf)* (accessed January 2, 2018).

[63] Third Amended Complaint (October 25, 2016), *City of Chicago v. Purdue Pharma L.P., et al.,* N.D. III. (No. 1:14 CV 04361).

[64] *Id.*

evidence, and conclude[d] that the risk of addiction is manageable for patients regardless of past abuse histories."[65]

Similarly, the American Geriatrics Society released guidelines in 2009 for the management of persistent pain in older patients.[66] While acetaminophen remained the preferred option for the treatment of chronic pain patients, the American Geriatrics Society recommended opioids—as opposed to aspirin or ibuprofen—for those unable to gain relief from Tylenol and similar products.[67] According to the city of Chicago complaint, the guidelines included these recommendations: "All patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation)," and "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[68] The American Geriatrics Society also partnered with the American Academy of Pain Medicine and Janssen to create the 2009 patient education guide entitled, "Finding Relief: Pain Management for Older Adults," which stated that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."[69]

Lobbying to Defeat Measures to Restrict Overprescription

Advocacy groups have engaged in extensive lobbying efforts to either defeat legislation restricting opioid prescribing or promote laws encouraging opioid treatment for pain. In 2014, for example, the Academy of Integrative Pain Management and the American Cancer Society Cancer Action Network led an effort to protect a 2001 Tennessee law that made it difficult to discipline doctors for overprescribing opioids and prohibited them from refusing to prescribe opioids unless they referred the patient to another "opioid-friendly" doctor.[70]

According to a joint investigation by the Associated Press and the Center for Public Integrity, the Academy of Integrative Pain Management and the American Cancer Society Cancer Action Network have contacted legislators and other officials about opioid measures in at least 18 States.[71] More broadly, the American Cancer Society Cancer Action Network reportedly maintains "about 200 lobbyists around the country opposed to opioid restrictions even in some cases where they specifically exempted cancer patients."[72] In an example of the general legislative reach of these groups, the U.S. Pain Foundation has "participated in more than 30 State and national advocacy coalitions, alliances, and task forces . . . [and is] actively engaged in 70 legislative bills in 20 States with the support of 250 advocates engaged in outreach to policymakers."[73]

Efforts to Criticize or Undermine CDC Guidelines

On March 15, 2016, the CDC issued guidelines providing prescribing recommendations for "primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care."[74] In introducing these guidelines—"the first national standards for prescription painkillers,"[75] as *The New York Times* reported—the CDC noted that opioid

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[65] *Id.*

[66] "Chronic Pain Guidelines Suggest Opioids," *New York Times* (May 12, 2009) *(http://query.nytimes.com/gst/fullpage.html?res=9806E0D71E3AF931A25756C0A96F9C8B63).*

[67] *Id.; see also* "Pharmacological Management of Persistent Pain in Older Persons: American Geriatrics Society Panel on the Pharmacological Management of Persistent Pain in Older Persons," *Journal of the American Geriatrics Society* (August 2009).

[68] Third Amended Complaint (October 25, 2016), *City of Chicago v. Purdue Pharma L.P., et al.,* N.D. III. (No. 1:14 CV 04361).

[69] *Id.*

[70] "Politics of Pain: Drugmakers Fought State Opioid Limits Amid Crisis," The Center for Public Integrity (December 15, 2016) *(www.publicintegrity.org/2016/09/18/20200/politics-pain-drugmakers-fought-state-opioid-limits-amid-crisis).*

[71] *Id.*

[72] "Industry Uses 50-State Strategy to Weaken Drug Laws," *The Journal* (September 22, 2016) *(https://the-journal.com/articles/1047-industry-uses-50-state-strategy-to-weaken-drug-laws).*

[73] U.S. Pain Foundation, Annual Report *(www.uspainfoundation.org/about-us/annual-report/)* (accessed October 3, 2017).

[74] Department of Health and Human Services, Centers for Disease Control and Prevention, "CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016" (March 15, 2016) *(www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1er.pdf). See also* Deborah Dowell et al., "CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016," *JAMA Internal Medicine* (April 19, 2016).

[75] "CDC Painkiller Guidelines Aim to Reduce Addiction Risk," *New York Times* (March 15, 2016) *(www.nytimes.com/2016/03/16/health/cdc-opioid-guidelines.html).*

prescriptions per capita had increased 7.3 percent from 2007 to 2012, "more than 165,000 persons died from overdose related to opioid pain medication in the United States" from 1999 to 2014, and "the death rate associated with opioid pain medication" had increased "markedly" in the previous decade.[76] The guidelines explained that non-opioid therapies are preferred for chronic pain and recommended that physicians prescribe immediate-release opioids at the lowest effective dosage and evaluate the benefits and harms of continued opioid use within 1 to 4 weeks of starting opioid therapy.[77] The guidelines also noted that for opioid therapy for acute pain, "[t]hree days or less will often be sufficient; more than 7 days will rarely be needed."[78]

These guidelines represented an important step—and perhaps the first major step from the Federal Government—toward limiting opioid prescriptions for chronic pain in the face of an unprecedented public health crisis. A majority of the groups described in this report, however, strongly criticized the content of the guidelines, the process by which the CDC drafted them, or the experts who assisted during their development. In fact, *The New York Times* reported that the release of the CDC guidelines ended "months of arguments with pain doctors and drug industry groups, which had bitterly opposed the recommendations on the grounds that they would create unfair hurdles for patients."[79] As Dr. Andrew Kolodny, executive director of Physicians for Responsible Opioid Prescribing, has explained, "[t]he opioid lobby has very actively blocked interventions that might result in more cautious prescribing or reduced prescribing. They've very clearly defended their financial stake in the status quo."[80]

In 2016, for example, the immediate past president of the American Academy of Pain Medicine, Daniel Carr, criticized the prescribing guidelines, stating "that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence."[81] Similarly, several advocacy groups criticized draft guidelines in 2015, arguing that the "CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliations, and conflicts of interest of the individuals who participated in the construction of these guidelines."[82] Dr. Richard Payne, a physician affiliated with the Center for Practical Bioethics, made a similar argument, criticizing the CDC guidelines as the product of "conflicts of interests in terms of biases [and] intellectual conflicts"—while himself maintaining "financial links to numerous drug companies."[83] The Washington Legal Foundation also strongly criticized the guidelines on procedural grounds, claiming CDC had developed its guidelines in an "overly secretive manner" and in violation of the Federal Advisory Committee Act, which called "into question the viability of the entire enterprise."[84] The Washington Legal Foundation

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[76] Department of Health and Human Services, Centers for Disease Control and Prevention, "CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016" (March 15, 2016) *(www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1er.pdf).*

[77] *Id.*

[78] *Id.*

[79] "CDC Painkiller Guidelines Aim to Reduce Addiction Risk," *New York Times* (March 15, 2016) *(www.nytimes.com/2016/03/16/health/cdc-opioid-guidelines.html).*

[80] "Opioid Epidemic: Ex-DEA Official Says Congress Is Protecting Drug Makers," *Guardian* (October 31, 2016) *(www.theguardian.com/us-news/2016/oct/31/opioid-epidemic-dea-official-congress-big-pharma).*

[81] Practical Pain Management, "Responses and Criticisms Over New CDC Opioid Prescribing Guidelines" *(www.practicalpainmanagement.com/resources/news-and-research/responses-criticisms-over-new-cdc-opioidprescribing-guidelines)* (accessed September 28, 2017).

[82] "Chronic Pain Groups Blast CDC for Opioid Guidelines," *Pain News Network* (September 22, 2015) *(www.painnewsnetwork.org/stories/2015/9/22/chronic-pain-groups-blast-cdc-for-opioid-guidelines).*

[83] "Pro-Painkiller Echo Chamber Shaped Policy Amid Drug Epidemic," The Center for Public Integrity (September 19, 2016) *(www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic).*

[84] Washington Legal Foundation, "Re: Guideline for Prescribing Opioids for Chronic Pain" (November 17, 2015) *(www.wlf.org/upload/litigation/misc/CDCComments-Opioids.pdf).* In addition to its work related to the pharmaceutical industry, the Washington Legal Foundation has also recently challenged the validity of Consumer Financial Protection Bureau enforcement actions, raised objections to certain Department of Labor disclosure requirements, and sought to enjoin the enforcement of a local ordinance requiring health warnings in advertisements for sugary drinks, among other initiatives. *See* Washington Legal Foundation, "2016 Annual Report (2016)" *(www.wlf.org/pdf/WLF2016AnnualReport.pdf).* WLF previously maintained a relationship with the Philip Morris tobacco company during regulatory disputes with the Food and Drug Administration throughout the 1990s. *See, e.g.,* Letter from Steven C. Parrish, senior vice president, corporate affairs, Philip Morris, to Daniel J. Popeo, chairman and general counsel, Washington

claimed, moreover, that "[s]tate governments and the medical community are unlikely to accept any guidelines tainted by charges that they were prepared in secret without meaningful stakeholder input."[85] When the CDC published its final opioid prescribing guidelines, Richard A. Samp, Washington Legal Foundation general counsel, reportedly believed the guidelines "were inherently biased, crafted by people who already had strong views about what opioid policy should look like."[86]

The fact that these groups registered their opposition while receiving funding from the opioids industry raises the appearance—at the very least—of a direct link between corporate donations and the advancement of opioids-friendly messaging. Relatedly, in a March 2017 article published in *JAMA Internal Medicine,* researchers from Johns Hopkins University and Brandeis University examined industry payments to over 150 organizations that had submitted comments on the draft CDC guidelines.[87] After coding guideline comments by supportiveness and reviewing financial disclosures, including annual reports, tax returns, and self-reported information, researchers found "opposition to the guidelines was *significantly* more common among organizations with funding from opioid manufacturers than those without funding from the life sciences industry."[88] Accordingly, a "major concern is that opposition to regulatory, payment, or clinical policies to reduce opioid use may originate from groups that stand to lose financially if opioids sales decline."[89] In an extended version of their findings, the researchers are more explicit: "[O]pposition to more conservative opioid use may, at least in part, be financially motivated."[90]

Efforts to Limit Accountability

Certain advocacy groups and professional societies have also organized legal efforts to challenge government actions to punish physicians engaging in opioid overprescription and executives responsible for fraudulent marketing of opioid products. In 2005, for example, the National Pain Foundation submitted to the U.S. Court of Appeals for the Fourth Circuit an amicus brief in support of Dr. William Hurwitz,[91] a doctor convicted "of 16 counts of drug trafficking, [for] prescrib[ing] massive quantities of medicine to patients in chronic pain."[92] Prosecutors asserted that Dr. Hurwitz "prescribed excessive amounts of Oxycodone and other dangerous narcotics—in one instance more than 1,600 pills a day—to addicts and others, some of whom then sold the medication on a lucrative black market."[93] In defense of Dr. Hurwitz, the National Pain Foundation suggested that "[t]he conviction [in the trial court] broke ground by holding that a doctor acting in the good faith belief that he was serving the best medical interest of his patient could be found to be a drug dealer."[94] Similarly, the Washington Legal Foundation filed an amicus brief challenging the exclusion of three former Purdue executives from participation in Federal health-care programs for 12 years for their admitted failure to prevent the fraudulent marketing of

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Legal Foundation (March 21, 1996) *(www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=zhfw0096);* Philip Morris, "REM Monthly Report" (April 1994) *(www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=fphm0071);* memorandum from BSMG Worldwide to Philip Morris, "Communications Plan—Supersized" (February 25, 1999) *(www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=xmyd0068).*

[85] Washington Legal Foundation, "Re: Guideline for Prescribing Opioids for Chronic Pain" (November 17, 2015) *(www.wlf.org/upload/litigation/misc/CDCComments-Opioids.pdf).*

[86] "The CDC Just Told American Doctors to Rethink Pain Treatment and Opioid Addiction," *Vice* (March 17, 2016) *(https://news.vice.com/article/the-cdc-just-told-american-doctors-to-rethink-pain-treatment-and-opioid-addiction).*

[87] Dora H. Lin et al., "Financial Conflicts of Interest and the Centers for Disease Control and Prevention's 2016 Guideline for Prescribing Opioids for Chronic Pain," *JAMA Internal Medicine* (March 2017).

[88] *Id.* (emphasis added).

[89] *Id.*

[90] Dora H. Lin et al., "Potential Financial Conflicts of Interest and Federal Opioid Guidelines: A Cross-Sectional Study (2017)" (manuscript provided to minority staff).

[91] Brief for Amici, The American Pain Foundation, "The National Pain Foundation and The National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction" (September 8, 2005), *United States v. William Eliot Hurwitz,* 4th Cir. (No. 05–4474).

[92] "Pain Doctor is Guilty of Drug Trafficking," *Washington Post* (April 28, 2007) *(www.washingtonpost.com/wp-dyn/content/article/2007/04/27/AR2007042702204.html).*

[93] *Id.*

[94] Brief for Amici, The American Pain Foundation, "The National Pain Foundation and The National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction" (September 8 2005), *United States v. William Eliot Hurwitz,* 4th Cir. (No. 05–4474).

OxyContin.[95] In a brief filed with the U.S. Court of Appeals for the District of Columbia Circuit, the Washington Legal Foundation argued— unsuccessfully—that the exclusion raised serious constitutional due process concerns.[96]

FULL EXTENT OF INDUSTRY INFLUENCE ON GROUPS IS UNKNOWN

This report does not capture the full extent of the financial ties between opioid manufacturers and patient advocacy groups and professional societies. According to the Associated Press and the Center for Public Integrity, for example, opioid manufacturers "spent more than $880 million nationwide on lobbying and campaign contributions from 2006 through 2015—more than 200 times what those advocating for stricter [opioid] policies spent."[97]

Moreover, payments between 2012 and 2017 may not fully reflect historical funding activities by manufacturers, given that several of the most prominent advocates in this space historically—the American Pain Foundation, for example—no longer operate. The fact that opioid prescribing, as measured in morphine milligram equivalents (MME) per capita, peaked between 2010 and 2012 before declining from 2012 to 2015 may also suggest more robust financing of advocacy groups in the pre-2012 period.[98]

In addition, the data contained in this report may not even capture the full extent of payments between the covered manufacturers and patient advocacy groups and professional societies. This report is based on information provided voluntarily to the committee at the request of the ranking member—information which certain manufacturers changed following further inquiries from the minority staff. A timeline of interactions between the committee, manufacturers, and advocacy groups appears below as Figure 9.

As mentioned above, Ranking Member McCaskill sent requests for payments information to Purdue, Janssen, Insys , Depomed, and Mylan on March 28, 2017.[99] On April 25, 2017, Depomed provided an initial response, closely followed a response from Purdue on May 11, 2017, and a response from Janssen on June 12, 2017.[100] Following extensive discussions with minority staff, Mylan provided payments information on October 5, 2017.[101]

On October 5, 2017, Ranking Member McCaskill sent requests for payment information directly to 15 advocacy groups and professional societies.[102] Following these letters, several manufacturers volunteered additional or revised data. After further due diligence, for example, Janssen reported an additional $7,500 payment to the American Academy of Pain Medicine and an additional $128,000 in cumulative payments to the Academy of Integrative Pain Management.[103] Purdue also provided updated information showing an additional $70,552 in payments to the American Academy of Pain Medicine, $415,574 in payments to the American Pain Society, and $17,755 in payments to the American Society of Pain Management Nursing.[104] For the first time, Purdue also reported $1,091,025 in payments to the Academy of Inte-

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[95] Brief of Washington Legal Foundation as Amicus Curiae in Support of Appellants Urging Reversal (June 29, 2011), *Friedman v. Sebelius,* D.C. Cir. (No. 11–5028); *Friedman v. Sebelius,* 686 F.3d 813 (D.C. Cir. July 27, 2012)

[96] Brief of Washington Legal Foundation as Amicus Curiae in Support of Appellants Urging Reversal (June 29, 2011), *Friedman v. Sebelius,* D.C. Cir. (No. 11–5028).

[97] "Politics of Pain: Drugmakers Fought State Opioid Limits Amid Crisis," The Center for Public Integrity (December 15, 2016) *(www.publicintegrity.org/2016/09/18/20200/politics-pain-drugmakers-fought-state-opioid-limits-amid-crisis).*

[98] *See* Dr. Gery P. Guy Jr. et al., "Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015," *CDC Morbidity and Mortality Weekly Report* (July 7, 2017) *(www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm).*

[99] *See, e.g.,* letter from Senator Claire McCaskill to Santosh Vetticaden, interim chief executive officer of Insys Therapeutics, Inc. (March 28, 2017).

[100] Production from Depomed to the Senate Homeland Security and Governmental Affairs Committee (April 25, 2017); production from Purdue Pharma to the Senate Homeland Security and Governmental Affairs Committee (May 11, 2017); production from Johnson & Johnson to the Senate Homeland Security and Governmental Affairs Committee (June 12, 2017).

[101] Production from Mylan to the Senate Homeland Security and Governmental Affairs Committee (October 5, 2017).

[102] *See, e.g.,* letter from Senator Claire McCaskill to Steven P. Stanos, president, American Academy of Pain Medicine (October 5, 2017).

[103] *See* Production from Johnson & Johnson to the Senate Homeland Security and Governmental Affairs Committee (June 12, 2017); production from Johnson & Johnson to the Senate Homeland Security and Governmental Affairs Committee (November 10, 2017).

[104] *See* production from Purdue Pharma to the Senate Homeland Security and Governmental Affairs Committee (May 11, 2017); production from Purdue Pharma to the Senate Homeland Security and Governmental Affairs Committee (November 13, 2017).

grative Pain Management—the company had not searched for payments to the American Academy of Pain Management, the previous name of the organization—and $168,500 in payments to the American Cancer Society Cancer Action Network.[105] Purdue additionally reported over $91,000 in payments associated with incomplete entity names in company records.[106]

A comparison of payments information from the five manufacturers and the information advocacy groups provided directly to the committee revealed several discrepancies. Most significantly, Insys Therapeutics initially failed to report $2,500,000 in responsive payments to the U.S. Pain Foundation for the "Gain Against Pain" patient assistance program.[107] The company also did not report $12,500 in payments the Academy of Integrative Pain Management reported receiving in 2014 and 2015 and could not confirm or deny these payments after further due diligence.[108] (Insys did, however, report an additional $3,050 in payments to the Academy of Integrative Pain Management during 2012.[109]) Purdue also failed to report $40,000 in corporate roundtable dues to the American Geriatrics Society Health in Aging Foundation; according to the American Geriatrics Society, this foundation received all payments Purdue directed to the organization between 2012 and 2017.[110]

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[105] *Id.* As stated above, the total for the American Cancer Society Cancer Action Network also included payments from Purdue to the American Cancer Society that could potentially apply to the Cancer Action Network.

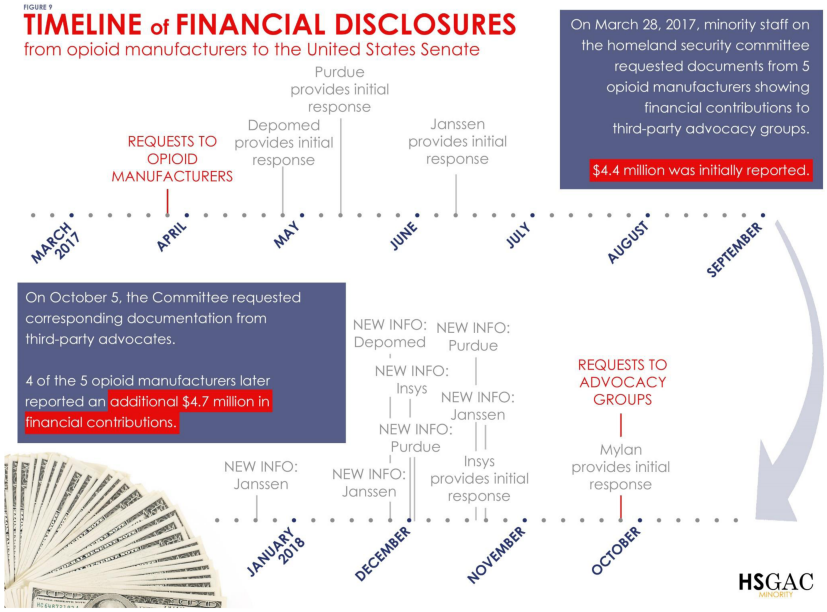
[106] Production from Purdue Pharma to the Senate Homeland Security and Governmental Affairs Committee (November 13, 2017).

[107] *See* letter from Paul Gileno, U.S. Pain Foundation, to Senator Claire McCaskill (October 5, 2017); letter from Brian D. Smith, counsel for Insys Therapeutics, to Senator Claire McCaskill (November 10, 2017). As stated above, one payment between Insys and the U.S. Pain Foundation related to this program—a $250,000 payment on April 7, 2017—fell outside of the scope of the March 28, 2017 requests, and is not included in this total. *See* email from Brian D. Smith, counsel for Insys Therapeutics, to Senate Committee on Homeland Security and Governmental Affairs minority staff (December 1, 2017).

[108] *See* production from the Academy of Integrative Pain Management to the Senate Homeland Security and Governmental Affairs Committee (October 31, 2017); Brian D. Smith, counsel for Insys Therapeutics, briefing with Senate Committee on Homeland Security and Governmental Affairs minority staff (November 28, 2017).

[109] Email from Brian D. Smith, counsel for Insys Therapeutics, to Committee on Homeland Security and Governmental Affairs minority staff (December 1, 2017).

[110] Letter from Nancy E. Lundebjerg, American Geriatrics Society, to Senator Claire McCaskill (October 11, 2017). According to counsel for Purdue, the company could verify three out of four payments to the American Geriatrics Society Health in Aging Foundation. Reginald J. Brown, Counsel for Purdue Pharma, briefing with Senate Committee on Homeland Security and Governmental Affairs minority staff (November 29, 2017).



In addition, Depomed later reported five additional responsive payments—totaling $17,600 to the American Chronic Pain Association and $28,174.95 to the Academy of Integrative Pain Management—after receiving further correspondence from minority staff.[111] According to Depomed, these payments "were for advertising or promotional purposes," and the company initially considered them outside the scope of the March 28, 2017, requests.[112] Finally, in response to information from minority staff, Janssen representatives also reported the company had made an additional $68,500 in payments to the American Pain Society and an additional $76,475 in payments to the American Academy of Pain Medicine via a third party during the 2012–2017 time period.[113]

CONCLUSION

The privacy the advocacy groups discussed above have guarded for their donors has come at a high price for the public debate on chronic pain and opioid use in the United States. As a 2011 study in the *American Journal of Public Health* noted, a tension exists between the status of advocacy organizations as "among the most influential and trusted stakeholders in U.S. health policy," and the reality that their "positions closely correspond to the marketing aims of pharmaceutical and device companies."[114] The findings in this report indicate that this tension exists in the area of opioids policy—that organizations receiving substantial funding from manufacturers have, in fact, amplified and reinforced messages favoring increased opioid use. By aligning medical culture with industry goals in this way, many of the groups described above may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic.

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[111] Email from Catherine A. Byrd to Committee on Homeland Security and Governmental Affairs minority staff (December 1, 2017); letter from J. Evans Rice, counsel for Depomed, to Senator Claire McCaskill (December 5, 2017).

[112] *Id.*

[113] Daniel F. Donovan, counsel for Janssen, briefing with Senate Committee on Homeland Security and Governmental Affairs minority staff (December 11, 2017); Daniel F. Donovan, counsel for Janssen, briefing with Senate Committee on Homeland Security and Governmental Affairs minority staff (January 17, 2018); email from Daniel F. Donovan, counsel for Janssen, to Committee on Homeland Security and Governmental Affairs minority staff (January 31, 2018).

[114] Sheila M. Rothman et al., "Health Advocacy Organizations and the Pharmaceutical Industry: An Analysis of Disclosure Practices," *American Journal of Public Health* (April 2011).

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

Thank you, Chairman Hatch, for convening this vitally important hearing, which gives the committee an opportunity to examine the opioid issue while it works on bipartisan legislation under the chairman's leadership. I'm going to have some comments on that process in a moment, but here's where I want to begin my remarks.

It is long past time to get the opioid executives before this committee, have them raise their right hands, and hold them accountable for their role in creating a public health calamity that is killing tens of thousands of Americans each year.

Some years ago, I participated in a House hearing where a panel of tobacco executives said under oath that their products were not addictive. And in my view, there's a clear parallel you can draw to this issue today.

Back then it was tobacco companies that concealed the dangers of their products and denied they were addictive. Now it's the opioid companies, including those that manufacture the drugs and those that distribute the drugs, that have misled the country about the dangers of their products. The opioid executives, however, have avoided the spotlight that Congress put on the executives of the big tobacco companies.

That has got to change, colleagues. The executives need to be brought before this committee and held accountable. Flooding American communities with these drugs is big business, and so-called "safer" opioid pills keep the cash registers ringing. Congress would be derelict in its responsibilities if it pretends there is no profit motive or corporate scheming behind this addiction crisis.

In 2015, more than 52,000 Americans died of a drug overdose. In 2016, it increased to 64,000. In 2017, it was 71,000. There's a tragic and well-documented pattern of opioid addiction escalating into abuse of heroin and fentanyl. Now an even stronger narcotic called carfentanil is spreading. Carfentanil is supposed to be used as a sedative for elephants. It's so potent and dangerous, first responders are advised to wear hazmat suits when they're around it. That's the horrifying level of danger plaguing our communities as a result of this epidemic.

Those of us looking for answers also have to deal with the paradoxical reality that cutting down the supply of opioids too sharply could drive even more people to heroin and other drugs, leading to even more overdose deaths. There is no easy way out of this crisis. With that said, I believe Congress has an opportunity to take bipartisan action. For example, there must be a way to address what I call the "prescription pendulum." Doctors used to be criticized for prescribing too conservatively. Now they're criticized fairly for prescribing too much. There's got to be a safer middle ground.

I remember a case from my days as the head of the Oregon Gray Panthers. A gentleman called me and said his 92 year old father was in pain and couldn't get a prescription. Ninety-two years old, and his doctor said "No no no, the risk of addiction is way too high." Compare that with the fact that today, one in three Medicare patients has a prescription for opioids.

I've also heard powerful, agonizing stories from parents in Oregon who've lost children to this epidemic. At a roundtable, I met Kerry Strickland, who lost her son Jordan to an overdose. Jordan was a star athlete in the tiny Columbia River town of Knappa. When he suffered an injury, he was prescribed opioids. He started using heroin, and for years he struggled in the battle between addiction and recovery. I went to school on a basketball scholarship myself. It's heartbreaking to hear these stories, which are far too common. I've heard them in every corner of my home State, in communities of all stripes.

Here on this committee, under Chairman Hatch's leadership, there is bipartisan interest in finding new legislative proposals to help make a difference. And the chronic care legislation that just became law shows that this committee can work together on the big health policy challenges. So the chairman and I are working with every member to identify meaningful policies that can achieve broad, bipartisan support. Colleagues on both sides have done a lot of work on this issue. On our side, Senator Brown has been tireless. And I particularly want to mention how fortunate the committee is to have the senior Senator from Missouri on our roster. Nobody has outworked Senator McCaskill when it comes to investigating how this crisis came to be and how to hold accountable those who are responsible.

Particularly important to this committee is the vital role Medicaid plays in treatment. Four out of 10 working-age Americans suffering from opioid addiction rely on Medicaid. It's the largest source of funding for treatment in the country, so in my view, Medicaid is going to be a key part of any solution.

The landmark reforms to our child welfare system that this committee led on a bipartisan basis, the Family First Act, are also going to help curb this epidemic. Family First is all about keeping families together whenever possible. So under the law, if a parent is swept up in opioid addiction, a grandparent or another close relative can step in to care for youngsters while mom or dad gets the treatment they need. It would provide support for both the parent's treatment and services for the relatives. The end result you hope for is a family that's able to stay together safely. It's going to take hard work between HHS and the States to prepare for this major reform, but the chairman and I are determined to see this law implemented as intended.

Finally, a warm welcome to our witnesses, one of whom, Kim Brandt, is a Finance Committee veteran. It's great to have Kim back to work on this vital subject.

Thank you, Chairman Hatch. I look forward to continuing our work on this critical issue.

UNITED STATES SENATE
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

February 5, 2016

The Honorable Sylvia Mathews Burwell
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Burwell:

Prescription opioid addiction is a serious condition, and its increased prevalence in recent years is cause for alarm. Since 2000, the rate of deaths from opioid-related overdoses has increased by 200% and in 2014 alone, 61% of all overdose deaths were opioid-related.[1] A recent examination of Medicare Part D prescribers found that total opioid prescriptions are dominated by general practitioners in the primary care setting.[2] While the study found that opioid prescriptions are concentrated in select specialty services such as pain, and anesthesia, data from Medicare Part D suggests opioid prescribing in the program is a "widespread practice relatively indifferent to individual physicians, specialty or region."[3]

Consequently, I was alarmed to read of efforts by the members of the Interagency Pain Research Coordinating Committee (IPRCC) to weaken efforts underway at the Centers for Disease Control and Prevention (CDC) to develop guidance on opioid prescribing practices.[4] A preliminary review by my staff of the IPRCC has raised a number of concerns including what appear to be personal and institutional conflicts of interest of non-Federal IPRCC members related to opioid manufacturers. The Associated Press also has reported on some of these apparent conflicts.[5] I am writing today to seek clarification on the procedures and conflict of interest requirements that govern operation of, and membership on, the IPRCC.

As you know, the Secretary of Health and Human Services was required by law to establish the IPRCC.[6] In addition to members appointed by the Secretary from Fed-

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[1] CDC, "Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014," *https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm.*

[2] Jonathan H. Chen, et al., "Distribution of Opioids by Different Types of Medicare Providers," *JAMA Intern. Med.* 2015, available at *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2474400.*

[3] *Id.*

[4] *Politico,* "HHS split on CDC opioid prescription guidelines," by Brett Norman, December 3, 2015, *https://www.politicopro.com/staff/brett-norman.*

[5] *Associated Press.* "Federal pain panel rife with links to pharma companies," by Matthew Perrone, January 27, 2016, *https://apnews.com/6e22f8ffcded4b2e9ba278bcc00f4f53.*

[6] Sec. 409J. Pub. L. 111–148.

eral agencies that conduct pain care research and treatment, the Secretary is required to appoint six non-Federal members who are scientists, physicians, or other health professionals.[7] The Secretary is also required to appoint six members who are representatives of leading research, advocacy and services organizations for individuals with pain-related conditions.[8] The statute makes no provision that representatives of the pharmaceutical industry are included on the panel. The statute also does not specify terms of service of board members, but it is my understanding that members are appointed to specific terms. At the December 3, 2015 meeting of the IPRCC at which the CDC opioid guidance was discussed, several members whose terms had expired were allowed to continue to serve on the Committee and to participate in the meeting.[9]

Several non-Federal IPRCC members, their organizations, or both, appear to be recipients of funding from major pharmaceutical companies that manufacture opioids or related products at levels that raise concerns regarding the potential for conflicts of interest. These financial and professional relationships raise serious concerns about the objectivity of the panel's members that deserve additional review. In addition, three non-Federal IPRCC public members appear to have strong connections to opioid-related drug manufacturers.

One public member who attended the December 3rd meeting—Ms. Myra Christopher—is financially supported through an endowed chair at the organization that employs her—the Center for Practical Bioethics. According to publicly available records, the $1.5 million endowment for that chair came from Purdue Pharma, the manufacturer of the opioid Oxycontin—and was established while she was the chief executive of the organization.[10] Funding for the endowment was provided by Purdue Pharma in three $500,000 allocations in 2008, 2009, and 2011 respectively.[11] She has remained on the staff of that organization.[12]

In addition to the endowment supporting Ms. Christopher's employment, Purdue Pharma provides substantial funding to the organization that employs Ms. Christopher. For instance, in 2013, publicly available records indicate Purdue Pharma contributed $100,000 to the Center, making the company its second largest contributor that year.[13] As noted above, Ms. Christopher's term of service had expired, but she continued to participate in the Committee's December 3rd deliberations.

One of the IPRCC's other non-Federal members—Dr. Richard Payne—is also employed by the Center for Practical Bioethics.[14] I am concerned that this single organization with significant ties to a major opioid manufacturer had two paid staff sitting as committee members at the same time.

I also note that Dr. Payne appears to have additional ties to Purdue Pharma. In 2013, Dr. Payne reportedly received $2,000 in travel and lodging from the company to attend a meeting for which he received an additional $4,700 for "services other than consulting, including serving as faculty or as a speaker" from a Purdue affiliate—Purdue Transdermal Technologies L.P.[15] Dr. Payne was selected to be one of

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[7] Sec. 409J(b)(2)(B)(i).

[8] Sec. 409J(b)(2)(B)(ii).

[9] According to the committee roster provided by the Department, three of the six public members of the committee had terms that expired on July 31, 2015—Myra J. Christopher, Center for Practical Bioethics; Tina M. Tockarshewsky, The Neuropathy Association; and Christin L. Veasley, Chronic Pain Research Alliance. All attended the December 3, 2015 meeting, *http://iprcc.nih.gov/meetings/12-3-2015_IPRCC_Meeting.htm.*

[10] McBride, Lock, and Associates, "Report of Examination of the Center for Practical Bioethics, Inc., Kansas City, MO for the Year Ended December 31, 2008," April 13, 2008, *http://gkccf.guidestar.org/nonprofit.aspx?orgid=1193.*

[11] McBride, Lock, and Associates, "Report on Examination of the Center for Practical Bioethics, Inc., Kansas City, MO as of and for the Year Ended December 31, 2010," July 21, 2011, *http://gkccf.guidestar.org/nonprofit.aspx?orgid=1193.*

[12] Based on tax records and the organization's annual reports, it appears that Ms. Christopher did not step down as president and CEO of the Center until mid-2011. The Greater Kansas City Community Foundation makes publicly available the records for the organization at *http://gkccf.guidestar.org/nonprofit.aspx?orgid=1193* (accessed January 28, 2016).

[13] *Ibid.*

[14] According to Center's website, Dr. Payne is listed as Center staff. *https://www.practicalbioethics.org/about-us/staff.* The Center's Form 990 for 2013 and 2014 each list Dr. Payne under Part VII, "Officers, Directors, Trustees, Key Employees, and Highly Compensated Staff," with annual compensation exceeding $111,000, *http://gkccf.guidestar.org/nonprofit.aspx?orgid=1193.*

[15] Centers for Medicare and Medicaid Services Open Payments, *https://openpaymentsdata.cms.gov/physician/1094555.* Open Payments also includes a report for 2014

Continued

two coordinators of the IPRCC efforts to critique the proposed CDC guidelines according to the minutes of the December 3, 2015 meeting.[16]

Another public member of the IPRCC—Cindy Steinberg—is the National Policy Director of the U.S. Pain Foundation. This organization appears to receive substantial funding from opioid manufacturers. According to publicly available documents posted on the Foundation's website, a majority of the organization's funding in 2012 came from major pharmaceutical manufacturers.[17] That year the organization received more than $180,000 from pharmaceutical manufacturers including Pfizer ($50,000), Purdue Pharma ($30,000), Teva ($43,000), Endo ($30,000), Johnson & Johnson ($7,500), and the trade group PHRMA ($20,000).[18] The organization's most recent IRS filing for 2014 shows that the organization continues to receive large contributions from the pharmaceutical industry, including $104,800 from Purdue Pharma.[19]

A third public member—Penney Cowan—heads the American Chronic Pain Association. The organization reports receiving corporate support from 11 companies that manufactured opioid-based drugs—AbbVie, Collegium Pharmaceutical, Depomed, Egalet, Janssen, Mallinckrodt, Pfizer, Purdue, Shionogi, Teva, and Zogenix.[20] Its "corporate champion," which appears to be its highest corporate contributor, is AstraZeneca. The company produces and markets a drug to relieve opioid-induced side-effects—Movantik.[21] Furthermore, the organization's advisory board includes J. David Haddox, Purdue Pharma's vice president for health policy.[22] The advisory board also includes Dr. Judith Paice, one of the IPRCC scientific members. Dr. Paice is the second coordinator of the IPRCC critique of the CDC guidelines.

I am requesting that you provide the following information within twenty-one (21) days from the date of this letter:

(1) The Department's policies on appointments to and terms of service for non-Federal members of the IPRCC.

(2) The personal and organizational conflict of interest policies and disclosure requirements for non-Federal members of the IPRCC.

(3) Confirmation that employees and representatives of the Center for Practical Bioethics and the U.S. Pain Foundation who serve on the IPRCC, as well as all other members of the IPRCC, fully disclosed the financial and institutional support they and their organizations receive from Purdue Pharma and other pharmaceutical manufacturers.

(4) A description of the process by which the IPRCC comments concerning the CDC guidelines were drafted and approved by the Committee.

Thank you for assistance in this matter. If you or your staff have questions concerning this request please contact David Berick, Chief Investigator for the Democratic staff of the Finance Committee, at 202–224–4515.

Sincerely,

Ron Wyden
Ranking Member

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showing that Dr. Payne received an honoria of $1,500 from Teva Pharmaceuticals USA, Inc., another manufacturer of opioid prescription drugs, along with travel and lodging associated with the event, *http://www.uspainfoundation.org/*.

[16] Interagency Pain Research Coordinating Committee, December 3, 2015 meeting minutes, *http://iprcc.nih.gov/meetings/12-3-15_Meeting_Minutes.htm* (accessed January 28, 2016).

[17] U.S. Pain Foundation, Form 990 for tax year 2012, at *http://uspainfoundation.org/Docs/2012-990-taxes-signed-complete.pdf* (accessed January 28, 2016).

[18] *Ibid.*

[19] U.S. Pain Foundation, Form 990 for tax year 2014, at *http://www.uspainfoundation.org/wp-content/uploads/2015/12/2014-taxes.pdf* (accessed January 28, 2016).

[20] American Chronic Pain Foundation, "Partners and Contributors," at *https://theacpa.org/Partners-Contributors* (accessed January 28, 2016). Zogenix sold its pain franchise in May 2015.

[21] AstraZeneca, "Movantik™ (naloxegol) tablets for the treatment of opioid-induced constipation in adult patients with chronic non-cancer pain launched in the U.S.," March 31, 2015, *http://www.astrazeneca-us.com/media/press-releases/Article/20150330-movantik-launched-in-the-us.*

[22] The advisory panel also includes three doctors who received $1,000 or more from opioid-related pharmaceutical companies according to Open Payments data for 2014. One of those doctors, Steven Stanos, received over $40,000 in consulting fees and other reimbursements from three companies—Mallinckrodt, Pfizer, Inc., and Zogenix, Inc. in 2013 and 2014. Centers for Medicare and Medicaid Services Open Payments, *https://openpaymentsdata.cms.gov/physician/138667.*

U.S. Senate
Committee on Finance

UNITED STATES SENATE
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

June 23, 2016

The Honorable Sylvia Mathews Burwell
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Burwell:

On April 8, 2016, I received a response from Dr. Francis Collins to my February 5, 2016 letter regarding apparent conflicts of interest associated with the Interagency Pain Research Coordinating Committee (IPRCC).

After reviewing Dr. Collin's response, I am even more concerned that the Department of Health and Human Services does not adequately consider financial and organizational conflicts of interest when creating and managing advisory committees. For example, an opioid manufacturer directly funded an endowment for one of the committee's participants, and despite this relationship, that individual participated on the panel—including deliberations regarding the CDC's opioid prescription guidelines. In my view, this is indicative of a flawed conflicts of interest policy.

Dr. Collins also asserts that these conflicts of interest are absent given that committee members are not representatives of their organizations when they serve on the committee. This assertion conflicts with the requirements of the authorizing statute which establishes that 6 of the 12 non-Federal members ". . . shall be members of the general public, *who are representatives of leading research, advocacy, and service organizations* . . . " (emphasis added).[1]

Dr. Collins's assertion that committee members are not representatives of the organizations is further undercut by the committee's website,[2] minutes,[3] and members' statements at meetings. For example, Dr. Richard Payne, one of the two panel members who lead the panel's discussion of the proposed CDC opioid prescribing guidelines, identified himself as being "from Duke and the Center for Practical Bioethics in Kansas City" during that discussion.[4] I would note that although the meeting roster and minutes identify Dr. Payne as being affiliated with Duke, they do not identify his affiliation with the Center.[5]

In regards to the concerns I raised about two employees of a single organization filling 2 of the 12 statutorily designated, non-Federal positions failing to provide balance—like Payne, Ms. Myra Christopher also is employed by the Center for Practical Bioethics—Dr. Collins reiterated his argument that members do not represent their own organizations. Dr. Collins also insisted that HHS has taken great care to ensure that committee ". . . membership is balanced in terms of the points of view and the functions performed . . ." when this appears not to have been the case.

Dr. Collins's acceptance of these conflicts is of serious concern, particularly considering that Dr. Payne, in his capacity as a panel member moderating the discussion on the CDC prescribing guidelines, appeared intent on holding CDC to a much higher conflict of interest standard than NIH has appeared to have done with its own IPRCC panel members.

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[1] 42 U.S.C. 284q.

[2] National Institutes of Health, December 3, 2015 IPRCC meeting roster, December 3, 2015, *https://iprcc.nih.gov/meetings/2015/12-3-2015_IPRCC_Meeting_Roster.htm,* accessed on June 16, 2016.

[3] National Institutes of Health, meeting minutes, Interagency Pain Research Coordinating Committee, December 3, 2015, *https://iprcc.nih.gov/meetings/12-3-2015_Meeting_Minutes.htm,* accessed on June 16, 2016.

[4] National Institutes of Health, Interagency Pain Research Coordinating Committee—December 2015, 6:05:58 (comments at 4:58:15), December 3, 2015, *https://videocast.nih.gov/summary.asp?Live=17523&bhcp=1,* accessed on June 16, 2016.

[5] *Supra,* notes 2 and 3.

During the December meeting, Dr. Payne questioned both the methodology the CDC took in developing its opioid prescribing recommendations, and the objectivity of CDC's reviewers:

> So I guess just one more question and follow-up from me. So if there is strong recommendations (sic) with weak evidence, that suggests that you are heavily dependent on kind of the expertise of the reviewers, which then leads to the question of who are the reviewers, and what were the processes by which the reviewers were selected—who they were, how transparent was the process by which they were working, etc. . . . Were there any conflict of interest (sic)—beyond just financial conflict of interest—but conflicts of interests in terms of, possible—you know—perceptions, biases, intellectual kinds of conflicts of interest or confluence, conflicts of interest that need to be disclosed as part of the guideline dissemination process? . . . It just seems to me that if there is weak evidence, then you are—having been involved with guideline processes myself in the old [Agency Healthcare Research and Quality] days—it does really suggest you are very dependent on the expert reviewers and then the question is, you know, do you have a really kind of—for want of a better term—balanced perspective in terms of who is reviewing what.[6]

Given these continuing concerns, please provide responses to the questions and information requests below:

1. According to the letter of April 8, 2016, candidates for the public and scientific panels "are reviewed for eligibility through criteria for leadership, expertise, and contributions to pain cure and relevant research by NIH staff and Institute and Center Directors with pain care research expertise."
   a. Please provide the standards for each of the above-listed criteria, and any such guidance that is used by staff to evaluate candidates in the selection process.
   b. Please provide an analysis of each individual committee member, and how each scientific and public member of the IPRCC met these criteria as of December 2015.
   c. Please provide any documents, including but not limited to: emails, memos, notes, or any additional written or electronic materials that discuss the appointment of past or present members to the IPRCC and their qualifications met the required standards.
2. The statute establishing the committee requires that six non-Federal members "shall be appointed from among scientists, physicians, and other health professionals, and that the remaining six shall be appointed from members of the public, who are representatives of leading research, advocacy, and service organizations for individuals with pain-related conditions."
   a. Please provide the standards and any relevant guidance utilized to evaluate and select the scientific appointees, in addition to the members of the public serving on the committee.
   b. Please provide a member-by-member analysis of how each scientific and public member of the IPRCC met this criteria, as of December 3, 2015.
   c. Please provide any documents, including, but not limited to: emails, memos, or any additional written or electronic materials that discuss the appointment of former or current members on the IPRCC, and the ways in which their qualifications met the required standards.
3. According to the letter received on April 8, 2016, "the nomination slate is drafted at the National Institute of Neurological Disorders and Stroke (NINDS), forwarded to the NIH Director for concurrence then approved by the Secretary." Please provide all nomination slates that were drafted by the NINDS, and occurrences or alterations made by the NIH Director and the Secretary since the creation of the Panel.
4. According to the April 8, 2016 letter, "under some circumstances, [committee member's] terms may be extended administratively for a specific period."
   a. Please detail all policies and guiding materials that were utilized in setting standards and terms for extension.

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[6] National Institutes of Health, Interagency Pain Research Coordinating Committee—December 2015, 6:05:58 (comments at 5:01:16), December 3, 2015, *https://videocast.nih.gov/summary.asp?Live=17523&bhcp=1,* accessed on June 16, 2016.

b. Please provide a list of all IPRCC members, past or present, whose terms have been extended.
c. For each such person, provide the documentation and material proof that these guiding policies were used in the approval of each member's term extension.

5. According to the April 8, 2016 letter, "the conflict of interest policies and disclosure requirements for non-Federal members of the IPRCC follow agency policies for members of Federal advisory committees."

   a. Please provide all such policies and disclosure requirements.
   b. Do agency policies differ from the Department's policy? If so, please explain how they differ.
   c. Please provide a list of all advisory committees within NIH to which these "agency policies" apply regarding conflicts of interest.

6. According to the April 8, 2016 letter, "before serving as a member of the IPRCC, each non-Federal member is appointed as a Special Government Employee, and is required to file a detailed financial disclosure form (OGE 450), which is updated bi-annually during their term of service." The letter also notes that each member disclosed "the research support or earned income they receive from pharmaceutical manufacturers and other biomedical entities."

   a. Please provide completed copies of these forms for each non-Federal member since the inception of the IPRCC.
   b. Please provide a detailed, written itemization of the research support or earned income received by each IPRCC member from pharmaceutical manufacturers and other biomedical entities, and associated documentation disclosing this support or income.

7. According to the April 8, 2016 letter, IPRCC members are "advised, in writing, of applicable standards of conduct, including conflict of interest statutes, and must affirm with signature that they received and read the information."

   a. Please provide copies of the above-referenced materials that were provided to members.
   b. Please provide the signed forms for each non-Federal member of the IPRCC since its inception.

8. According to the April 8, 2016 letter, IPRCC members "agree to recuse, consistent with applicable law, from discussions that might specifically involve a particular company or product."

   a. Please provide a list of all instances in which IPRCC members recused themselves from committee discussions, the dates, and the topics of the discussion.
   b. Please provide a list of all instances when the IPRCC discussed prescription opioids, including but not limited to those manufactured by or being developed by Purdue Pharma, Pfizer, Inc., Teva Pharmaceuticals, Teva, Endo, Johnson & Johnson, AbbVie, Collegium Pharmaceutical, Depomed, Eglat, Janssen, Mallinckrodt, Shionogi, or Zogenix.
   c. Please provide a list of all instances when the IPRCC received written or oral communications or presentations related to its work from representatives of any of the companies listed in question (b), other manufacturers of prescription opioids, or any group or organization that represents or is funded by manufacturers of prescription opioids.

The public expects governmental advisory committees to be impartial authorities when it comes to research and guidance on policy. When conflicts of interest are not sufficiently transparent or accounted for that impartiality can too easily be called into question. Given the public health epidemic rooted in prescription opioid addiction, current policy governing these powerful drugs merits particularly close scrutiny and at this time appears to be inadequate.

Please provide your responses to this request by June 30, 2016. If you or your staff have questions concerning this matter, please contact David Berick or Peter Gartrell of the Democratic staff at (202) 224–4515.

Sincerely,

Ron Wyden
Ranking Member

UNITED STATES SENATE
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

July 1, 2016

Dr. Victor J. Dzau, M.D.
President
National Academy of Medicine
500 5th Street, NW
Washington, DC 20001

Dear Dr. Dzau:

I am writing to you in regards to the provisional committee member appointments to the Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse committee ("opioid committee") that the National Academy of Medicine ("NAM") announced for public comment on June 14, 2016.[1] I am concerned that the Academy's review and the corresponding announcement failed to fully disclose or address important information related to potential conflicts of interest and bias.

Specifically, these omissions concern provisional committee members, Dr. Gregory Terman and Dr. Mary Lynn McPherson. In both cases, my concerns relate to leadership positions that they hold or have held in professional societies with substantial ties to the pharmaceutical industry, and, specifically, opioid manufacturers. These relationships suggest conflicts and biases that should have been made public when the provisional committee announcement was made last month, and require further examination by the Academy.

The proposed work on which the NAM is about to embark is of great importance to my constituents in Oregon, where prescription opioid abuse is a major public health problem, as well as the jurisdictional interests of the Senate Committee on Finance. Opioid addiction and treatment have a great impact on agencies in this Committee's jurisdiction, such as Medicaid and Medicare. By 2020, public and private spending on the treatment of substance abuse disorder(s) are anticipated to reach $42.1 billion, compared with $24.3 billion in 2009.[2] Medicare and Medicaid are expected to account for a third of this spending.[3]

Gregory Terman

The NAM announcement failed to disclose that Dr. Terman was president of the American Pain Society ("APS") from 2014–2016; that he has been on the board of directors since 1998, or that he has been a member of the society for more than 30 years.[4] In his role as a board member, Terman has represented APS, an advocacy group that has substantial financial ties to opioid manufacturers, before the Food and Drug Administration ("FDA").[5] Terman also acknowledged to the FDA in 2014 that APS receives money from opioid manufacturers:

> The American Pain Society and that society has taken money from companies making long acting opiates in the past. Although I have never received money personally from such companies in other work for the FDA I have had to declare money given to the organization as well.[6]

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[1] The National Academies of Science, Engineering, and Medicine, "Committee Membership Information, Pain Management, and Regulatory Strategies to Address Prescription Opioid Abuse," IOM–HSP–16–05, *https://www.nationalacademies.org/cp/CommitteeView.aspx?key=49792,* accessed on July 1, 2016.

[2] Substance Abuse and Mental Health Administration, Projections of National Expenditures for Treatment of Mental and Substance Use Disorders, 2010–2020, SMA–14–4883, 2014, *https://store.samhsa.gov/system/files/sma14-4883.pdf,* 30–31.

[3] *Ibid.*

[4] American Pain Society, "University of Washington Anesthesiologist Gregory W. Terman, M.D., Ph.D. Becomes President of the American Pain Society," June 23, 2014, *http://americanpainsociety.org/about-us/press-room/gregory-terman-aps-president,* accessed July 1, 2016.

[5] Food and Drug Administration, "Risk Evaluation and Mitigation Strategies for Certain Opioids" (transcript), May 27, 2009, p. 88, *http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM211814.pdf,* accessed July 1, 2016.

[6] Food and Drug Administration, Postmarketing Requirements for the Class-Wide Extended-Release/Long-Acting Opioid Analgesics, Participant Disclosure Form, May 19–20, 2014, *http://www.fda.gov/downloads/Drugs/NewsEvents/UCM392235.pdf,* accessed July 1, 2016.

A closer review shows that the organization has received hundreds of thousands of dollars from opioid manufacturers, and, in return, provides industry sponsors significant access to the organization's leadership.

The APS maintains a "corporate council" that is made up of pharmaceutical manufacturers who contribute to the APS.[7] The council's page currently show eight members of the council—AstraZeneca, Depomed, Endo, Mallinckrodt, Purdue, Pernix, Pfizer, Teva—that donated at least $132,500 to APS, based on financial contribution levels required to be classified as a member of the "Corporate Circle" ($25,000), "Executive Level" ($15,000), and "Associate" ($7,500).[8] Please refer to Attachment 1 for more details about the benefits APS offers its corporate council members.

In addition, the APS lists commercial supporters on its website, which shows that in 2013 six pharmaceutical manufacturers contributed $225,000 to various APS programs.[9] The contributors were Eli Lilly, Millenium, Purdue, Pfizer, Teva, and Zogenix.[10] The contributions fund programs including grants, meeting sponsorship, awards, and sponsorship of the organization's electronic newsletter.[11]

One of the roles of the APS board is to review and approve position statements. Several of the position statements are associated with Federal actions related to opioids, including actions by the FDA.[12] One such statement opposed more stringent labeling guidelines for the use of opioid painkillers, partly due to the organization's assertion that there were insufficient data to justify changes.[13] Terman was among the co-signers of this statement, which was sent to FDA. More recently, the American Pain Society submitted comments to the CDC on its opioid guidance. Major points in the letter included:

- Discouraging specific dosage limits;
- Criticizing the guidelines for being reliant on insufficient data;
- Encouraging exclusion of any reference to cancer pain;
- Raising concerns about qualifications of reviewers were confined to experts in toxicology and epidemiology; and
- Criticizing the exclusion of guidelines for pediatric pain care.[14]

The APS also is a member of the Pain Care Coalition, a policy advocacy coalition that includes the American Academy of Pain Medicine, and the American Society of Anesthesiologists. It bills itself as "a national coalition for responsible pain care." Public records show that the coalition spent more than $121,000 for lobbying activities in 2015, a year during which Terman was president of APS, including pain care legislation, NIH appropriations, and meetings with the U.S. House of Representatives, the Department of Health and Human Services, and the Department of Justice.[15]

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[7] American Pain Society, "Corporate Council Members," *http://americanpainsociety.org/get-involved/corporate-council/members,* accessed July 1, 2016.

[8] American Pain Society, "Corporate Council," *http://americanpainsociety.org/get-involved/corporate-council/overview,* accessed July 1, 2016.

[9] American Pain Society, "APS Transparency of Commercial Support for 2013," *http://americanpainsociety.org/uploads/get-involved/transparency-of-support-2013.pdf,* accessed July 1, 2016.

[10] *Ibid.*

[11] American Pain Society, "Commercial Support," *http://americanpainsocietv.org/get-involved/commercial-support/overview,* accessed July 1, 2016.

[12] American Pain Society, "Position Statements," *http://americanpainsociety.org/about-us/position-statements/overview,* accessed July 1, 2016.

[13] Roger Filligim, et al., letter to Margaret A. Hamburg, August 8, 2012, *http://americanpainsociety.org/uploads/about/position-statements/fda-opioids-letter.pdf,* accessed July 1, 2016.

[14] American Pain Society to Deborah Dowell, January 13, 2016, *http://www.regulations.gov/#!documentDetail;D=CDC-2015-0112-3700,* accessed July 1, 2016.

[15] Powers, Pyles, Sutter, and Verville, P.C., Lobbying Report to Clerk of the House of Representatives and Secretary of the Senate, first quarter 2015 (April 20, 2015), *http://soprweb.senate.gov/index.cfm?event=getFilingDetails&filingID=00983e5d-4368-4b6f-9004-d10f6ce76b1f&filingTypeID=51,* accessed July 1, 2016; Powers, Pyles, Sutter, and Verville, P.C., Lobbying Report to Clerk of the House of Representatives and Secretary of the Senate, second quarter 2015 (July 15, 2015), *http://soprweb.senate.gov/index.cfm?event=getFilingDetails&filingID=87f41d5e-16bc-4480-aa16-9a4b625e8e79&filingTypeID=60,* accessed July 1, 2016; Powers, Pyles, Sutter, and Verville, P.C., Lobbying Report to Clerk of the House of Representatives and Secretary of the Senate, third quarter 2015 (October 14, 2015), *http://soprweb.senate.gov/index.cfm?event=getFilingDetails&filingID=60bceb42-2073-454d-b6bb-c628e4ac74bb&filingTypeID=69,* accessed July 1, 2016; Powers, Pyles, Sutter, and Verville, P.C., Lobbying Report to Clerk of the House of Representatives and Secretary of the Senate, fourth quarter 2015 (Janu-

Continued

In addition to his ties to APS, the NAM failed to note that Terman is a temporary voting member of the FDA's science board.[16] This position presents another potential organizational conflict of interest since FDA has commissioned the Academies to conduct this study as part of the FDA's reexamination of its approach to balancing the risks of opioid prescription use.[17]

Mary Lynn McPherson

Another provisional appointee at issue is Mary Lynn McPherson, who appears to have had significant ties to the pharmaceutical industry dating back at least 2 decades. Her extensive ties to opioid manufacturers and related businesses raise significant concerns about potential conflicts of interest and bias, and deserve further examination.

McPherson's curriculum vitae show she has received grants and residencies worth at least $300,000 that were sponsored—or paid directly—by opioid manufacturers.[18] Between 1997 and 2004, she listed three residencies funded by Purdue Pharma and three more funded by Purdue Frederick that totaled $253,500.[19] In 2010, she received a $50,000 unrestricted educational grant from King Pharmaceuticals.[20]

McPherson's association with opioid manufacturers is ongoing, as demonstrated by her authorship of a continuing education presentation that was supported by Purdue Pharma.[21] This presentation was published in 2014 and is current through 2017. Another current continuing education activity she authored promotes the idea of "pseudoaddiction," which has increasingly been viewed as a dangerous—and false—justification to overprescribe prescription opioids.[22] Of this concept, former FDA Commissioner David A. Kessler recently wrote:

> Equally dangerous was the notion that there was virtually no dose ceiling. The mantra was: "Prescribe until patients achieve pain relief." And then there was the flawed concept of pseudoaddiction: If the patient comes in and is showing signs of drug seeking, that doesn't mean the patient is actually addicted to opioids; it more likely means that he or she just needs more opioids to control pain. So the first response should be to prescribe more.[23]

None of the ongoing financial ties with opioid manufacturers discussed above were noted by the NAM in its biography about McPherson. I believe these omissions were a significant oversight.

McPherson and the American Society of Pain Educators

McPherson's biography on the NAM website did disclose her role as president of the American Society of Pain Educators ("ASPE"). What the NAM does not disclose, and what I have detailed below, is that:

- ASPE is sponsored in part by opioid manufacturers;
- APSE's board of directors and advisory board include individuals closely associated with, and in some cases, employed as consultants by, opioid manufacturers; and

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ary 15, 2016), *http://soprweb.senate.gov/index.cfm?event=getFilingDetails&filingID=9579f732-eb68-4af4-b3e1-2ea0f83b4cac&filingTypeID=78,* accessed July 1, 2016.

[16] Food and Drug Administration, Science Board to the Food and Drug Administration, committee roster, March 1, 2016, *http://www.fda.gov/downloads/advisorycommittees/committees meetingmaterials/scienceboardtothefoodanddrugadministration/ucm488096.pdf,* accessed July 1, 2016.

[17] Robert M. Califf, et al., "A Proactive Response to Prescription Opioid Abuse," *New England Journal of Medicine,* 374 (April 14, 2016), *http://www.nejm.org/doi/full/10.1056/NEJMsr 1601307.*

[18] Mary Lynn McPherson, curriculum vitae, March 2, 2015, *http://mlmcpherson.weebly.com/ biographycv.html,* accessed July 1, 2016.

[19] *Ibid.*

[20] *Ibid.*

[21] Mary Lynn McPherson, "Prescription Opioids for Chronic Pain—Minimizing the Risks, Maximizing the Benefit," 0798–0000–14–174–LOI–P&T, December 3, 2014, *http://www. freece.com/Files/Classroom/ProgramSlides/cb9bb72c-252e-43c4-b220-354da5819ef4/PO_ho_cp. pdf,* accessed July 1, 2016.

[22] Mary Lynn McPherson, "The Pain Stops Here: Part 5—Opioid Therapy," 0798–0000–14–100–HOI–P&T, May 11, 2015, *http://www.freece.com/Files/Classroom/ProgramSlides/56ae 4493-b051-496c-a547-0047e05bcbb6/slidedocument_0798000014100H01PT.pdf,* accessed July 1, 2016.

[23] David A. Kessler, "The Opioid Epidemic We Failed to Forsee," *The New York Times,* May 6, 2016, *http://www.nytimes.com/2016/05/07/opinion/the-opioid-epidemic-we-failed-to-foresee. html?_r=O,* accessed July 1, 2016.

- ASPE does not appear to be an independent organization. Rather it was founded and is managed by Aventine HealthSciences, a communications firm that organizes continuing education events and conferences related to pain treatment and related services.

The APSE webpage lists two corporate members—AbbVie and Purdue Pharma L.P.—both of which are manufacturers of opioids. It is unclear how much these companies contributed to the organization because ASPE does not make available its tax forms on its website. The charitable information database Guidestar also does not appear to have tax records for the organization on file.

In addition to being president of ASPE, the organization's website lists McPherson as chair of a seven-person board of directors.[24] My staff found that at least three of the six other APSE board members have significant financial ties to the pharmaceutical industry. In addition to the financial ties to opioid manufacturers on the board of directors, two of the six members of the organization's advisory board[25] have significant financial ties to the pharmaceutical industry, and opioid manufacturers, specifically.

ASPE and Aventine

It also is not clear whether ASPE is an independent entity. ASPE was incorporated in 2004 by three employees of Aventine HealthSciences, a medical communications firm.[26] The ASPE board's current secretary is a managing partner of Aventine.[27] Aventine continues to manage the daily operation of ASPE, and ASPE board members, including Dr. McPherson, participate in Aventine business activities such as *PAINWeek* and *PAINWeek Journal.* If there are direct management and financial ties between ASPE and Aventine, then those relationships would be relevant to McPherson's leadership role at ASPE and should be disclosed and reviewed for bias and potential conflicts of interest.

Aventine describes itself as a "highly niched medical communications agency focused on pain and neuroscience . . . [that] has become an information resource to all pain management stakeholders: pharmaceutical companies, payers, health-care providers, and patients."[28] Since 2007, the company also has managed *PAINWeek,* which began as an annual conference in Las Vegas. Aventine has patented *PAINWeek,* describing it as providing "educational services, namely, conducting workshops, seminars and special events in the nature of exhibitions to promote awareness on pain issues."[29] The company appears to receive a great deal of sponsorship money from the pharmaceutical industry, including several opioid manufacturers, for its *PAINWeek* franchise.

Aventine's overlapping roles running ASPE and *PAINWeek* are significant concerns given Dr. McPherson's leadership position at ASPE. The two franchises also appear to be very closely related both in terms of personnel and frequent cross-promotion of activities. McPherson and several members of the ASPE board are listed as presenters for *PAINWeek* and have video presentations on the organization's website and social media channels[30] In addition, McPherson and four other members of ASPE's boards are on the editorial board of *PAINWeek Journal.*[31] McPherson's curriculum vitae also show that she received a $65,000 unrestricted education grant from Aventine in 2011.[32]

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[24] American Society of Pain Educators, "Board of Directors," *http://www.paineducators.org/home/board-of-directors/,* accessed on July 1, 2016.

[25] American Society of Pain Educators, "Advisory Board," *http://www.paineducators.org/home/advisorv-board/,* accessed on July 1, 2016.

[26] Attachment 2.

[27] American Society of Pain Educators, "Debra Weiner," *http://www.paineducators.org/home/board-of-directors/weiner/,* accessed July 1, 2016.

[28] Linkedln, Aventine Health Sciences, *https://www.linkedin.com/company/aventine-healthsciences,* accessed July 1, 2016.

[29] U.S. Patent and Trademark Office, *PAINWeek* (Registration No. 4659545), December 23, 2014 (via Trademark Electronic Search System), *http://tmsearch.uspto.gov/bin/gate.exe?f=tess&state=4806:t8vqvh.1.1.*

[30] *PAINWeek,* "Brainfood," *http://www.painweek.org/brainfood/,* accessed July 1, 2016; YouTube, "Informed Deprescribing: The Medication Regimen in Advanced Illness," June 22, 2016, *https://www.voutubc.com/watch?v=093E0cEcVaVI,* accessed July 1, 2016.

[31] *PAINWeek Journal, http://www.painweek.org/painweek-journal/,* accessed July 1, 2016.

[32] Mary Lynn McPherson, curriculum vitae, March 2, 2015, *http://mlmcpherson.weebly.com/biographycv.html,* accessed July 1, 2016.

PAINWeek receives financial support from numerous pharmaceutical manufacturers and opioid makers. The 2015 national conference included sponsored programs "presented by AstraZeneca, Cara Therapeutics, Depomed, Indivior, Iroko, kaleo, Pernix, Purdue Pharma, Salix, and Teva Pharmaceuticals."[33] The company's website also includes numerous banner advertisements from opioids manufacturers, and a video-and-slide presentation sponsored by Zogenix, the manufacturer of Zohydro.[34] The *PAINWeek* franchise has expanded to include regional conferences held in 11 different states, which also include multiple sponsored programs and presentations, as well as "*PAINWeek* at Sea," an ocean cruise offering CME classes.[35]

In 2015, Aventine sold the rights to *PAINWeek* to a media firm, Tarsus Group plc, in a deal worth as much as $50 million, depending on deferred payments linked to performance.[36] A press release at the time of the sale stated that *PAINWeek* provided "Tarsus with increased exposure to a key area of the preventative medicine market."[37] The release noted that Aventine would continue to manage *PAINWeek* through at least 2018.[38]

The Academy's Disclosures and Due Diligence

The potential sources of bias and conflicts of interests for Terman and McPherson described in this letter should have been publicly disclosed, since they meet or exceed the NAM test of "relevant information bearing on the committee's composition and balance . . . concerning potential sources of bias and conflict of interest pertaining to his or her service on the committee."[39]

If NAM was aware of these relationships and did not publicize them, the omissions may undermine the public's confidence that the organization has done everything it can to ensure that the committee can "address its charge objectively." If NAM was unaware of these relationships or made the committee selections knowing that the relationships existed, the Academy should consider restarting the provisional appointment process, including a *de novo* review of committee members' experience and potential biases and conflicts of interest.

The National Academy's history of vetting potential committee members to study issues related to pain and opioid use leaves much to be desired. I have recently raised conflict of interest concerns with Health and Human Services Secretary Sylvia Burwell regarding Myra Christopher who was a member of the committee that produced the 2011 Institute of Medicine report "Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research."[40] At the time, Christopher had a significant financial relationship with the opioid manufacturer Purdue Pharma through its funding of Christopher's employer—the Center for Practical Bioethics, and an endowed chair.[41]

My staff has been unable to thoroughly examine all of the members given the limited time available to review the provisional committee members. Still, the omissions that have been identified are extremely troubling, and strongly suggest that the Academy should undertake a more thorough review not only of Drs. Terman and McPherson, but other provisional members of the committee.

Please include this letter in the permanent record for consideration before committee membership is finalized. Thank you for your consideration of this important issue.

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[33] *PAINWeek,* "*PAINWeek* 2015: A Huge Success!", September 14, 2015, *http://www.painweek.org/news_posts/painweek-2015-a-huge-success/,* accessed July 1, 2016.

[34] *PAINWeek,* "Extended-Release Opioids for Pain Management: A Roundtable Discussion," *http://www.painweek.org/pernix14/,* accessed July 1, 2016.

[35] *PAINWeek,* Agenda for Nashville regional conference, *http://conference.painweek.org/painweekend/locationsanddates/nashville-tn,* accessed July 1, 2016; *PAINWeek,* "Conferences," *http://www.painweek.org/conferences/,* accessed July 1, 2016.

[36] Tarus Group plc, "Corporate Activity and Trading Update," May 22, 2015, *http://www.londonstockexchange.com/exchange/news/market-news/market-news-detai1/TRS/12362035.html,* accessed July 1, 2016.

[37] *Ibid.*

[38] *Ibid.*

[39] The National Academies of Science, Engineering, and Medicine, "Committee Membership Information, Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse," IOM–HSP–16–05, *https://www.nationalacademies.org/cp/CommitteeView.aspx?key=49792,* accessed on July 1, 2016.

[40] Senator Ron Wyden to the Honorable Sylvia Mathews Burwell, February 5, 2016, *http://www.finance.senate.gov/imo/media/doc/Wyden%20Letter%20to%20HHS_Opioid%20Conflicts.pdf:* accessed July 1, 2016.

[41] *Ibid.*

Sincerely,

Ron Wyden
Ranking Member

Enclosures: American Pain Society Corporate Council website
American Society for Pain Educators certificate of incorporation

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Attachment 1

AMERICAN PAIN SOCIETY

Corporate Council

Connect Directly with Pain Professionals

The APS Corporate Council provides industry partners with a direct connection to APS members, a multidisciplinary community of more than 2,500 leaders in the study and treatment of pain. Companies whose products and services support the pain profession can meet with APS leaders annually at a 1-day Corporate Council Roundtable to engage in ongoing dialogue on hot topics and future trends in the field. In addition, council members can network at the annual scientific meeting's President's Recognition Reception, a private reception with APS board members, committee chairs, and other leaders where award recipients are recognized.

Why Join?

- Reach more than 2,500 leaders in the study and treatment of pain.
- Meet with the leaders in pain to exchange ideas and knowledge.
- Join APS to enhance patient outcomes.

Membership Levels

APS has tailored membership tiers to offer you various levels of involvement based on your company's objectives and financial resources. Corporate Council dues are set on a 12-month cycle. Click here to see a list of current Corporate Council members.

Corporate Circle ($25,000)

An exclusive, high-level corporate partnership is available to a limited group of industry supporters, offering benefits that will reinforce your company's industry leadership position, offer key networking opportunities, and fulfill multiple marketing objectives.

Executive ($15,000)

A mid-level partnership that offers enhanced benefits designed to maximize your impact on the leaders in the study and treatment of pain. This level will provide additional opportunities for visibility, research, and communication.

Associate ($7,500)

An entry-level corporate partnership that offers a variety of benefits designed to fit the needs of your company and reach leaders in the study and treatment of pain.

Benefits

Corporate Council Roundtable

Meet with APS leaders to exchange ideas and knowledge. This 1-day meeting is designed to facilitate an ongoing dialogue between industry and APS leaders. This is a unique opportunity for open discussion on hot topics and future trends in the field of pain and is a way for both the association and industry to capitalize on each other's strengths to advance the specialty of pain and enhance patient care. The purpose of the roundtable is to:

- Inform the Corporate Council about the APS strategic plan and achievements;
- Provide socioeconomic updates;
- Review practice development initiatives; and
- Offer industry feedback and guidance to the society.

President's Recognition Reception

You will be invited to network with APS board members, committee chairs, and leaders at a private reception during the APS Annual Scientific Meeting. The reception recognizes the many award recipients, including the Clinical Centers of Excellence in Pain Management Award.

APS Communications

Receive all APS communications and stay informed. You will receive *The Journal of Pain,* APS's official, frequently cited, indexed journal. The journal provides a forum for scholarly presentations and commentaries on issues and controversies. Each issue presents reports of original clinical and scientific research. *APS E-News* delivers relevant monthly information such as the latest pain news, information on advocacy related to pain, and clinical trials.

Clinical Practice Guidelines

Receive access to clinical practice guidelines that are created by interdisciplinary panels with expertise in methods used to critique and synthesize published research and other sources.

Contact

Joseph Maginot
Professional Relations and Development
847–375–4873

Attachment 2

C-102B Rev 8/02

AMC
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AUG 31 2006
STATE TREASURER
0100919991

New Jersey Division of Revenue

Certificate of Amendment to the Certificate of Incorporation
(For Use by Domestic Non-profit Corporations)

Pursuant to the provisions of Title 15A:9-4 New Jersey Non-profit Corporation Act, the undersigned corporation executes the following Certificate of Amendment to its Certificate of Incorporation:

1. Name of the Corporation: American Society of Pain Educators, Inc.
2. Corporation Number: 0100919991
3. Article 5. of the Certificate of Incorporation is hereby amended to read as follows:
   The Corporation shall have no members.
4. The corporation [X] has [ ] does not have members.
   A. For Corporations WITH members:
      Number entitled to vote 7 Voting FOR 7 Voting AGAINST 0
      If any class or classes of members are entitled to vote as a class, set forth the number of members of each class, the series of votes of each class voting for and against, and the number of members present at the meeting, OR
      X Adoption was by unanimous written consent without meeting.
      Date of Adoption: March 1, 2006
   B. For Corporations WITHOUT members:
      Number of Trustees Voting FOR Voting AGAINST
      Trustees present at meeting OR
      _____Adoption was by unanimous written consent without meeting
      Date of Adoption:
5. Other Provisions:

Signature: B Eliot Cole, MD
(Must be Ch. Of Bd. Pres. Or Vice Pres)

Date: 8/10/06

Name: B. Eliot Cole, President
(Type Name and Title)

****

This document MUST be filed in triplicate.

NJ Division of Revenue, PO Box 308, Trenton, NJ 08646

CGO

C-104G Rev. 7/1/02

FILED
JUL - 6 2007
STATE TREASURER

New Jersey Division of Revenue

CERTIFICATE of CHANGE of REGISTERED OFFICE &/or REGISTERED AGENT

(For Use by Domestic and Foreign, Profit and Non-profit Corporations)

0100919991

CORPORATION NAME:
American Society of Pain Educators Inc.

STATE OF ORIGINAL INCORPORATION:
N.J.

IMPORTANT - INCLUDE INFORMATION ON BOTH THE PRIOR AND NEW AGENT

PRIOR AGENT NAME:	NEW AGENT NAME:
Jeffrey Tarnoff	Jeffrey Tarnoff
PRIOR AGENT STREET ADDRESS	NEW AGENT STREET ADDRESS
7 Oak Pl., Suite 7	6 Erie St.

CITY	STATE	ZIP	CITY	STATE	ZIP
Montclair	NJ	07042	Montclair	NJ	07042

The corporation states that the address of its new registered office and the address of its new registered agent are identical. Further, the changes designated on this form were authorized by resolution duly adopted by its board of directors or members.

By: [signature] (Signature of Officer) Title: Chairman of the Board (Type)

Date: 6/28/2007

NOTE - This form must be executed by the chairman of the board, the president, or the vice president of the corporation.

FEES: Change of Agent Name-$25.00
Change of Agent Address-$25.00
Change of Both-$25.00

MAIL TO: NJ Division of Revenue
PO Box 308
Trenton, NJ 08646

Make checks payable to: TREASURER, STATE of NEW JERSEY (NO CASH PLEASE)

FILED

FEB 6 2004

State Treasurer

New Jersey Department of State
Division of Commercial Recording
Certificate of Incorporation, Non-Profit
(Title 15A:2-8 New Jersey Domestic Nonprofit Corporation Act)

This is to Certify that, there is hereby organized a corporation under and by virtue of the above noted statute of the New Jersey Statutes.

1. Name of the Corporation: **American Society of Pain Educators Inc.**

2. The purpose for which this corporation is organized is: The mission is to facilitate the creation of Credentialed Clinical Pain Educators and provide continuing education activities for their training. The Credentialed Clinical Pain Educator will serve to assist primary care healthcare providers in the development of appropriate diagnoses, best treatment options, and management of all varieties of pain, with an emphasis on patient counseling and education.

3. Registered Agent: Jeffrey Tarnoff

4. Registered Office: Aventine HealthSciences, 7 Oak Place, Suite 7, Montclair, New Jersey 07042

5. The corporation: Shall have members. _X_ Yes __ No
If yes, qualification will be set forth in the bylaws.

6. Method of electing trustees will be as set forth in the bylaws

7. The first board of directors shall consist of 3 directors.
The names and addresses of the initial directors:
Jeffrey Tarnoff, Aventine HealthSciences, 7 Oak Place, Suite 7, Montclair, New Jersey 07042
Debra Weiner, Aventine HealthSciences, 7 Oak Place, Suite 7, Montclair, New Jersey 07042
Barry Cole, MD, MPA, Aventine HealthSciences, 7 Oak Place, Suite 7, Montclair, New Jersey 07042

8. The duration of the corporation is: perpetual.

9. Set forth Name and Address of Incorporator:

Business Filings Incorporated, Mark Schiff, AVP
8025 Excelsior Dr. Suite 200, Madison, WI 53717.

1366210
2608205

0100091991

FEB-06-2004 13:33 P.03

10. This corporation is organized exclusively for charitable, religious, educational, and scientific purposes, including, for such purposes, the making of distributions to corporations that qualify as exempt corporations under section 501(c)(3) of the Internal Revenue Code, or the corresponding section of any future federal tax code.

Notwithstanding any other provisions of these articles, this corporation shall not carry on any activities not permitted to be carried on by a corporation exempt from Federal income tax under section 501(c)(3) of the Internal Revenue Code of 1986 or the corresponding provision of any future United States Internal Revenue law.

No part of the net earnings of the organization shall inure to the benefit of, or be distributable to its members, trustees, officers, or other private persons, except that the organization shall be authorized and empowered to pay reasonable compensation for services rendered and to make payments and distributions in furtherance of the purpose set forth in the purpose clause hereof. No substantial part of the activities of the organization shall be the carrying on of propaganda, or otherwise attempting to influence legislation, and the organization shall not participate in, or intervene in (including the publishing or distribution of statements) any political campaign on behalf of any candidate for public office.

Upon the dissolution of the corporation, assets shall be distributed for one or more exempt purposes within the meaning of section 501(c)(3) of the Internal Revenue Code of 1986, or corresponding section of any future Federal tax code, or shall be distributed to the Federal, state, or local government for a public purpose. Any such assets not so disposed of shall be disposed of by a court of competent jurisdiction of the county in which the principal office of the corporation is then located, exclusively for such purposes.

In Testimony whereof, each undersigned incorporator has caused this certificate to be signed this 4th day of February, 2004.

Signature: Mark Schiff

Mark Schiff, AVP of
Business Filings Incorporated

Prepared for: **American Society of Pain Educators Inc.**

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UNITED STATES SENATE
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

May 5, 2017

The Honorable Thomas E. Price
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Price:

I write to you with concern about the proposed composition of a Food and Drug Administration (FDA) workshop scheduled for May 9th and 10th in Silver Spring, MD, that will examine how medical providers use and prescribe opioids to treat pain. A preliminary list of organizations scheduled to participate in the workshop, "Training Health Care Providers on Pain Management and Safe Use of Opioid Analgesics—Exploring the Path Forward," includes many groups with deep financial ties to opioid manufacturers.[1]

Given these financial relationships between manufacturers and the participating pain groups, I request that you delay the workshop until the Department of Health and Human Services (HHS) can conduct a full conflict-of-interest review of all proposed participants. Such a review will ensure that the workshop provides a genuine balance of views. Following this review, HHS should consider including additional groups or organizations that have both (a) worked on opioid prescriber practices, and (b) can certify they have not received funds from—and are not currently partnering with—opioid manufacturers. These steps would improve the balance of the workshop, and diminish the influence of companies that have a financial stake in loosening opioid prescriber guidelines.

As you noted in recent remarks at the National Rx Drug Abuse and Heroin Summit, the prescribing practices of medical providers treating pain has contributed to the opioid overdose crisis the Nation now faces.[2] The Centers for Disease Control and Prevention (CDC) found that "sales of prescription opioids in the U.S. 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."[3] As you pointed out during the summit, this rapid rise of opioid prescriptions has had devastating consequences for millions of Americans.[4]

In addition to the human toll of opioid use disorder, overdoses and death, the rise in associated health costs has had a major impact on programs within the jurisdiction of the Senate Committee on Finance. By 2020, public and private spending on substance abuse disorder treatment is expected to reach $42.1 billion, compared to $24.3 billion in 2009.[5] Medicare and Medicaid costs are expected to account for a third of this spending.[6] The Affordable Care Act (ACA) has been an important link to care for people seeking treatment for substance use disorder. Leading health economists estimate that repealing the ACA would result in coverage losses for "about 2.8 million Americans with a substance use disorder, of whom about 222,000 have an opioid disorder."[7] The spike in opioid use has also led to higher transmission rates of blood borne diseases such as HIV and hepatitis, adding to the costs of the epidemic.[8]

The FDA workshop has the potential to build on the work the CDC has performed in recent years, which resulted in national guidelines that medical providers can follow when prescribing opioids. Specifically, the FDA workshop is set to discuss:

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[1] The preliminary list of participants included 26 non-Federal participants: American Medical Association, American Academy of Physician Assistants, American Association of Nurse Practitioners, American Academy of Integrative Pain Management, American Society of Addiction Medicine, American Pharmacist Association, American Dental Association, American Osteopathic Association, American Pain Society, Federation of State Medical Boards, National Governors Association, Project Lazarus, New Mexico, Medical Board of California, Permanente Medical group Northern California, Moffitt Cancer Center, Veterans Health Administration, Department of Defense, Duke University, Indian Health Service, Pain Action Alliance to Implement a National Strategy, PatientsLikeMe, American Chronic Pain Association, National Fibromyalgia and Chronic Pain Foundation, Consumers Union, and Facing Addiction.

[2] Department of Health and Humans Services, "Secretary Price Announces HHS Strategy for Fighting Opioid Crisis," April 19, 2017, *https://www.hhs.gov/about/leadership/secretary/speeches/2017-speeches/secretary-price-announces-hhs-strategy-for-fighting-opioid-crisis/index.html.*

[3] Centers for Disease Control and Prevention, "Opioid Overdose: Prescribing Data," *https://www.cdc.gov/drugoverdose/data/prescribing.html,* accessed May 5, 2017.

[4] *Supra,* note 2.

[5] Substance Abuse and Mental Health Administration, "Projections of National Expenditures for Treatment of Mental and Substance Use Disorders, 2010–2020," SMA–14–4883, 2014, *https://store.samhsa.gov/system/files/sma14-4883.pdf,* 30–31.

[6] *Ibid.*

[7] Richard G. Frank and Sherry Glied, "Keep Obamacare to keep progress on treating opioid disorders and mental illnesses," *The Hill,* January 11, 2017, *http://thehill.com/blogs/punditsblog/healthcare/313672-keep-obamacare-to-keep-progress-on-treating-opioid-disorders.*

[8] Philip J. Peters, et al., "HIV Infection Linked to Injection Use of Oxymorphone in Indiana, 2014–2015," *New England Journal of Medicine,* 375:229–239, July 21, 2016, *http://www.nejm.org/doi/full/10.1056/NEJMoa1515195#t=abstract.*

- The role of health-care provider training in improving pain management and ensuring the safe use of opioids.
- How best to provide appropriate training in pain management and safe opioid use to health-care providers who prescribe or are directly involved in the management or support of patients with pain.
- Issues and challenges associated with possible changes to Federal efforts to educate health-care providers on pain management and the safe use of opioids.[9]

Unfortunately, the apparent financial relationships between opioid manufacturers and pain advocacy groups participating in the workshop raise serious conflict-of-interest concerns that could undercut efforts to curb over-prescribing. I have continued to investigate the role of opioid manufacturers spending millions of dollars to fund pain groups through arrangements like pay-to-play corporate councils that grant companies access to executives and membership of the organizations. The pain groups, which also receive money from the companies through advertising, grants and other forms of sponsorship, have worked, oftentimes in concert with other industry-funded groups, to steer State and Federal policy toward favoring opioids as a treatment for pain. For example, four of the six groups detailed in this letter co-signed a letter in 2015 criticizing the CDC's draft of guidelines on opioid prescribing practices.[10]

Additional information regarding the financial ties between opioid manufacturers and organizations participating in the workshop include the following:

- **American Academy of Integrative Pain Management:** Until recently, this group was known as the American Academy of Pain Management.[11] The name change appears to be little more than cosmetic. The content of the group's website remains largely unchanged, and the group is still heavily funded by opioid manufacturers, with a corporate council consisting of AstraZeneca, Endo, Janssen, Mallinckrodt, Medtronic, Pernix, Pfizer, Purdue and Teva.[12] Regarding the corporate council, the academy states that it "greatly values its relationships with the commercial sponsors who make the products that enable members to provide the best pain care possible. To that end, AIPM considers commercial sponsors to be an integral part of the pain care team."[13] In return for membership dues, corporate council members receive access to leadership and data the organization collects.[14] Similarly, the State policy arm of the organization, the State Pain Policy Advocacy Network, is sponsored by Endo, Janssen, Medtronic, Pfizer, Purdue, and Teva; the only non-opioid sponsors are the American Cancer Society and Livestrong.[15] Moreover, the Associated Press and Center for Public Integrity reported last year that the organization "receives 15 percent of its funding from pharmaceutical companies . . . [and] its state advocacy project is 100 percent funded by drug makers."[16] Under the previous name, the organization led a letter to the Centers for Disease Control and Prevention criticizing the draft opioid prescribing guidelines.[17]

- **American Chronic Pain Association:** I previously raised concerns about this organization's participation in HHS's Interagency Pain Research Coordinating

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[9] "Training Health Care Providers on Pain Management and Safe Use of Opioid Analgesics—Exploring the Path Forward," Public Workshop, 82 Fed. Reg. 18300 (April 18, 2017), *https://www.federalregister.gov/documents/2017/04/18/2017-07821/training-health-care-providers-011-pain-management-and-safe-use-of-opioid-analgesics-exploring-the.*

[10] Pat Anson, "Chronic Pain Groups Blast CDC Opioid Guidelines," *Pain News Network,* September 22, 2015, *https://www.painnewsnetwork.org/stories/2015/9/22/chronic-pain-groups-blast-cdc-for-opioid-guidelines.*

[11] American Academy of Integrative Pain Management, "Leading Pain Organization Changes Name, Brings Alternative Solutions to Complex Pain Challenges," June 17, 2016, *http://blog.aapainmanage.org/leading-pain-organization-changes-name-brings-alternative-solutions-complex-pain-challenges/,* accessed May 5, 2017.

[12] American Academy of Integrated Pain Management, "Corporate Council," *http://www.aapainmanage.org/about/corporate-council/,* accessed May 5, 2017.

[13] American Academy of Integrated Pain Management, "AIPM Announces New Corporate Council Program," October 4, 2016, *http://www.aapainmanage.org/announcement/academy-announces-new-corporate-council-program/,* accessed May 5, 2017.

[14] *Ibid.*

[15] *http://sppan.aapainmanage.org/supporters.*

[16] Liz Essley Whyte, Geoff Mulvihill, and Ben Wieder, "Politics of pain: Drug makers fought State opioid limits amid crisis," Associated Press and Center for Public Integrity, September 18, 2016, *https://www.publicintegrity.org/2016/09/18/20200/politics-pain-drugmakers-fought-state-opioid-limits-amid-crisis.*

[17] *Supra,* note 10.

Committee (IPRCC) because of its ties to industry.[18] The association reports receiving corporate support from 11 companies that manufactured opioid-based drugs—AbbVie, Collegium Pharmaceutical, Depomed, Egalet, Janssen, Mallinckrodt, Pfizer, Purdue, Shionogi, Teva, and Zogenix.[19] Its "corporate champion," which appears to be its highest corporate contributor, is AstraZeneca,[20] which produces and markets a drug to relieve opioid-induced side effects—Movantik.[21] Furthermore, the organization's advisory board includes J. David Haddox, Purdue Pharma's Vice President for Health Policy.[22] However, the organization's connections to Purdue are not limited to Haddox; every page of the website states that "Development of this new ACPA website was made possible through an unrestricted educational grant from Medtronic Foundation and Purdue Pharma." The association also has promoted Purdue-funded initiatives such as a Spanish language website[23] and a guide for pain patients.[24] The association's advisory board includes four doctors who have received thousands of dollars from opioid manufacturers including Endo, Purdue, Mallinckrodt, Pfizer, Teva, Depomed and Zogenix, according to Open Payments data.[25] One of the doctors received $75,000 in payments over 3 years.[26] Another advisory board member, Dr. Judith Paice, served as the second coordinator of the IPRCC critique of the CDC guidelines.[27]

- **American Pain Society (APS):** This organization has for years reported receiving money from opioid manufacturers, prompting an investigation by the Senate Finance Committee in 2012.[28] APS in 2013 reported that six pharmaceutical manufacturers contributed $225,000 to various APS programs,[29] including grants, meeting sponsorship, awards, and sponsorship of the organization's electronic newsletter.[30] Contributors to APS include Teva, Purdue, Pharma, Eli Lilly, Millenium and Zogenix.[31] The organization currently maintains a "corporate council" consisting of 11 pharmaceutical companies, most of which manufacturer opioids or opioid-related products.[32] These companies appear to have paid APS at least $180,000, based on the minimum financial requirements advertised on the organization's website; in return for dues, companies are granted access to the organization's leadership and members.[33] As recently as April 2017, the organization presented its electronic newsletter as being funded by Purdue Phanna.[34] This is apparently a long-standing relationship; in 2013, for example, APS indicated that Purdue contributed $45,000 annually to sponsor

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[18] Senator Ron Wyden to Health and Human Services Secretary Sylvia Mathews Burwell, February 5, 2016, *https://www.finance.senate.gov/imo/media/doc/Wyden%20Letter%20to%20HHS_Opioid%20Conflicts.pdf.*

[19] American Chronic Pain Association, "Partners and Contributors," *https://theacpa.org/Partners-Contributors,* accessed May 5, 2017. Zogenix sold its pain franchise in May 2015.

[20] *Ibid.*

[21] AstraZeneca, "Movantik™ (naloxegol) tablets for the treatment of opioid-induced constipation in adult patients with chronic non-cancer pain launched in the U.S.," March 31, 2015, *http://www.astrazeneca-us.com/media/press-releases/Article/20150330-movantik-launched-in-the-us.*

[22] American Chronic Pain Association, "Advisory Board," *https://theacpa.org/Advisory-Board,* accessed May 5, 2017.

[23] American Chronic Pain Association, "PAIN Exhibit Launches Website in Spanish," October 28, 2013, *https://theacpa.org/news/PAIN-Exhibit-Launches-Website-in-Spanish,* accessed May 5, 2017.

[24] American Chronic Pain Association, "About Partners: Helping you do more to build pain awareness," *https://theacpa.org/About-Partners,* accessed May 5, 2017.

[25] American Chronic Pain Association, *https://theacpa.org/Advisory-Board.*

[26] Centers for Medicare and Medicaid Services, Steven P. Stanos (Open Payments), *https://openpaymentsdata.cms.gov/physician/138667/payment-information,* accessed May 5, 2017.

[27] *Supra,* note 18.

[28] Senators Max Baucus and Charles Grassley to Catherine Underwood, May 8, 2012, *https://www.finance.senate.gov/imo/media/doc/05092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20to%20American%20Pain%20Society.pdf,* accessed May 5, 2017.

[29] American Pain Society, "APS Transparency of Commercial Support for 2013," *http://americanpainsociety.org/uploads/get-involved/transparency-of-support-2013.pdf,* accessed May 5, 2017.

[30] American Pain Society, Commercial Support, *http://americanpainsociety.org/get-involved/commercial-support/overview,* accessed May 5, 2017.

[31] *Ibid.*

[32] American Pain Society, "Corporate Council Members," *http://americanpainsociety.org/get-involved/corporate-council/members,* accessed May 5, 2017.

[33] *Supra,* note 30.

[34] American Pain Society, *E-News,* April 2017, *http://americanpainsociety.org/education/e-news/2017/april/society,* accessed May 5, 2017.

the newsletter.[35] Furthermore, two of the four doctors on the organization's board of directors[36] have received substantial payments from opioid manufacturers, according to Open Payments data.[37] The organization's immediate past president, Gregory Terman, was dismissed from a National Academy of Medicine panel studying opioid addiction, following conflict-of-interest concerns I raised to the academy.[38]

- **National Fibromyalgia and Chronic Pain Foundation:** This organization appears to receive funding from Purdue Pharma, and is closely associated with other organizations and people who have long-standing financial ties to opioid manufacturers. Purdue funded one of foundation's trademarked initiatives, "Leaders Against Pain," in 2012.[39] The organization's founder, Jan Chambers, also is a member of industry-funded groups noted elsewhere in this letter. Chambers is an advisory council member for Pain Action Alliance to Implement a National Strategy[40] (see more information below) and the State Pain Policy Advocacy Network which, as noted above, is reportedly fully funded by drug makers.[41] The Foundation also lists a number of "affiliated organizations" that have established connections to opioid manufacturers.[42] Written products Chambers has produced also raise conflict-of-interest concerns, both because of their content and co-authors. For example, Chambers was co-author of a paper, featured in an American Academy of Pain Management publication, which criticized the Drug Enforcement Administration's decision to classify hydrocodone as a Schedule III narcotic.[43] The paper was co-authored by AAPM's president, Bob Twillman; a Utah physician, Lynn Webster, who reported receiving $160,000 from drug makers between 2013 and 2015;[44] and three employees of Millennium Health. In the same year the paper was published, Millenium Health paid "$256 million to resolve alleged violations of the False Claims Act for billing Medicare, Medicaid and other federal health care programs for medically unnecessary urine, drug and genetic testing and for providing free items to physicians who agreed to refer expensive laboratory testing business to Millennium."[45] The Foundation also signed on to the American Academy of Pain Management letter challenging the CDC guidelines noted above.[46]
- **Pain Action Alliance to Implement a National Strategy:** Also known by its acronym, PAINS, this group is run by the Center for Practical Bioethics, which has received substantial donations from opioid manufacturers. The Center was one of several groups investigated by the Committee on Finance in 2012 for its links to industry and its role in promoting the use of prescription opi-

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[35] *Supra,* note 29.

[36] American Pain Society, "Board of Directors," *http://americanpainsociety.org/about-us/who-s-who-in-aps/board-of-directors,* accessed May 5, 2017.

[37] Centers for Medicare and Medicaid Services, Mark Wallace, (Open Payments), *https://openpaymentsdata.cms.gov/physician/64875/payment-information,* accessed May 5, 2017; Centers for Medicare and Medicaid Services, Edward Michna, (Open Payments), *https://openpaymentsdata.cms.gov/physician/247077/summary,* accessed May 5, 2017.

[38] Matthew Perrone, "Painkiller panel drops experts linked to pharma industry," Associated Press, July 6, 2016, *http://www.seattletimes.com/business/painkiller-panel-drops-experts-linked-to-pharma-industry/.*

[39] National Fibromyalgia and Chronic Pain Association, "National Fibromyalgia and Chronic Pain Association Hosting Leaders Against Pain™ National Training Event for New and Veteran Support Group Leaders and Patient Advocates in DC," *PRWeb,* September 25, 2012, *http://www.prweb.com/releases/nfmcpa/09_24_2012/prweb9923245.htm,* accessed May 5, 2012.

[40] PAINS Project, "Advisory Committee," *http://painsproject.org/who-we-are/advisory-committee/,* accessed May 5, 2017.

[41] State Pain Policy Advocacy Network, "SPPAN Leadership," *http://sppan.aapainmanage.org/leadership,* accessed May 5, 2017.

[42] National Fibromyalgia and Chronic Pain Association, "Affiliate and Education Organizations," *http://www.fmcpaware.org/affiliate-organizations.html,* accessed May 5, 2017.

[43] Jan Chambers, et al., "An Online Survey of Patients' Experiences Since the Rescheduling of Hydrocodone: The First 100 Days," *Pain Medicine,* September 16, v. 17 no. 9, *https://academic.oup.com/painmedicine/article/17/9/1686/2399259/An-Online-Survey-of-Patients-Experiences-Since-the.*

[44] Centers for Medicare and Medicaid Services, Lynn Webster (Open Payments), *https://openpaymentsdata.cms.gov/physician/1136720/summary,* accessed May 5, 2017.

[45] Department of Justice, "Millennium Health Agrees to Pay $256 Million to Resolve Allegations of Unnecessary Drug and Genetic Testing and Illegal Remuneration to Physicians," October 19, 2015, *https://www.justice.gov/opa/pr/millennium-health-agrees-pay-256-million-resolve-allegations-unnecessary-drug-and-genetic,* accessed May 5, 2017.

[46] *Supra,* note 10.

oids.[47] The financial relationship between the Center and opioids manufacturers is ongoing. In 2013, publicly available records indicate Purdue Pharma contributed $100,000 to the Center, making the company the second largest contributor to the group that year.[48] When Finance Committee staff reviewed the Center's website in August 2015, it listed several corporate supporters, including opioid manufacturers, among its donors between January 2014 and March 31, 2015: Janssen Pharmaceuticals, Mallinckrodt Pharmaceuticals, Medtronic, Inc., Purdue, Teva Pharmaceuticals, and Zogenix. The website has since been updated to show 2016 sponsors, which still shows Purdue among them.[49] Moreover, the leadership of PAINS, Myra Christopher and Richard Payne, have longtime financial relationships with opioid manufacturers. During Christopher's time as CEO of the Center, Purdue Pharma established a $1.5 million endowment for that chair[50] through three $500,000 allocations in 2008, 2009, and 2011 respectively.[51] Dr. Payne, meanwhile, continues to receive money from opioid manufacturers. In 2013, Dr. Payne reportedly received $2,000 in travel and lodging from Purdue to attend a meeting for which he received an additional $4,700 for "services other than consulting, including serving as faculty or as a speaker" from a Purdue affiliate—Purdue Transdermal Technologies L.P.[52] Dr. Payne also received $7,538 from Teva in 2015.[53] Moreover, PAINS also signed onto the American Academy of Pain Management letter to CDC noted above.[54]

- **Project Lazarus:** In a 2015 presentation to the FDA, this organization's founder, Frederick Brason, disclosed financial relationships with Ameritox, Indivior, Kaleo, Purdue, and Zogenix.[55] The organization's website also shows it is partnering with KemPharm, which is developing several opioid-based drugs;[56] the Academy of Integrative Pain Management, noted above; and the American Academy of Pain Medicine.[57] Last month, Purdue Pharma touted its funding of the organization in a press release on its website.[58] The organization also has partnered with other industry-funded groups in signing the American Academy of Pain Management letter to CDC cited above. In addition to the industry relationships of Project Lazarus and its founder, a 2016 *Washington Examiner* article questioned the effectiveness of the organization's work, noting that after a temporary decline, opioid overdose rates in the county where the organization works, have been on the rise.[59] The amount of money the organization has received from industry is difficult to gauge. Project Lazarus was an independent nonprofit until 2011, when the director transferred all of its assets to a religious

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[47] Senators Max Baucus and Charles Grassley to John G. Carney, *https://www.finance.senate.gov/imo/media/doc/05092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20to%20Center%20for%20Practical%20Bioethics1.pdf.*

[48] The Greater Kansas City Community Foundation makes publically available the records for the organization at *http://gkccf.guidestar.org/nonprofit.aspx?orgId=1193,* accessed May 5, 2017.

[49] Center for Practical Bioethics, "Our 2016 Community Supporters," *https://practicalbioethics.org/support-our-mission/community-supporters?highlight=WyJwdXJkdWUiXQ,* accessed May 5, 2017.

[50] McBride, Lock, and Associates, "Report of Examination of the Center for Practical Bioethics, Inc., Kansas City, Missouri for the Year Ended December 31, 2008," April 13, 2008, *http://gkccf.guidestar.org/nonprofit.aspx?orgId=1193.*

[51] McBride, Lock, and Associates, "Report on Examination of the Center for Practical Bioethics, Inc., Kansas City, Missouri as of and for the Year Ended December 31, 2010," July 21, 2011, *http://gkccf.guidestar.org/nonprofit.aspx?orgId=1193.*

[52] Centers for Medicare and Medicaid Services, Richard Pain (Open Payments), *https://openpaymentsdata.cms.gov/physician/1094555,* accessed May 5, 2017.

[53] *Ibid.*

[54] *Supra,* note 10.

[55] Fred Wells Brason, "Exploring Naloxone Uptake and Use Public Meeting," July 1–2, 2015, *https://www.fda.gov/downloads/Drugs/NewsEvents/UCM454759.pdf,* accessed May 5, 2015.

[56] KemPharm, Inc., "Product Portfolio: Pain," *http://www.kempharm.com/pages/pipeline/pain.php,* accessed May 5, 2017.

[57] Project Lazarus website, *https://www.projectlazarus.org/,* accessed May 5, 2017.

[58] Purdue Pharma, L.P., "Purdue Pharma, Project Lazarus, and Safe Kids NC Partner to Improve Public Health Outcomes in North Carolina through the North Carolina Disposal Initiative," April 5, 2017, *http://www.purduepharma.com/news-media/2017/04/purdue-pharma-project-lazarus-and-safe-kids-nc-partner-to-improve-public-health-outcomes-in-north-carolina-through-the-north-carolina-disposal-initiative/,* accessed May 5, 2017.

[59] Paige Winfield Cunningham, "Model program to fight drug abuse falls flat," *Washington Examiner,* April 3, 2016, *http://www.washingtonexaminer.com/model-program-to-fight-drug-abuse-falls-flat/article/2587359.*

organization that he controlled, Coastlands Ministries.[60] Publically available tax records for Coastlands Ministries show that it received a $500,000 grant in 2012, but the donor is undisclosed.[61] The group also signed onto the American Academy of Pain Management letter to CDC noted above.

The long-standing and ongoing financial relationships between opioid manufacturers and participants in the upcoming FDA workshop warrant your intervention to investigate and minimize potential conflicts of interest when addressing a matter literally of life and death. I appreciate your attention to this important issue and your consideration of my requests.

Sincerely,

Ron Wyden
Ranking Member

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[60] Project Lazarus, Form 990–EZ for the year ending 2011, *http://990s.foundationcenter.org/990_pdf_archive/270/270602284/270602284_201112_990EZ.pdf,* accessed May 5, 2017.

[61] Coastlands Ministries, Form 990 for the year ending 2015, *http://990s.foundationcenter.org/990_pdf_archive/562/562087110/562087110_201512_990.pdf,* accessed May 5, 2017.

COMMUNICATIONS

ALLIANCE FOR THE TREATMENT OF INTRACTABLE PAIN (ATIP)
3591 Nestling Lane
Fort Mill, SC 29708
(803) 566–8011

From: Richard A Lawhern, Ph.D.
Co-Founder and Corresponding Secretary

To: U.S. Senate
Committee on Finance
Dirksen Senate Office Bldg.
Washington, DC 20510–6200

April 16, 2018

Subject: "Tackling Opioid and Substance Use Disorders in Medicare, Medicaid, and Human Services Programs"

This letter submits a statement for the record in April 19, 2018 public hearings of the Senate, subject as above. I write as a co-founder of the Alliance for the Treatment of Intractable Pain. We are an organization of over 250 medical professionals, health-care writers, knowledgeable pain patients and caregivers. We have previously addressed other government forums, among them the FDA Opioid Policy Steering Committee (January 30, 2018), and State regulatory agencies in Washington, Ohio, and Illinois.

This statement offers a White Paper on Prescription Opioids and Chronic Pain, attached. This Paper is available online at *https://atipusa.org/2018/04/02/atip-white-paper-on-prescription-opioids-and-chronic-pain/* and was downloaded over 5,000 times in the first week of its availability. It has been shared with hundreds of House and Senate Staff engaged in health-care policy. It is extensively referenced from both medical literature and current media.

We advocate that immediate legislation is necessary, if the intended charter of these hearings is to bear fruit. The Senate must join the House in directing the U.S. Centers for Disease Control and Prevention to withdraw and rewrite the March 2016 Guidelines on prescription of opioid analgesics to adults with non-cancer chronic pain. CDC officials have acknowledged that overdose death statistics due to prescription drugs have been inflated by almost 100% for years. In their present form, the Guidelines are actively dangerous due to weak science and anti-opioid bias which violates research standards of the CDC itself. Guidelines omit pertinent science on opioid metabolism, leading to "one size fits all" regulations which are destroying pain management and patient quality of life for millions of citizens.

Thank you for your attention. Please call on us if we may contribute further. We can send medical experts to follow-up hearings or provide staff support during the coming weeks before passage of legislation.

Richard A. Lawhern, Ph.D.

The Alliance for the Treatment of Intractable Pain (ATIP)
Available online at *https://atipusa.org*

A White Paper

Prescription Opioids and Chronic Pain

Richard A. Lawhern, Ph.D.

1. Main Points

1.1. There Are Over 116 Million Chronic Pain Patients in the U.S. (Institute of Medicine)

Chronic pain is defined as pain lasting longer than 90 days or otherwise exceeding medically expected recovery times. Once diagnosed, many chronic pain patients will have debilitating severe pain for the rest of their lives. For many, pain is resistant (refractory) to a wide range of therapies.

For millions of people, management of severe pain has for years included prescription opioid medications as a key element. Opioid medications frequently make a life-or-death difference in quality of life. However, at present, patients with severe pain are being made scapegoats for a perceived—and largely false—"epidemic" of opioid addiction and overdose deaths, which have been misattributed to prescription analgesics.[1, 2, 3, 4]

There are presently no reliable replacements for opioids.[5] Due to under funding of research on treatments for pain, there are no significant prospects for new treatments in the foreseeable future.

1.2. March 2016 CDC Chronic Pain Guidelines

In March 2016, the Centers for Disease Control released updated guidelines for prescription of opioids in adult, non-cancer chronic pain. Outcomes of these guidelines have been horrific for millions of patients. The CDC guidelines[6] recommended that general practitioners should perform an analysis of risks and benefits before prescribing more than 90 Morphine Milligram Equivalent Daily Dose (MMEDD). Although originally phrased as voluntary, the Guidelines became a statutory requirement on the Department of Veterans Affairs, 3 months before CDC published its final guideline. Non-VA Hospitals and doctors across America quickly interpreted the Guidelines on safety review as a mandatory maximum dose standard.[7, 8]

Fearing sanctions by the U.S. Drug Enforcement Agency or State authorities if they prescribe opioids to people who need them, doctors are leaving pain management practice in droves.[9] Availability of pain management specialists is dropping in most areas of the U.S. and Canada. Pharmacies are limiting inventories of opioid medications, and challenging doctors' prescriptions on grounds of corporate policy. Patients with legitimate prescriptions are being turned away.[10]

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[1] Mark Edmund Rose, "Are Prescription Opioids Driving the Opioid Crisis? Assumptions vs. Facts," *Pain Medicine,* December 17, 2017, *https://doi.org/10.1093/pm/pnx048.*

[2] Carl L. Hart, Ph.D., "People Are Dying of Ignorance, Not Because of Opioids," *Scientific American,* November 1, 2017, *https://www.scientificamerican.com/article/people-are-dying-because-of-ignorance-not-because-of-opioids/.*

[3] Stefan J. Kertesz and Adam J. Gordon, "Strict limits on opioid prescribing risk the 'inhumane treatment' of pain patients." *Stat. News,* February 24, 2017 (see reader comments), *https://www.statnews.com/2017/02/24/opioids-Prescribing-limits-pain-patients/.*

[4] Jacob Sullum, "Opioid Commission Mistakenly Blames Pain Treatment for Drug Deaths," *Reason Magazine,* November 2, 2017.

[5] Agency for Healthcare Research and Quality, "Noninvasive, Nonpharmacological Treatment for Chronic Pain: A Systematic Review," Draft circulated, December 2017, pp vii, 270.

[6] Dowell D., Haegerich T.M., and Chou R., "CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016," *JAMA,* 2016;65, doi:10.1001/jama.2016.1464, *https://jamanetwork.com/journals/jama/fullarticle/2503508.*

[7] Jacob Sullum, "America's War on Pain Pills is Killing Addicts and Leaving Patients in Agony," *Reason Magazine,* April 2018 edition.

[8] Jeffrey A. Singer, M.D., "Let's Stop the Hysterical Rhetoric About the Opioid Crisis," Cato Institute—Commentary, August 31, 2017, *https://www.cato.org/publications/commentary/lets-stop-hysterical-rhetoric-about-opioid-crisis.*

[9] Matthew Adams, "Dr. Steven Ziegler interview with George Knapp," February 22, 2018, *https://www.youtube.com/watch?v=Ci_snaj4mkE&feature=youtu.be.*

[10] Pauline Bartolony, "The Other Opioid Crisis: Hospitals Are Running Short of Powerful Painkillers," *Los Angeles Times,* March 16, 2017, *http://www.latimes.com/business/la-fi-opioid-painkiller-hospitals-20180316-story.html#nws=mcnewsletter.*

The U.S. Centers for Medicare and Medicaid estimate that approximately 1.6 million older citizens are presently maintained on opioid doses at levels above 90 MMED.[11] U.S. CDC has estimated that over 19 million prescriptions were written in 2016 for "high dose" (over 90 MMED) opioids for all purposes—acute, chronic, or palliative care treatment.[12] However, among doctors who remain in pain management practice, many are discharging high-dose patients or coercing them to quickly taper down to levels below 90 MMED—levels that are ineffective in hundreds of thousands of patients. Many high-dose patients are being discharged without management for withdrawal symptoms.[13]

Effects of CDC Guidelines are compounded by restrictive legislation in several U.S. States, which are imposing limits on dose levels, the number of days a prescription may extend , and/or the number of renewals allowed. Tens of thousands of patients are being driven into outright agony, with significant suicide risk.[14, 15] Among patients treated by the Veterans Administration, hundreds of suicides have been confirmed.[16]

1.3. Weak Evidence for CDC Guidelines

Medical evidence underlying the CDC Guidelines is extremely weak, absent or biased.

The Core Experts writing group that authored the CDC Guidelines included no practicing Board Certified Pain Management specialists who had experience managing patients in community settings. Psychiatrists in addiction management dominated the group. There was no representation by the CDC's own medical ethics group.

The majority of the published studies that the CDC used as evidence in the writing of the Guidelines were evaluated as "Type 4"—"Subject to significant limitations and uncertainties."[17] Significant studies, which contradicted assumptions of the writers group, were omitted.[18] Four studies quoted by CDC to justify risk thresholds for opioid daily dose were mutually contradictory and inconsistent.[19] Methodology for comparing different opioids (Morphine Milligram Equivalent Daily Dose) is founded upon opinion and pseudoscience.[20]

The four studies used by the Guidelines writers do show an increased risk of apparent overdose death associated with high dosing. However, the absolute annual risk of dying with doses greater than 100 MMED was estimated at 0.21 to 0.25%/year.

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[11] U.S. Health and Human Services Centers for Medicare and Medicaid, "Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies, and 2019 Draft Call Letter," *https://www.regulations.gov/docket?D=CMS-2017-0163.*

[12] U.S. Centers for Disease Control and Prevention, "Annual Surveillance Report of Drug-Related Risks and Outcomes, United States 2017," Table 1B, August 21, 2017, *https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf.*

[13] Bob Tedeschi, "A 'civil war' over painkillers rips apart the medical community—and leaves patients in fear," *Stat. News,* January 17, 2017, *https://www.statnews.com/2017/01/17/chronic-pain-management-opioids/.*

[14] Geralyn Datz, "Chronic Pain—A Suicide Story," *National Pain Report,* February 26, 2018, *http://nationalpainreport.com/chronic-pain-a-suicide-story-8835614.html.*

[15] Thomas Kline, M.D., Ph.D., "Pain Related Suicides," February 2018, Medium Corporation, *https://medium.com/@ThomasKlineMD/suicides-associated-with-non-consented-opioid-pain-medication-reductions-356b4ef7e02a.*

[16] Art Levine, "How the VA Fueled the Opioid Crisis and Is Killing Thousands of Veterans," *Newsweek,* October 27, 2017, *http://www.newsweek.com/2017/10/20/va-fueled-opioid-crisis-killing-veterans-681552.html.*

[17] Stephen A. Martin, M.D., EdM; Ruth A. Potee, M.D., DABAM; and Andrew Lazris, M.D., "Neat, Plausible, and Generally Wrong: A Response to the CDC Recommendations for Chronic Opioid Use," Medium Corporation, September 7, 2016, *https://medium.com/@stmartin/neat-plausible-and-generally-wrong-a-response-to-the-cdc-recommendations-for-chronic-opioid-use-5c9d9d319f71.*

[18] Noble M., Treadwell J.R., Tregear S.J., Coates V.H., Wiffen P.J., Akafomo C., Schoelles K.M., and Chou R., "Opioids for Long Term Treatment of Non-Cancer Pain," *Journal of Pain and Symptom Management,* Vol. 35, No. 2, February 2008, updated December 2010, *http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006605.pub2/abstract;jsessionid=7ADC6E2B68764AD8E13574321C769E2B.f04t04.*

[19] Richard A. Lawhern, "Tracking Down the 'Research' Behind the CDC's Opioid Prescribing Guidelines," *National Pain Report,* August 10, 2016, *http://nationalpainreport.com/tracking-down-the-research-behind-the-cdcs-opioid-prescribing-guidelines-8831122.html.*

[20] Michael E. Schatman, Ph.D.; and Jeffrey Fudin, PharmD, "The Myth of Morphine Milligram Equivalent Daily Dose," *Medscape,* March 18, 2018, *https://www.medscape.com/viewarticle/863477.*

In a related study by one of these authors, the annual risk of overdose death with a MMED of greater than 400 was 0.5%.[21]

Even if we accept the questionable methodology of some of these studies without challenge, it still seems reasonable to compare their estimated risks of death to outcomes of other drug therapy. Consider, for instance, medical conditions like atrial fibrillation, for which thousands of patients are treated every year. Atrial fibrillation is very common in older patients, as is deep venous thrombosis and associated pulmonary embolism.

A risk of prescription opioid overdose of 0.25%/year is comparable to the risk of fatal hemorrhage with the best anticoagulants available for preventing stroke due to atrial fibrillation. The estimated risk of death from so-called "very high dose" opioids (0.5%/year) is comparable to the risk of fatal hemorrhage with Warfarin for stroke prevention (0.38–0.5%/year). So why do we focus on the supposed "risk" of opioid overdose attending the treatment of severe chronic pain? This is a "risk" that many patients in agony would consider trivial. It is comparable to risks of other drug therapies.

Because of very high dropout rates among pain patients treated with placebos, there are few published randomized double-blind trials of the long-term effectiveness of opioids in chronic pain. However, the CDC writers misinterpreted the rarity of trials to assert that opioids are ineffective.[22, 23] The writers violated research standards of the CDC itself by failing to disclose that criteria for including trials of opioids were different and more stringent than those applied to non-opioid analgesics and behavioural therapies.[24]

Although medical professionals often label patient reports "anecdotal," many thousands report they have been stable on opioid medications for years and received substantial benefits in reduced pain, improved mobility, and better quality of life. Many of these patients are being discharged or coerced to taper down medications to less than therapeutic levels.[25]

The term "opioid induced hyperalgesia" is sometimes seen in medical literature as a justification for claiming that opioid analgesics really aren't effective. The claim is that due to some mechanism of the nervous system, opioids cause the body to become more sensitive to pain after a short period of exposure. However, no medical consensus exists on what this mechanism might be, or any criteria for confirming this unproven diagnosis. A search of the medical literature reveals no reports of patients whose pain improved with reduction in opioid dosage.

A label is not a diagnosis.

1.4. The Confounding Problem of Individual Metabolism

The CDC writers group also ignored well-established medical literature, which examines variations between individuals in their ability to metabolize (break down) opioid pain relievers.[26, 27] Six key liver enzymes are involved in metabolism for 90% of all medications. Due to genetic polymorphism, the expression of these enzymes can vary significantly between individuals. The result is that millions of patients are poor metabolizers of opioids, passing very low amounts of active breakdown products across the blood-brain barrier. Others are "hyper-active" metabolizers, in whom opioids pass through the body so rapidly that pain is reduced for only minutes rather than hours.

Both of these populations can potentially benefit from opioid therapy—but not below the 90 MMED dose limits recommended in the CDC Guidelines. Some pain manage-

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[21] Gomes T., et al., "Trends in opioid mortality among socioeconomically disadvantaged patients," *Open Med.,* 2011;5:E13–E22.

[22] *Op. cit.,* Martin et al.

[23] Brooke Keefer, "A Former Federal Peer Reviewer's Analysis of the Draft CDC Guidelines," *National Pain Report,* December 30, 2015, *http://nationalpainreport.com/a-former-federal-peer-reviewers-analysis-of-the-draft-cdc-guidelines-8828910.html.*

[24] Baraa O. Tayeb, Ana E. Barreiro, Ylsabyth S. Bradshaw, Kenneth K.H. Chui, and Daniel B. Carr, "Durations of Opioid, Nonopioid Drug, and Behavioral Clinical Trials for Chronic Pain: Adequate or Inadequate?", *Pain Medicine,* Volume 17, Issue 11, November 1, 2016, Pages 2,036–2,046, *https://academic.oup.com/painmedicine/article/17/11/2036/2447887.*

[25] *Op. cit.,* Tedeschi.

[26] Tom Lynch and Amy Price, "The Effect of Cytochrome P450 Metabolism on Drug Response, Interactions, and Adverse Events," *American Family Physician,* August 1, 2007, *https://www.aafp.org/afp/2007/0801/p391.html.*

[27] Howard S. Smith, M.D., "Opioid Metabolism," *Mayo Clinic Proceedings,* 2009 July, 84(7): 613–624, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2704133/.*

ment specialists identify the range of "minimum therapeutic dose" for opioids as 20 to 1,000 MMED.[28] There are published case reports of "hyper-dose" patients who do well on dose levels over 2,000 MMED, with no unacceptable side effects or observed symptoms of addiction.[29]

The CDC Guidelines have had such horrific results that some of the writers in the Core Expert's group and outside reviewers of the document have disavowed it.[30] Additional medical professionals have directly opposed proposed changes in Medicare and Medicaid rules intended to implement CDC Guidelines as a mandatory standard of practice.[31]

2. Mythologies of Chronic Pain and Addiction

It is becoming clear that major implicit but mostly unstated assumptions of the CDC Guideline writers were inappropriate or outright fallacious.[32] Among these assumptions is the claim that all opioid prescriptions should be regarded as immediate addiction risks for all patients exposed to them. We now know this assumption to be false.

2.1. Media Narrative

We've all heard media stories about young people who quickly became addicted after minimal exposure to medically managed opioids descending into a spiral of drug seeking, life failure, and eventual overdose death. Such stories are tragedies for the families that actually experience them.

Families grieve. They demand that government "do something." Their stories are very influential in our public conversation about substance abuse and overdose deaths. It is small wonder that government policy has focused centrally on reducing the availability of medical opioids.

2.2. Focus on Prescription Reduction

Is the present focus on reduction of medical supply appropriate? Almost certainly not! No matter how tragic these stories are, they are neither typical nor representative. As noted by Dr. Nora Volkow and Thomas A. McMillan, Ph.D. of the U.S. National Institutes of Drug Abuse.

"Unlike tolerance and physical dependence, addiction is not a predictable result of opioid prescribing. Addiction occurs in only a small percentage of persons who are exposed to opioids—even among those with pre-existing vulnerabilities. . . . Older medical texts and several versions of the Diagnostic and Statistical Manual of Mental Disorders (DSM) either overemphasized the role of tolerance and physical dependence in the definition of addiction or equated these processes (DSM–III and DSM–IV). *However, more recent studies have shown that the molecular mechanisms underlying addiction are distinct from those responsible for tolerance and physical dependence, in that they evolve much more slowly, last much longer, and disrupt multiple brain processes*" (emphasis—ATIP).[33]

Even the statistics of the CDC itself have proven to be faulty, over-magnifying what has been called a "prescription opioid crisis." CDC has acknowledged that it has reported as "prescription opioid overdoses," deaths that were in fact due to illegally imported fentanyl and its analogs. They called their reported prescription opioid overdose rate "significantly inflated"[34] over several years. For 2016, this "inflation"

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[28] Stephen Nadeau, M.D. [a specialist in pain management with over 100 published peer-reviewed papers in medical literature]. Personal correspondence with the author.

[29] Forest Tennant, M.D., DrPH, "Ultra High Dose Opioid Therapy—Uncommon and Declining, but Still Needed," *Practical Pain Management,* May 2013, *https://www.practicalpainmanagement.com/treatments/pharmacological/opioids/ultra-high-dose-opioid-therapy-uncommon-declining-still-needed.*

[30] Stefan Kertsz, et al., "An Opioid Metric Based on Dose Alone? 80 Professionals Respond to NCQA," *Medium,* March 22, 2017, *https://medium.com/@StefanKertesz/an-opioid-quality-metric-based-on-dose-alone-80-professionals-respond-to-ncqa-6f9fbaa2338.*

[31] Lev Facher, "Proposed Federal Limits to Opioid Prescriptions Draw Opposition From Physicians and Patients," *Stat. News,* March 6, 2018, *https://www.statnews.com/2018/03/06/cms-rule-limits-opioid-prescriptions/.*

[32] *Op. cit.,* Rose.

[33] Nora D. Volkow, M.D., and Thomas A. McLellan, Ph.D., "Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies," *NEMJ* 2016; 374:1253–1263, March 31, 2016, *http://www.nejm.org/doi/full/10.1056/NEJMra1507771.*

[34] Jeffrey A. Singer, M.D., "CDC Researchers State Overdose Death Rates From Prescription Opioids Are Inaccurately High," Cato at Liberty, March 22, 2018, *https://www.cato.org/blog/cdc-researchers-state-overdose-death-rates-prescription-opioids-are-inaccurately-high.*

amounted to nearly doubling the number of deaths attributed to prescription medications.[35]

2.3. Large-Scale Medical Studies

We also know from recently published, large-scale studies of surgical patients treated with opioids after discharge, that opioid abuse emerging from managed medical exposure is rare among patients who are profiled carefully before surgery. Millions of patients have such exposures every year.

A 2018 study reported in the *British Medical Journal* examined outcomes among more than 586,000 patients prescribed opioids for the first time after surgery.[36] Less than 1% continued renewing their prescriptions longer than 13 weeks, 0.6% were later diagnosed with Opioid Abuse Disorder during follow-up periods averaging 2.6 years between 2008 and 2016. Likelihood of diagnosis increased with the length of prescriptions, but rose only modestly as dose levels increased from under 20 to over 120 MMED.

It is quite possible—even likely—that the diagnosis of Opioid Abuse Disorder in many of these patients was incorrect. The diagnosis is typically made by treating physicians without recourse to accepted definitions of the disorder such as the American Psychiatric Association Diagnostic and Statistical Manual, 5th edition. Many doctors who diagnose patients with abuse are general practitioners who lack sufficient training in addiction and have little experience evaluating the behaviours that actually define drug addiction. Likewise, some physicians confuse patient reports of emerging chronic pain—caused by failed surgery—for potential opioid abuse.

During the period of the study, doctors increasingly became concerned with being sanctioned by law enforcement authorities for their use of opioid doses high enough to reliably manage pain. Thus they may have diagnosed drug abuse to protect themselves—not their patients, who were often summarily discharged.

A 2016 study reported in the *Journal of the American Medical Society*[37] tracked long-term opioid prescriptions in non-surgical patients, and compared prescription rates to 642,000 patients who received 1 of 11 common types of surgery. Opioid prescriptions were defined as "chronic" when 10 or more scripts were written in 1 year or a prescription was renewed continuously for more than 120 days.

In this study, the rate for chronic prescriptions of opioid analgesics among millions of non-surgical patients was estimated at 0.136%. (Parenthetically, this finding strongly suggests that "doctor shopping" is not a significant source of opioids abused by people with addiction.) For 4 of the 11 surgical procedures studied, the same rate of prescriptions occurred after surgery as before. For the seven remaining procedures, long-term opioid prescriptions rose by factors varying from 1.28 (0.174%) for caesarean delivery, up to 5.07 (0.69%) for total knee replacement.

The highest rate of post-surgical chronic prescriptions occurred for total knee replacement—a procedure known to cause lingering pain in many who undergo it.[38,39] It is likely that many on-going prescriptions after knee replacement reflected chronic post-surgical pain, rather than issues of opioid misuse. Although not examined in the study, this outcome may also be true of other procedures where long-term prescribing was observed.

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[35] Josh Bloom, Ph.D., "The CDC Quietly Admits it Screwed Up Counting Opioid Pills," *American Council on Science and Health,* March 19, 2018, *https://www.acsh.org/news/2018/03/19/cdc-quietly-admits-it-screwed-dishonestly-counting-pills-12717.*

[36] Gabriel A. Brat, Denis Agniel, Andrew Beam, Brian Yorkgitis, Mark Bicket, Mark Homer, Kathe P. Fox, Daniel B. Knecht, Cheryl N. McMahill-Walraven, Nathan Palmer, and Isaac Kohane, "Postsurgical prescriptions for opioid naive patients and association with overdose and misuse: retrospective cohort study," *BMJ* 2018;360:j5790, *http://www.bmj.com/content/360/bmj.j5790.long.*

[37] Eric C. Sun, Beth D. Darnall, Laurence C. Baker, and Sean Mackey, "Incidence of and Risk Factors for Chronic Opioid Use Among Opioid-Naive Patients in the Postoperative Period," *JAMA Internal Medicine* 2016;176(9): 1286–1293, *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2532789.*

[38] G.M. Woolhead, J.L. Donovan, and P.A. Dieppe, "Outcomes of Total Knee Replacement: A Qualitative Study," *Rheumatology,* Volume 44, Issue 8, August 1, 2005, pages 1032–1037, May 3, 2005, *https://academic.oup.com/rheumatology/article/44/8/1032/1772033.*

[39] Michael J. Bade, Wendy H. Kohrt, and Jennifer E. Stevens-Laplsey, "Outcomes Before and After Total Knee Arthroplasty Compared to Healthy Adults," *J. Orthop. Sports Phys. Ther.* 2010 Sept.; 40(9): 559–567, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3164265/.*

These studies demonstrate beyond any reasonable contradiction that managed medical exposure does not by itself significantly raise risks of opioid abuse in surgical patients who are properly screened for previous opioid exposure. This outcome directly contradicts the false claim that addiction starts with just a few pain pills in any large number of people.

3. Addiction Risks

It may well be asked, what are the risks of opioid involvement or addiction among patients who have already experimented with drugs before they see a doctor? Volkow and McMillan offer us some insight on this question.[40] The CDC does not publish definitive statistics on this issue. But well-established demographics can offer general guidance. In the great majority of cases, the typical beginning addict and the typical chronic pain patient are different people.

3.1. The Demographics of Addiction and Chronic Pain

We now know that the most common beginning opioid abuser is an adolescent or early-20's male who has a history of family trauma, prolonged unemployment, and often mental health issues. This population is generally medically under-served. It is unusual for young males in economically distressed regions of the U.S. to be seen by a doctor. When they are seen, it is unusual for them to be prescribed pain relievers for more than a few days. As noted by Volkow and McMillan, a few days are insufficient to cause drug dependency, much less addiction.

By contrast, the typical chronic pain patient (by a ratio of 60/40 or higher compared to men) is a woman in her 40s or older who has a history of traumatic injury, failed back surgery, neuropathic pain, fibromyalgia, or other disorders which generate prolonged severe pain.[41] Among women whose lives are stable enough that they can see a doctor repeatedly, addiction to opioids is quite uncommon.

Clearly, "some" patients of any age may become physically dependent on opioids for pain relief, or later display the obsessive drug seeking and self-destructive behaviors which define Opioid Use Disorder. But equally clearly, the overlap between addiction and chronic pain occurs in a relatively small minority. To deal with our public health crisis constructively, public policy must centrally address the majority of people with addiction, before plotting excursions to help the outliers.

3.2. More Misleading Statistics

A statistic often quoted in popular media is that over 70% of all people with addiction report that their first exposure to opioids was from prescription drugs. So how are these young men and women exposed to prescriptions? The answer is almost entirely through theft and diversion of unused medications left over after legitimate patients no longer need them. Seventy-five percent of people with addiction who begin this way never saw a doctor for pain.[42] Few are able to sustain a developing addiction from home supplies. They soon begin purchasing street drugs—either illegal drugs like heroin (often laced with illicitly-manufactured fentanyl), or safer, but diverted, prescription drugs that cost much more.

3.3. The Role of Self-Administered Poly-Pharmacy

It has also become clear in recent years that overdose deaths only rarely involve a single prescription opioid given by a doctor to a pain patient. When the Commonwealth of Massachusetts did an extensive analysis of 2 years of overdose-related fatalities, they discovered that in only 9% of 1,657 deaths did medical examiners detect an opioid in post-mortem examinations that could be tracked to the State Prescription Drug Monitoring Program.[43]

The best predictor for overdose related death was self-administered poly-pharmacy, not a medically managed prescription. It can be credibly argued that such poly-pharmacy seems a plausible consequence of *under*-treatment of pain, rather than over-prescription. In 79% of 154 Massachusetts deaths where a prescription opioid was

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[40] *Op. cit.,* Volkow and McMillan.

[41] American Academy of Pain Medicine "AAPM Facts and Figures on Pain" (current edition accessed November 11, 2017), *http://www.painmed.org/patientcenter/facts_on_pain.aspx.*

[42] National Survey on Drug Use and Health, quoted by Maia Szalavitz in "Opioid Addiction Is a Huge Problem, but Pain Prescriptions Are Not the Cause," *Scientific American,* May 10, 2016, *https://blogs.scientificamerican.com/mind-guest-blog/opioid-addiction-is-a-huge-problem-but-pain-prescriptions-are-not-the-cause/.*

[43] Commonwealth of Massachusetts, "An Assessment of Opioid-Related Deaths in Massachusetts (2013–2014)," September 2016, *https://www.mass.gov/files/documents/2016/09/tx/chapter-55-report.docx.*

detected, the prescribed dose was below the 90 MMED threshold of risk identified in the CDC Guidelines. Likewise, two-thirds of the prescriptions were more than 30 days out of date, suggesting that some of those who died may have been cut off from pain management.

4. The Myth of Opioid Alternatives

Another mythology that greatly distorts our public conversation about opioid pain relievers is the idea that safer alternative therapies for pain exist and would be used if only they were covered by medical insurance. This assumption was explicit in recommendations of the CDC Guidelines. However, this idea is unfortunately naive and largely unsupported by medical evidence.

4.1. AHRQ Review of Existing Data

In December 2017, the U.S. Agency for Healthcare Research Quality (AHRQ) circulated a draft "Systematic Review" of published trials data on non-pharmacological and non-invasive therapies for treatment of pain.[44] The yearlong review identified 4,470 published trials for techniques including Rational Cognitive Therapy, mindfulness, psychological counseling, acupuncture, massage, yoga, spinal manipulation and low-level laser therapy, among others. Five common types of pain were addressed: chronic low back pain, chronic neck pain, fibromyalgia, tension headache, and osteoarthritis.

After a rigorous multi-level quality review by medical experts, only 205 published trials were chosen for inclusion in the Systematic Review. The main reasons for study rejection were failure to follow patients for at least 30 days after trial, and failure to sufficiently document treatment protocols to establish repeatability of results. Among the surviving trials, AHRQ applied the assessment "Medical Evidence Weak" more than 100 times.

A further and potentially disqualifying weakness of the trials literature was that few investigators bothered to document the nature and protocols of "usual treatment" to which these non-invasive therapies were generally added or compared. In point of fact, "usual therapy" often comprises NSAIDs or opioid analgesics. But most trials reported in the literature do not establish the precise protocols that were followed under "usual treatment."

4.2. Alternative Therapies May Be no Better Than Placebo

The AHRQ systematic review made an effort to dress up a pig in ballet tights, by claiming that at least a few of the trials they examined demonstrated measurable improvement in outcomes. However a detailed probe of details of the report brings us to a different insight. The most supportable conclusion that we may draw from the AHRQ systematic review is that non-invasive, non-pharmacological therapies can help some patients, some of the time—when applied as adjuncts to treatment with analgesics. But the present state of knowledge does not permit us to establish whether such alternative therapies are in fact any more effective than placebo.

The one true test of alternative therapies would be to test their efficacy in reducing opioid dosage in patients with pain severe enough to warrant chronic opioid management. Such a study has never been done. Thus, non-pharmacological therapies do not offer realistic "replacements" for analgesic treatment.

5. A Necessary Way Forward

Much public and government discussion of opioid addiction and overdose deaths is now focused on restriction of prescriptions to people in pain, and restriction of opioid supply overall. However, it is clear that this focus is miss-placed. The "war" on drugs has become a war on pain patients.[45]

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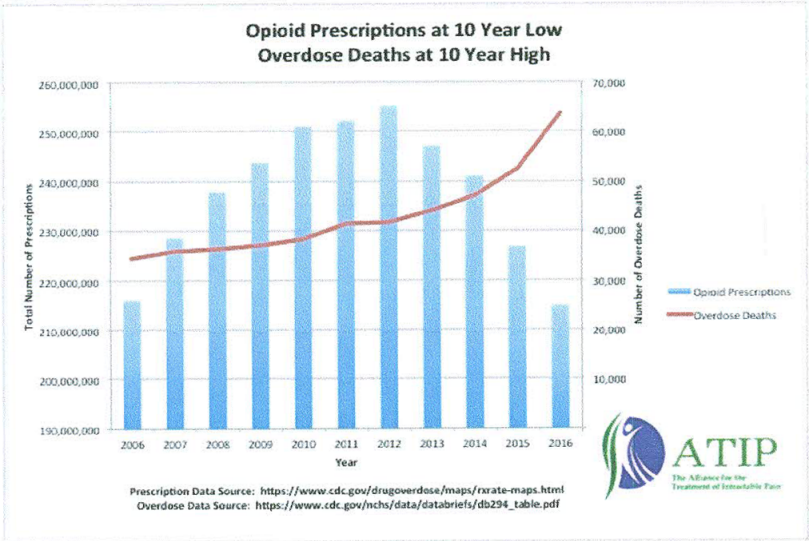
[44] Agency for Healthcare Research and Quality, "Noninvasive, Nonpharmacological Treatment for Chronic Pain: A Systematic Review," circulated in draft, December 2017.

[45] Cheryl K. Chumley, "Opioid Regulation Not the Way to Fight ODs, Cure Addiction," *The Washington Times,* February 15, 2018, *https://www.washingtontimes.com/news/2018/feb/15/opioid-regulation-not-the-way-to-fight-ods-cure-ad/*.

Figure 1: Opioid Prescriptions vs Overdose Deaths



Even the most basic attention to overdose and prescription statistics must reveal that attempts to mode rate the opioid "epidemic" by restricting supply have failed. According to the CDC, prescriptions are now at a 10-year low, but overdose-related deaths continue to escalate.[46]

5.1. Review of CDC Data

It is also becoming clear that further restrictions on medical opioid supply will do nothing to moderate the trends revealed in Figure 1. There is evidence that restrictions may indeed be contributing to increased deaths, by driving chronic pain patients into the streets for pain relief—or otherwise—into decline, disability, and suicide.[47]

5.2. A Necessary First Step

A necessary first step in correcting the horrid outcomes of the 2016 CDC Guidelines must be their formal withdrawal for a major re-write to correct multiple biases, errors and omissions. Board-Certified Pain Management physicians experienced in community-based, long-term treatment of chronic pain patients should lead such an effort.

This rewriting must be supported by a wide range of stakeholders, including providers from hospice, palliative care, cancer treatment, and patients or their advocates as voting members. Guideline development must be conducted using a publicly transparent process, supported by sufficient staff to process, analyze, and integrate external input.

5.3. Guideline Recommendations

Recommendations must be evidence-based, and guiding principles must include the following:

There is no one-size-fits-all patient or therapy. Medical professionals, responding to the needs of the patient, must tailor all pain treatment.

1. There can be no generalized single threshold of risk for Opioid Use Disorder versus opioid dose level or duration. There is no science to support such a threshold. Doctors must be able to trial their patients on different medications

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[46] Short, Paul K., "Opioid Prescriptions Move to a 10 Year Low," *https://atipusa.org/2018/01/13/opioid-prescriptions-move-to-a-10-year-low/*.

[47] *Op. cit.,* Jacob Sullum.

and dose regimes, perhaps combined with ancillary non-pharmaceutical therapies.

2. Medically managed exposure to opioid analgesics may create physical dependence without symptoms of addiction in patients treated long-term. Dependence, when it occurs, is an acceptable and physiologically expected outcome of effective pain treatment. Withdrawal symptoms can be managed with appropriately gradual tapering, if change or reduction of medication is medically indicated.
3. There is no medical evidence of benefit and ample evidence of needless harms in forced reductions of dose for patients who are medically stable and who benefit from existing dose regimes.
4. Risk of opioid abuse or protracted opioid prescription in properly screened, opioid-naive post-surgical patients is significantly less than 1%. Doctors need training to distinguish between patients in whom prolonged need for opioid prescription is an in dictator for development of chronic pain rather than an indicator of opioid misuse.
5. Patient screening for opioids should be oriented to identifying patients who have previous or present non-medical opioid exposure, in order to apply enhanced management protocols and make referral for drug abuse treatment where appropriate. The costs of urine testing are now outrageously high. False positives of urine testing are replete, and must be substantially reduced through better education and understanding of their results as they are often misused as grounds for patient dismissal.[48]
6. A single deviation from an opioid management contract—however minor—is all too often viewed as adequate reason to discharge a chronic pain patient from care. However, best available medical evidence suggests that patients who "doctor shop" or "pharmacy shop" likely comprise less than 1% of all patients treated with opioid analgesics. Care must be taken to avoid patient stigmatization and false alarms in applying data from Prescription Drug Management Programs. Patient treatment contracts must recognize conditions and limitations of patient daily life before mandating arbitrary discharge or otherwise damaging the patient.
7. No physician who treats verifiable chronic pain should be subjected to disciplinary action or government sanction solely because of the gross volume of opioids that he or she prescribes. Without reference to the medical conditions and numbers of patients treated, volume of prescriptions is not a reliable indicator for drug diversion to opioid abusers or street markets.

A related step in avoiding further harms must be immediate direction from the U.S. Congress to the Department of Veterans Affairs, to cease enforcement of the present VHA no-opioids policy. It is now well established that such policy is causing significant numbers of patient suicides in Veteran and non-Veteran populations.

Finally, pending issuance of a new CDC prescription guideline, all US States must stand down from efforts to impose further limitations on opioid prescribing for acute, chronic, or terminal pain. Enforcement of existing State limitations on dose level or duration should be suspended. If and when re-considered, such limitations must be grounded on published medical evidence of benefit and qualified by exceptions for chronic, intractable, or terminal pain conditions.

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May 3, 2018

U.S. Senate
Committee on Finance
Dirksen Senate Office Building

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[48] Fudin Argoff C.E., Alford D.P., Fudin J., Adler J.A., Bair M.J., Dart R.C., Gandolfi R., McCarberg B.H., Stanos S.P., Gudin J.A., and Polomano R.C., "Rational Urine Drug Monitoring in Patients Receiving Opioids for Chronic Pain: Consensus Recommendations." *Pain Medicine,* December 1, 2017.

Washington, DC 20510–6200

Re: April 19, 2018 hearing on "Tackling Opioid and Substance Use Disorder in Medicare, Medicaid, and Human Services Programs"

The American College of Osteopathic Family Physicians (ACOFP) is the professional organization representing more than 20,000 practicing osteopathic family physicians, residents, and students throughout the United States who are deeply committed to advancing our nation's health-care system by improving health-care delivery and outcomes, and ensuring that patients receive high-quality care.

Thank you for the opportunity to share our statement for the record for the April 19, 2018 hearing entitled, "Tackling Opioid and Substance Use Disorder in Medicare, Medicaid, and Human Services Programs." In addition to our statement below, we offer our continued support and commitment to work together on addressing the opioid epidemic. Should you need any additional information or if you have any questions, please feel free to contact Debbie Sarason, Manager, Practice Enhancement and Quality Reporting at (847) 952–5523 or debbies@acofp.org.

Sincerely,

Duane G. Koehler, DO, FACOFP *dist.*
ACOFP President 2018–2019

The American College of Osteopathic Family Physicians (ACOFP) appreciates the opportunity to provide this statement to the Senate Committee on Finance (Committee) regarding ways the federal government can combat the opioid crisis.

Overall, as an organization our osteopathic family medicine physicians practice in a variety of settings, including solo, small, rural, Native American/Indian health care, group, and alternative payment model practices. Our members treat many individuals suffering from pain and those who suffer from opioid addiction. We recognize the importance of addressing the ongoing opioid crisis that faces the nation.

Primary care physicians (PCPs) are at the frontlines of care and often are the first to uncover the presentation of behavioral health symptoms, including opioid addiction. PCPs are also in the unique position of diagnosing, treating and prescribing opioids, when medically necessary and clinically indicated. For these reasons, we believe PCPs are in a vital position to provide input on improving safe opioid use and on how to limit abuse.

Addressing the Opioid Epidemic

ACOFP believes the opioid epidemic must be addressed through a multifaceted, collaborative approach. Specifically, we believe each stakeholder and industry component has a role to play in combatting the opioid crisis. We support and encourage efforts to address the following areas:

- Prescribing practices of bad actors who inappropriately prescribe or prescribe unnecessary amounts or dosages of opioids;
- Ensuring insurers cover and incentivize the use of non-opioid pain management therapies or less addictive opioid medications;
- Providing additional training and certification in medication-assisted treatment (MAT) for substance use;
- Curbing "doctor shopping" through a prescription drug registry or "lock-in" program;
- Facilitating safe and efficient ways to dispose of unused/remaining opioids;
- Supporting the development of new, non-addictive pain medications; and
- Curbing access to illicit opioids.

Based on our members' firsthand experience with the opioid crisis, we offer the following comments on these areas of concern.

Prescribing Practices

ACOFP supports efforts to encourage responsible prescribing behavior, including curbing over-prescribing and monitoring to ensure "bad actors" are held responsible for clearly fraudulent prescribing practices. However, as solutions are being contemplated, we urge you to preserve patient access to pain management treatments, including medications that are consistent with best medical practices and clinical guidelines.

As family physicians, our primary concern is to ensure that clinically appropriate items and services are delivered efficiently to patients. This includes balancing pain management with the appropriate prescribing and use of opioids as well as the necessary follow-up to monitor for misuse or abuse. Clinically appropriate services, including non-opioid pain management, should be incentivized and reimbursed at an appropriate rate to ensure they are provided when needed.

Recently, there has been a heightened focus on prescribing practices as a potential contributor to the opioid epidemic. As you know, there are numerous factors related to the opioid epidemic. However, we believe that other factors including illegal opioids, such as heroin and fentanyl, currently play a more significant role than prescribing practices.[1] A recent report from the Centers for Disease Control and Prevention (CDC) found that opioid related overdose deaths increased 27.9 percent from 2015 to 2016 and that the increase "primarily [was] driven by deaths involving synthetic opioids, for which the rate doubled from 2015 to 2016."[2] Based on our experience, artificially limiting prescribing has had the unintended consequence of driving patients to illicit drug use.

Therefore, we strongly support an evaluation of the impact of laws that regulate length, quantity, and dosage of opioid prescriptions. We believe it will be critical to first study the effect of laws or regulations that limit prescribing practices and the impact they have on patient care. Such an assessment also will help to identify bad actors and the impact these policies have on patient quality outcomes.

Insurance Coverage

Currently, insurance coverage remains a significant barrier to transitioning patients from less addictive medications to medications with less abuse potential. For example, some insurers only will cover the less expensive (and highly addictive) short-acting opioids, but will not cover long-acting hydrocodone with abuse deterrent or alternatives like a Butrans patch. We believe this is counter to efforts to combat the opioid crisis.

We also believe that reimbursement for non-opioid pain management therapies needs to be revisited and updated. There are opportunities to change routine practices so that we are no longer a "prescribe-first" health-care system and instead work towards addressing and treating root causes of pain through non-pharmacological interventions such as osteopathic manipulative treatment (OMT). OMT is hands-on care that can help to alleviate and prevent pain, thereby reducing the need for addictive medications.

Medication-Assisted Treatment (MAT)

ACOFP is also committed to ensuring its members obtain training and certification in MAT for substance use disorders to bolster their osteopathic training and holistic treatment of patients. We recognize the distinct need for MAT and the benefits the certification provides in terms of recognizing potential problems and how to address them. We strongly support efforts to improve education, training, and certification opportunities.

Curbing "Doctor Shopping"

We strongly support efforts to share data to limit fraudulent access to prescription opioids. Efforts such as a lock-in program (as implemented by the Centers for Medicare and Medicaid Services (CMS) pursuant to the Comprehensive Addiction and Recovery Act of 2016) could be beneficial to ensure there is an ongoing relationship between the patient and physician. Lock-in programs enable physicians to monitor for signs of drug abuse and to intervene when medically necessary. Additional efforts, such as nationwide prescription drug monitoring programs (PDMPs) could help to limit fraudulent access to opioids. We appreciate and urge your continued focus in this area. We also offer our support in developing policies to leverage PDMPs.

Disposing of Unused Opioids, Developing New Medications, and Fighting Illicit Opioids

While not specifically related to the practice of family medicine, we also have concerns with properly disposing of remaining opioids and the importance and need for the development of new medications that are non-addictive, have favorable safety profiles, and are cost effective. We believe that these efforts should be a significant part of the strategy to address the opioid epidemic.

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[1] *See, https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates.*
[2] *See, https://www.cdc.gov/mmwr/volumes/67/wr/mm6712a1.htm.*

In terms of illicit opioids, our members have found it especially troubling that efforts to limit opioid prescriptions are offset by patients accessing lethal and illegal alternatives. As noted above, limiting prescribing can drive patients to fentanyl and other illicit opioids, which are now the largest driver of opioid-related overdose deaths. We urge you to take steps to limit the availability of illegal opioids.

Conclusion

ACOFP urges the Committee to consider the on-the-ground experience of family medicine physicians and the stark reality we face in combatting the opioid epidemic. Our members work with our patients to provide clinically appropriate medications and services to ensure patients are not unnecessarily suffering from chronic pain. At the same time, we are committed to addressing over-prescribing, but reiterate that prescribing practices are neither the sole nor the most significant cause of the opioid epidemic. We strongly urge the Committee to focus additional efforts on: (1) covering and incentivizing the use of non-opioid pain management therapies; (2) supporting training and certification in MAT; (3) curbing doctor shopping; (4) ensuring the safe and efficient disposal of unused opioids; (5) developing new, non-addictive analgesics; and (6) curbing access to illegal drugs.

LETTER SUBMITTED BY KRISTI BECKER

May 1, 2018

U.S. Senate
Committee on Finance
Dirksen Senate Office Building
Washington, DC 20510–6200

Re: "Tackling Opioid and Substance Use Disorders in Medicare, Medicaid, and Human Service Programs"

My name is Kristi, and I am a chronic pain patient. I've been diagnosed with degenerative disk disease, spinal stenosis, facet joint disease and spondylolisthesis. These diseases affect my entire spine and cause me significant pain every single day for the past 15 years. I was 30 when my pain started and was told I had the spine of a 60 year old.

I tried lidocaine patches, heating pad, ice packs, over the counter Icy Hot, Tiger Balm, Copper Fit, and all nonopioid options. My doctor prescribed Tramadol, Gabapentin, Naproxen, Flexeril, Tylenol, and Advil. All non-narcotic medications failed, nothing gave me any relief round the clock, I was always in pain.

I've tried physical therapy, aqua therapy, stretching, ultrasound therapy, chiropractic treatment, massage therapy, acupuncture, yoga, inversion table, TENS unit, biofeedback (cognitive behavioral health). I've received trigger point injections, steroid injections, SI injections, nerve ablation in multiple areas and levels of my spine. I had an implanted neurostimulator and an intrathecal pain pump implant.

These were not my first choice. I put off the neurostimulator for 5 years; when that didn't work, it was removed. Then 5 years ago I received an intrathecal pain pump; implanted in my lower abdomen, which delivers a low dose of pain medicine to my spinal fluid. While the pain pump helps with some lower back and leg pain, I still have no relief in my neck and shoulders. I am in need of pain medicine around the clock.

The rest did not provide adequate relief. I have tried every therapy my Pain Management Clinic has offered/suggested. I have been a model patient, submitting to pill counts, random urine screens, avoiding alcohol, securing my medications, using one pharmacy, and keeping all of my appointments.

Opioid pain medications help by managing my pain and allow me to work full time, work in my garden, care for my pets, home and family. They allow me to have some semblance of a life. I can go for walks, go geocaching, travel long distances, ride my bicycle, and even kayak with my husband.

Everything I tried failed to heal/help or adequately control my pain. Opioids and pain management are my last resort; without them, I will suffer constant pain. I won't be able to spend quality time, doing the things I love or spend time with people I care about. I will likely lose my ability to work full time, which is very important to me; also I carry the family's health insurance.

It is unlikely that my condition will improve and the effects of time and aging will make things worse. I am part of the C–50/Coalition of 50 State Pain Advocacy Group, a grass roots national organization, not funded by pharmaceutical companies. It is run by chronic pain patients advocating for a revision of the CDC Guidelines and a National Pain Policy Program.

Prescribing has markedly declined and the cause of the crisis is illicit fentanyl and heroin; anti-prescribing laws will not solve the problem. These laws will only further stigmatize patients, promote more fear among doctors and cause more suffering and death by cardiac/physiological issues and suicide.

These guideline are glossing over the fact that there is "a distinction between taking medicine to destroy function versus taking medicine to increase function."

Addiction is a serious problem in the United States and needs to be addressed. However, these guidelines are not accounting for chronic pain patients who follow the rules and are productive members of society.

Thank you for your time and consideration.

Kristi Becker

LETTER SUBMITTED BY ROBERT C. BRANSFIELD, M.D., DLFAPA

U.S. Senate
Committee on Finance
Dirksen Senate Office Bldg.
Washington, DC 20510–6200

April 23, 2018

Re: Association between the opioid crisis and the Lyme epidemic

Greetings:

As a psychiatrist, I have dealt with substance abuse problems on a daily basis for the past 45 years. Clearly there are many contributors to the opioid and substance abuse epidemic and only an approach that understands and addresses all of the facets of this problem will be effective. It is not just an opioid crisis, it is a substance abuse crisis. One of the greatest contributors this crisis is the inadequate treatment of psychiatric and general medical conditions.

I assume others have communicated to you sufficiently about this connection. I shall instead focus upon a different and often overlooked component to the substance abuse crisis. I shall give a representative case history describing something I have seen far too many times.

> A young patient acquires Lyme/tick-borne diseases and the diagnosis is missed, dismissed and/or they are undertreated. The symptoms progress over a period of years to include psychiatric symptoms, chronic pain and other symptoms. Eventually they are prescribed pain medications and/or other controlled substances and/or they acquire these medications through other means. Their use of pain medications (opioids) and other controlled substances increases and becomes an addiction. They may then turn to multiple physicians, multiple pharmacies, illegitimate sources of drugs and/or turn to illegal activity. They attempt to overcome their addiction, have a period of sobriety, then have some triggering event, relapse and take the dose of opioid they had previously used. However, the period of sobriety altered their tolerance to the drug and that same dose is now a lethal dose. They are discovered deceased and everyone is surprised, puzzled, and grief stricken.

The point I would like to make is that not only inadequately diagnosed and treated psychiatric and general medical conditions, but also inadequately diagnosed and inadequately treated Lyme/tick-borne diseases are components contributing to the substance abuse and opioid epidemic. Better attention to the Lyme epidemic contributing to the substance abuse epidemic can help protect health, improve economic stability, and save lives.

Sincerely,

Robert C. Bransfield, MD, DLFAPA

CENTER FOR FISCAL EQUITY

Statement of Michael G. Bindner

Chairman Hatch and Ranking Member Wyden, thank you for the opportunity to submit my comments on this topic. We will reprise our remarks from February of this year to the Ways and Means Health Subcommittee. That hearing discussed the ongoing opioid crisis, and the important role data, addiction prevention, and access to treatment play in addressing the crisis. The hearing also examined possible legislative solutions to combat opioid abuse. I submit these comments as past health research data manager, prevention community leader, and a current recovered abuser and Medicare patient. As it does apply to this issue, I will repeat our four-part tax reform plan, which is as follows:

- A Value-Added Tax (VAT) to fund domestic military spending and domestic discretionary spending with a rate between 10% and 13%, which makes sure very American pays something.
- Personal income surtaxes on joint and widowed filers with net annual incomes of $100,000 and single filers earning $50,000 per year to fund net interest payments, debt retirement and overseas and strategic military spending and other international spending, with graduated rates between 5% and 25% in either 5% or 10% increments. Heirs would also pay taxes on distributions from estates, but not the assets themselves, with distributions from sales to a qualified ESOP continuing to be exempt.
- Employee contributions to Old-Age and Survivors Insurance (OASI) with a lower income cap, which allows for lower payment levels to wealthier retirees without making bend points more progressive.
- A VAT-like Net Business Receipts Tax (NBRT), essentially a subtraction VAT with additional tax expenditures for family support , health care and the private delivery of governmental services, to fund entitlement spending and replace income tax filing for most people (including people who file without paying), the corporate income tax, business tax filing through individual income taxes and the employer contribution to OASI, all payroll taxes for hospital insurance, disability insurance, unemployment insurance and survivors under age 60.

The Ongoing Opioid Crisis

This national pandemic has been gaining steam for a long time. What was once the province of rural America and a few Doctors Feelgood has moved everywhere. Before opioids, the recreational pill of choice was the quaalude, which was before my time. It is the only drug war battle that could be won because there were few suppliers. That is not the case with opioids, which have old patents, new patents and suicidal hybrids that take life on a massive scale. This epidemic affects everyone, from workers with jobs and insured to poor and disabled people on Medicaid, both employed and not and Medicare beneficiaries, both disabled workers and mentally disabled recovering addicts and elderly who never thought they would become addicts, Indeed, the mentally ill former addicts have a much better chance of escaping addiction again because they know when to throw the pills away or they simply refuse them—I have done both.

The Role of Data

Properly used, Medicare care providers can track pharmacy data in an Accountable Care Organization where everything is in house. If outside pharmacies are available, this becomes harder but not impossible using Pharmacy and Medicare databases. Paper prescriptions are, of course, easier to abuse and should be entered into any tracking system, even if the scrip is not filled automatically. A photocopier, scanner or electronic printer can do amazing things when multiplying pain pills for groups of people. Of course, pharmacy networks can be hacked and overseas pharmacies can be accessed by the Internet, where perfectly legal appearing abusive prescriptions can be had with a credit card. While stopping such trafficking is not the job of Medicare, it does impact the system when beneficiaries become addicted. Creating a cyber-crime unit in HHS or a separate medical crimes unit in Homeland Security is called for here.

The Role of Addiction Prevention

The question of gateway drugs does come up. Alcohol and Opioids have similar uptake patterns according to research reported in the book *Beyond the Influence.* Of course, opioids are their own gateway if prescribed too long. In prior centuries, cannabis was used to detox both alcohol and opium addictions. While it is not rec-

ommended in most cases, the opioid crisis is not an excuse to resist the legalization of cannabis for either medical or recreational use and for some, is a better solution for chronic pain. It is time to admit defeat in the culture war on this subject and explore this alternative, even if those who are already addicts probably cannot or will not use it.

I spent years directing community addiction programs. They never kept me sober, prevented anyone from drinking and certainly did not prevent anyone who had an extended pain medication prescription from becoming an addict. They may be useful in helping people identify if they are at risk, but most children of alcoholics already know of the risks they have and drink anyway, becoming alcoholic if they are genetically destined to and not becoming alcoholic if not.

Addiction prevention is more helpful in medical offices, where proper screening may stop people who use alcohol from becoming cross-addicted to both alcohol and benzodiazepines by combining together. Likewise, educating doctors and changing pain management regimens from 30 days to 30 hours would prevent addiction, as well as research on both natural and synthesized cannaboids.

Access to Treatment

Access to both initial and continuing treatment is vital to both addiction and mental health care, as addiction can often uncover pre-existing psychiatric conditions that drug and alcohol use was covering up. Even for non-alcoholics, once addiction has been turned on by opioids, the patient can never drink safely again and even moderate or heavy drinking previously will have to end, along with any medicinal effect it had.

For initial treatment, the question is not just access for willing patients, but mandated treatment for the unwilling. The liberalization of commitment laws in the 1970s has likely gone too far. Our first clue was mental patients, especially veterans, living on the street. Even when forced into treatment, taking a sober breath in a few days, treatment plan or no, resulted in release and resumption of the previous lifestyle. This is not freedom or health. State laws or one overarching federal standard must make it easier for families, police, doctors, and social service agencies to begin mandatory treatment, with the outcome being assignment to medical care if required and housing beyond shelter space if not already possessed. While some will not need the latter, those who do, especially our nation's seniors, disabled and veterans, should not be sent back to the cold.

Ongoing treatment should be adequate. Medicaid will pay for a nurse practitioner to see a patient in a psychiatric rehabilitation program twice a month. Non-PRP patients are seen less often if their medication is stable. Affordable Care Act policies authorize fewer visits and Medicare provides for two visits a year, which is not enough even when stable. Talk therapy under Medicaid is weekly and includes any licensed professional. Medicare requires Social Workers and that requirement makes care less available. Stable patients may be seen once every few months, which is hardly effective for more than a brief check-in, especially if a patient is dual-diagnosed with addiction. The pool of allowable treatment professionals must be expanded so that nurse practitioners and licensed counselors can bill Medicare if more frequent visits are desired, with Doctors and Social Workers supervising treatment and proving occasional care, especially medication adjustments.

Early addiction after-care with an HMO (my experience) provided two sessions a week, going to one a week nearing discharge and self-paid sessions for the last few, which is a sign of recovery. If relapse is detected during this period, the addiction specialist should be empowered (and the patient funded) to go back into treatment, possibly in a more intense setting than originally. The therapist should be similarly empowered, even with patients with long-term sobriety. Needless to say, Medicare should pay for all of it.

Legislative Solutions

Several proposals were provided above regarding data security, Internet prescription abuse, cannabis legalization, expanding the pool of practitioners under Medicare and the power to initially hospitalize and re-hospitalize addicts and the mentally ill. Freedom requires a clear head but it does not require being a culture warrior. Any so-called Freedom Caucus member who uses that name should stop if they disagree with me and Drs. Ron and Rand Paul on the cannabis issue.

Our remaining comments will be in regard to our tax plan.

Medicare is a Hydra, taking money from the Hospital Insurance Tax, the high income dividend and capital gains surtax, patient premiums and copayments and the

general fund. Some of the reforms required will be cash intensive. Hospital Treatment will come out of HI and ACA/HI and the general fund. Aftercare will come from Part B or C, with some monies coming from the general fund, including three of every four premium dollars.

It is always important to note that the whole purpose of social insurance, including Medicare, is to prevent the imposition of unearned costs and payment of unearned benefits for not only the beneficiaries, but also their families. Cuts which cause patients to pick up the slack favor richer patients, richer children and grandchildren, patients with larger families and families whose parents and grandparents are already deceased, given that the alternative is higher taxes on each working member. Such cuts would be an undue burden on poorer retirees without savings, poor families, small families with fewer children or with surviving parents, grandparents and (to add insult to injury) in-laws.

Recent history shows what happens when benefit levels are cut too drastically. Prior to the passage of Medicare Part D, provider cuts did take place in Medicare Advantage (as they have recently). Utilization went down until the act made providers whole and went a bit too far the other way by adding bonuses (which were reversed in the Affordable Care Act). There is a middle ground, and the subcommittee's job is to find it and our job to help.

In our plan, funding Medicare has nothing to do with the income tax, so bullet two above can be disregarded. Likewise, we would repeal the Medicare and Affordable Care Act dividend and capital gains surtaxes targeted only at upper income taxpayers. Because the benefits are general, the taxation should be as well.

Bullet three on employer contributions to Social Security is also not affected by our proposal, which already moves the Medicare Hospital Insurance Tax paid by employees to the Net Business Receipts Tax/Subtraction VAT.

It could also be moved to bullet one, the Value-Added Tax taken on receipts (along with the Employer Contribution to Social Security), making that part of the tax border adjustable but at the cost of eliminating offsets that can be taken against the NBRT for providing direct insurance and care for employees and retirees, which would make the tax border non-adjustable (no zero rating). If the VAT is used, it would be considerably higher than the 13% proposed by either this Center or Michael Graetz. Just shifting taxes without accounting for ACA/HI inclusion would add 9.3% of income, making the VAT visible for 22.3% of every transaction. The VAT will fund any enhanced Internet law enforcement efforts, however, unless housed in HHS. VAT funding would also mean all savings must come from government enforcement rather than employer/taxpayer efficiency, which would put cost payment and cost cutting in the same hands.

Again, the Net Business Receipts Tax, bullet four, proposes to combine all employer income taxes, payroll taxes, ACA taxes and the HI payroll tax. It will include offsets, including an enhanced child tax credit and the health insurance exclusion. It will fund all social insurance costs, including those with state revenue participation, including education and we expect states to fund their share of this tax with matching taxes and the same VAT base.

One of the options is a personal retirement account holding employer voting stock and an insurance fund of such companies (a third to insurance). We believe such employee-owned firms will take bolder cost cutting measures without losing compassion for their retiree/shareholders who could even by-pass Medicare and be funded by an internal plan which must be at least as generous. Note that employee-owned firms could also pay all Part Band D premiums. More information on this aspect is available in our previous comments to the committee.

The NBRT can provide an incentive for cost savings if we allow employers to offer services privately to both employees and retirees in exchange for a substantial tax benefit, either by providing insurance or hiring health-care workers directly and building their own facilities. Employers who fund catastrophic care or operate nursing care facilities would get an even higher benefit, with the proviso that any care so provided be superior to the care available through Medicaid. Making employers responsible for most costs and for all cost savings allows them to use some market power to get lower rates, but no so much that the free market is destroyed.

This proposal is probably the most promising way to arrest health-care costs from their current upward spiral—as employers who would be financially responsible for this care through taxes would have a real incentive to limit spending in a way that individual taxpayers simply do not have the means or incentive to exercise. While

not all employers would participate, those who do would dramatically alter the market. In addition, a kind of beneficiary exchange could be established so that participating employers might trade credits for the funding of former employees who retired elsewhere, so that no one must pay unduly for the medical costs of workers who spent the majority of their careers in the service of other employers.

Let me also comment on Senator Sanders's proposal for Medicare for All. The reality is that Medicare is not as generous as younger people assume and that the Senator's proposal would eliminate those cost sharing features of Medicare, making it Medicaid for all (but with higher doctor reimbursements) and then replacing both Affordable Care Act and Health Insurance Exclusion supported policies with the expanding program. Of course, like Medicare and Medicaid, it will be impossible to do without using the Affordable Care Act's Accountable Care Organizations. In other words, health insurance companies are going nowhere nor will all cost control efforts be abandoned. We like our proposal better, which is more cooperative socialist than democratic socialist. In either case, however, something like the Net Business Receipts Tax/Subtraction VAT in bullet four will be necessary, especially if we are serious about fighting the opioid crisis.

A final word on drug testing. It should lead to treatment, not exclusion of benefits, especially medical benefits, but all other social benefits are as applicable, as no one should have to choose between getting treatment and feeding their children. You would think this would be obvious, but almost every other week some Tea Partier introduces legislation to test SNAP or TANF recipients. Their arguments are without merit.

Thank you for the opportunity to address the committee. We are, of course, available for direct testimony or to answer questions by members and staff.

LETTER SUBMITTED BY KATHLEEN M. CLARK

April 20, 2018

Member of the Idaho Pain Advocacy Group C–50

Dear Senators, I would like to introduce myself: I am a chronic pain sufferer. I was born without a left hip socket. This condition went undiagnosed until I was 8 years old! At the time, I was born in the small State of Rhode Island. My older sister and I went to the YMCA to learn how to swim. I remember vaguely, crying out in pain as I was trying to learn the swimming "frog kick." This caused me intense pain and the lifeguard called my parents. Next, I heard the words: "She doesn't have any hip socket." I spent my entire 3 month summer vacation in the hospital. First, for 6 weeks, I was in traction with weights and pulleys at the bottom of my bed. This was supposed to bring my femur bone (which was riding above my hip), down to at my hip level. Secondly, after that was accomplished, I had major surgery to have some semblance of a hip socket created. This was very painful post-op. In those days, parents weren't allowed to spend the night. My dad came every evening after work to see me and encourage me. Before going home, I had physical therapy. I walked on crutches for 1 year, and had a lift placed in my left shoe, as this was my shorter leg, and I limped quite pronounced. This is a hereditary condition, but yet my seven other siblings were lucky enough to not have this problem. All the surgeon recommended to my parents, make sure that she gets a hip x-ray every year. I do remember being around 14 years old and experiencing severe bone pain due to the fact that my left hip was growing. All I received: aspirin. This really did nothing for my pain.

Fast forward—I met my husband at age 21 and married. However, I still had bad pain spells. I also went into the field of nursing. First, I worked as an LVN, in Newport Beach, CA (I loved my hospital nursing job. This was the hospital where the famous western actor John Wayne died.) I always made certain that my patients were never in pain. It is like taking the Hippocratic Oath (which doctor's take); believe it or not, we nurses had to take a Nurses Oath. I did a lot of walking on my job. It was very physical work. Then I went back to school to become a Registered Nurse or RN. I was able to perform my job, until overwhelming pain took over my life. I had to quit my job. At age 25, I had an orthopedic surgeon who performed a primary total hip surgery. When he performed this surgery, he found that my left hip had dislocated, and I suffered from severe osteoarthritis. If I did not have this surgery then, my surgeon said that I would have been in a wheelchair. The next

amazing accomplishment: I gave birth (regular) to one beautiful daughter and all with a total hip replacement.

The worse thing I had to endure: four more total hip revision surgeries. Not many orthopedic surgeons wish to do these revision type surgeries. But, because I had been so active the glue material gave out and mechanical failure happened due to the fact that medical doctors cannot predict how long these hip replacement surgeries will last. At present, my last hip revision surgery on my left hip was in 2002. It has now lasted 15 years (the longest lasting yet). I have my left hip x-rayed yearly. Since 2013, my husband retired and he wanted to move to Idaho Falls, ID. He loves to fly-fish and builds bamboo fly fishing rods. I am so proud of him! My daughter obtained her Psy D in psychology for marriage and family therapy; she is also working with stroke patients and our military veterans suffering from PTSD. She lives in Spokane, WA.

I want to address now what has happened to me since the age of approximately 38 years. I tried acupuncture for my pain, but it did not work due to the fact that I had a lot of scar tissue. I tried psychology and was placed on an anti-depressant medication called Elavil. After about a month on this drug, I gained approximately 40 lbs. and it made me feel like a zombie. I tried the TENS unit without much success. All the TENS unit did was make my left hip and back nerves become extremely irritated. I tried psychology, biofeedback, imagery, all to no avail. All this time took about 10 years to try to relieve my constant nagging pain. My husband felt helpless, as I cried each night. So, when I made the decision to see a chronic pain doctor in southern California, I was so relieved that I started to cry!

Let me explain how my pain program worked to help me: first my medical doctor carefully did a hormone profile. He and I worked out a formula for the type of pain medication that worked for me, along with a muscle relaxant. We found out that I did well on 120 MMDs per day. Our program was zero tolerance policy. This meant that for 23 years, I had to visit my pain doctor each month. We could not go over the amount of pain medication which worked for us. (Remember, each individual is unique; what works for one person, may not work for another patient). My pain doctor gave us tools also which gave me a chance to use Icy Hot patches to my lower back and hip. I would take aspirin three times weekly. I would have my husband massage my leg when it went into awful spasms. I am a law-abiding citizen. We patients also had random drug urine testing, could use only one pharmacy, and never go "doctor shopping." Anyone not abiding by these rules, they would be kicked out of the pain program. I have been successful on my pain medication and I always told my doctor, please include me in a study if it would be helpful.

So, here in Idaho Falls, the pain doctors are usually anesthesiologists/pain doctors. I was with one doctor who gave me my med dosage which worked for me until the CDC guidelines came into effect. When this happened, it put a strain on the doctor/patient relationship. All of a sudden (with no input from myself), I found out that my pain meds had to be reduced down to the 90 MMD rule. Each pain doctor here in Idaho as well as nationwide is in total fear of losing their medical licenses if they prescribe over the 90 MMD rules. I also keep reading articles which state that there are not enough studies done to determine if opioid medications work. If I were only included in that study (sigh)! The addiction rate for a pain patient on long term meds is about 1–3%. This is quite low. But due to the ODs happening, the word opioid has been given a broad definition. There are quite a few lay-people who do not even know how these pain meds work. Here is a short education. Think about a diabetic person, they may need to take insulin injections in order to lower their blood sugar and have a life. My pain medication is a lifesaver. My pain disability is a disease and should be considered as such.

We do not get "high" from our pain medications, what we get is much needed pain relief. This gives me the ability to get out of bed, be able to socialize, be able to travel, and to summarize it all: to give me a "quality of life." Right now, this has been taken away from me and nobody even bothered to care. I want people to become educated to know that when taken correctly, pain medication is a life saver to us pain patients. I wish to let you know that Medicare/Medicaid is now under scrutiny and I voted against the CMS beginning to drop the pain dosage to the 90 MMDs each day. Why is the Federal Government interfering with my pain doctor relationship? I have heard of well-deserved physicians having their offices raided by the DEA; this is absurd. The CDC even came out to say that they were in error in reporting the number of overdoses that had taken place in the last year or two. So, is it right to say something that is not true? There are numerous pain sufferers like myself who have been maintained on a dosage which works for them. What has

happened to our great Nation? Since when has it become shameful to admit that we are experiencing pain? Another true fact: let's say you go in to the hospital to have an appendectomy. Yes, you experience pain, but it is short lived and goes away. Chronic pain lasts more than 90 days and is constant and unbearable. Please note that I want the Senate to understand the reason for we pain patients not wanting to have to be limited by this so called 90 MMD ruling. What needs to be done first? Please take away the fear of the pain doctor losing his medical license. What has been discovered? There is illicit fentanyl pouring in from places like China and Mexico, which is all sold on the dark web and delivered by the U.S. Postal Service. The DEA needs to concentrate their efforts in this area. It is true and sad, that a number of individuals have died from these bad drugs. However, I feel that each individual is responsible for their own actions. The Addictionists choose and continue to choose to take drugs to make them get "high" . . . nobody told me to put a needle in my arm to inject heroin.

To summarize: the general public, and the primary care physicians need to take pain management classes and reeducate themselves as to how these meds are vital to us pain patients to be able to have a life and not suffer. Imagine our poor veterans being cut off their pain medications. It is a travesty as to what is happening to our Nation. Nobody wants to take notice of us pain patients. I would love it if somebody would read my pain story. Let's get educated and realize that the pain meds are not what's causing evil in our society; it is imperative to have a quality of life. I am suffering along with 100 million other pain patients. My pain condition warrants the fact that the medications at 120 MMDs have worked for me for almost 27 years and I am still here. The last thing I would like to add is, many of us pain patients have pain flares which occur out of the blue. For instance, I do not have hardly any bone left in my left hip joint, and I have a metal rod which goes to the knee hammered into my femur bone. I have screws, nails (just like in a hardware store). When the barometric pressure drops and it rains, my entire hip goes crazy in pain. When this happens, my little bone that is left expands and it feels like my hip and thigh will burst. Another huge problem is that my blood pressure is not stable with the decreased dosage of pain medication. I already take two blood pressure pills from my primary care physician. My blood pressure has been high, around 150/100. This in itself could cause me to have a stroke. I found out that I currently have a broken screw in the hip socket which I have never experienced before. In nursing school, I not only had to take 2 days of state boards to receive my RN license, but I had to be well versed in all pain medications. I sometimes feel that not all doctors are aware of how certain pain meds work, and there are definitely some meds that shouldn't interact. But we pain patients know this. I write down each time I take a pain pill, I lock up always all of these medications. It is just not true to make a statement that pain medication will lead to heroin addiction. That is so very wrong to advertise. It would be nice to have a commercial which shares our stories. Much works needs to be done to change the mindset over this much uninformed topic. I have had to walk with a cane since the year 2002. I just want my life back.

Respectfully submitted,

Mrs. Kathleen Clark, RN (retired)

P.S.—I am an active member of the Advocacy for Pain Patients in Idaho, C–50.

IMPORTANT ADDED INFORMATION

My birth defect should be considered a disease condition. I have a totally deformed left hip socket. Imagine if I had diabetes. I would be treated with the appropriate medication—such as insulin to regulate my blood sugar levels and keep me alive. The same holds true for my pain condition. My pain medication works when my pain doctor and I can figure out a formula which works for me (remember, each person is a unique individual). What may work for one patient, may not work for another patient.

Secondly, there is genetic opioid testing for us pain patients. It is an invaluable tool which shows how our bodies metabolize opioid medicines. This has been around since approximately 2010. Also, doing a hormonal profile each year will give the pain doctor valuable information as to how hormone levels can affect pain levels. If a hormone level is out of balance, the pain doctor can make adjustments to fix this.

I have had my adrenal glands tested periodically. This is one hormone that a good knowledgeable pain doctor knows how to treat. I have taken DHEA supplements 3 times a week, approximately every 2 months.

COALITION OF 50 STATE PAIN ADVOCACY GROUPS

May 2, 2018

U.S. Senate
Committee on Finance
Dirksen Senate Office Bldg.
Washington, DC 20510–6200

Re: "Tackling Opioid and Substance Use Disorders in Medicare, Medicaid, and Human Services Programs," Thursday, April 19, 2018, Senate Finance Committee

The Senate Finance Committee has requested additional input from stakeholders and other interested parties for the record of the hearing "Tackling Opioid and Substance Use Disorders in Medicare, Medicaid, and Human Services Programs." As a nationwide advocacy group representing chronic intractable pain patients from all walks of life, we believe we bring a different perspective to the table. Below are our comments and suggestions to the Senate Committee on Finance.

As a starting point, two major points of clarification that must be made. One is that prescription opioids are not causing the current crisis. Illicit substances, such as heroin and fentanyl, are. In fact, opioid prescriptions have been falling dramatically and steadily since mid-2010. At the same time, the number of overdose deaths have been skyrocketing. The second point is that the vast majority of those currently addicted to illegal substances did not get their start with a legal physician's prescription for opioids. Study after study have found that the majority of these individuals begin by stealing from someone's legitimate supply, or purchasing pills on the street. Therefore, the tying of physician's hand will not stop this crisis. It needs to be stopped where it begins—on the streets. The major problem with overarching pain control guidelines, including the 2016 opioid guidelines by the CDC, is that the true intractable pain patients are swept up in the aftermath. Chronic intractable pain patients' dosages get reduced or removed, along with everyone else's, no matter the individual patient's situation. After the CDC Guidelines were revealed, many physicians stopped prescribing opioids altogether, and even more refused to prescribe above the suggested 90 MME, no matter the previous dosage of the patient. A lot of physicians stated that they feared retribution by governmental agencies if they continued to prescribe to chronic intractable pain patients as they had before the guidelines. These broad guidelines and other state regulation is now affecting those with cancer, those receiving and post-major surgery, and those in palliative and hospice care. Additionally, due to the DEA cutbacks in opioid products in their misguided attempted to stem to opioid crisis, hospitals are running low, or are completely lacking necessary pain medications for the sickest of patients. The madness must end.

In the case of chronic intractable pain patients, the major problem with this situation is that the logic behind removing or quickly reducing opioids for stable chronic intractable pain patients is untested and unproven. There have been no prospective clinical studies to show that discontinuing opioids for currently stable pain patients helps those patients or anyone else. While slowly weaning from some of their medications under a physician's supervision could theoretically be helpful to a minority of chronic pain patients, it seriously destabilizes the vast majority, and would likely promote the use of heroin or other illegal substances. Thus, the discontinuation of pain control medication for these patients, who rely on them in order to work, and be otherwise productive, contributes directly to the decompensation of the patient. A very ill chronic pain patient will no longer be able to work, or otherwise be productive, which will lead to more individuals on disability, Medicare, and Medicaid. Thus, an expensive, vicious downward cycle develops, as more formally stable patients have their pain control medications taken away, and they join the ranks of the disabled. Meanwhile, those on disability become sicker, and rely on the governmental safety nets more and more.

To significantly lessen the risk of OUD and SUDs within the greater Medicare and Medicaid populations, without harming those patients who rely on opioids to function in their daily lives, any and all regulation must be targeted. Specifically, instead of the broad regulations and guidelines of the past few years that paint every

person with an opioid prescription with one stroke, we suggest targeting certain aspects, such as:

- Establishing a uniform physician education program;
- Updating the ICD–10 codes for chronic intractable pain;
- Establishing a national Prescription Monitoring Program (PMP);
- Requiring that all prescription opiates are tagged with a unique identification number; and
- Requiring and covering genetic testing for medication metabolism markers.

Taken together, these suggestions will give physicians the tools they need in order to diagnose true chronic intractable pain patients, and monitor those patients who are already receiving opioids. We envision a uniform physician education program in the form of mandatory CME classes that would inform physicians of the steps needed to diagnose and treat intractable pain patients. Physicians could learn a guidelines for approaching newly diagnosed intractable pain patients, such as prescribing neuropathic agents and anti-inflammatories before trying opioids, running genetic testing to see how each patient metabolizes medications, and ordering targeted physical therapy for musculoskeletal pain and dysfunction. These classes could also discuss the benefits and drawbacks of alternative therapies, including acupuncture, massage, aqua therapy, etc. Physicians would also be instructed on guidelines for diagnosing chronic intractable pain.

Hand-in-hand with physician education, the suggestion to update the ICD–10 codes would eliminate uncertainty about the diagnostic criteria for chronic intractable pain patients. Currently, the ICD–10 has approximately 100 different codes for pain. Code R52.1 purports to address chronic intractable pain; however, it is included under the heading of "Pain, unspecified," and the description is intermixed with that of acute pain. Also, none of these codes properly addresses the biopsychosocial aspects of chronic intractable pain. A new code or updated code for chronic intractable pain would limit any confusion between chronic and acute pain for diagnostic purposes.

A federally mandated national PMP would help to eliminate any abuses of the system. Currently, most states have PMPs, while the rest have enacted legislation in order to establish them. However, a system to monitor patients nationally does not yet exist, although about 40 states are voluntarily participating in PMP Interconnect, a secure communications exchange platform that facilitates the transmission of PMP data across state lines to authorized requestors. A federally mandated system would combat prescription medication abuse and diversion with neighboring states, and allow CMS to monitor Medicare and Medicaid beneficiaries.

We also suggest that CMS work with the FDA to require that all prescription opioids be tagged with a unique identifier. This unique identifier would be akin to a car's VIN number and would allow the tracing of all opioid-based prescription medications. The major cause of the influx of prescription medications to the street is diversion, most of it out the back doors of pharmacies and distributors. If every type of opioid medication had a unique identifier, governmental agencies would be able to track the patterns of diversion and shut them down. This suggestion would assist the federal government is stopping the diversion of prescription medications, which is a significant problem in the opioid crisis.

Finally, CMS should both require and cover genetic testing for medication metabolism marker. More than 75% of people have genetic variations that determine how their bodies process and use medications. Because of these genetic differences, two people can take the same dose of the same medication, but respond in very different ways. For example, a medication might work very well for one patient, not at all for another, and causes serious side effects for a third. Especially when dealing with opioids, genetic testing is helpful to discover how quickly a patient will metabolize the medication without trial-and-error. This type of genetic testing, therefore, could assist physicians in determining the correct course of action for chronic intractable pain patients. Additionally, when a physician decides that opioids are necessary, this genetic testing will help physicians in determining what dosages are appropriate.

We hope that the above-referenced explanation of why broad legislation and regulations harms chronic intractable pain patients. We also hope that our suggestions on how to target specific legislation and regulations will assist you in your decision-making process. Thank you for your time and consideration.

Sincerely,

Valorie Hawk
Director and Founder

Amie Schaadt Knauer
Special Projects

Sherri Cantara Martin
Operations and Research

Rhonda Posey
Membership Coordinator

LETTER SUBMITTED BY CAROL EFAW
Member, Washington Pain Advocacy Group, C–50

May 2, 2018

U.S. Senate
Committee on Finance
Dirksen Senate Office Bldg.
Washington, DC 20510–6200

Re: "Tackling Opioid and Substance Use Disorders in Medicare, Medicaid, and Human Services Programs," Thursday, April 19, 2018

Since the CDC and DEA have been involved in the illicit fentanyl and heroin opioid crisis, their efforts have resulted in fewer medical providers and fewer prescriptions for legal pain medications. Their efforts have not helped to reduce opioid deaths but rather deaths are on the increase. Because of the DEA mandating production cuts, even hospitals are now having trouble obtaining necessary pain medications for post-operative patients.

I am a member of the C–50/Coalition of 50 State Pain Advocacy Groups, a grass roots national organization, not funded by pharmaceutical companies and run by patients advocating for a revision of the CDC guidelines and a National Pain Policy program.

A carve out MUST BE CREATED—not merely allowed to be created—for intractable pain patients under a Palliative Care exemption from CDC guidelines, Medicare restrictions, and federal and state laws.

National Pain Policy could include: (1) mandated genetic testing for hyper-metabolizing (no patient metabolizes medications alike); (2) standardized pain contracts (reasonable UAs, pill counts, one pharmacy); (3) intractable pain diagnostic code redefined so physicians are paid a higher fee for the extra time it takes to manage our complex cases; (4) the Palliative Care definition clarified to include all incurable, progressive conditions and exempt from CDC guidelines/Medicare restrictions, and patients' records protected for our lifetimes.

I am a pain patient and have been diagnosed with various inflammatory diseases including degenerative disk disease and scoliosis for over 40 years. I have tried numerous non-opioid medications including ibuprofen, aspirin, Lyrica, Gabapentin, steroids, and others too numerous to list, before being prescribed opioids. I have received over a dozen spinal steroid injections, acupuncture, massage, chiropractic care, bio-feedback, spinal braces, TENS units, as well as numerous courses of physical therapy. None of these healed my conditions and none adequately controlled my pain. And the spinal injections actually worsened my pain. Opioid pain medications help by managing my pain and allow me to care for myself, my family, and my home as well as work part-time from home as an advocate helping others. I am never completely free from pain nor do I ever experience a "high" from my medications. I am not a drug seeker and I resent being treated like a criminal by all parties involved in this heroin and illegal fentanyl "opioid crisis."

I have had cervical decompression/fusion surgery and was told last month I need the same surgery in my lumbar area. Because I already receive pain medications, my surgeon said she would not be giving me any additional pain relief after surgery. I cannot proceed with this surgery under these conditions without additional pain relief—regardless of the future consequences.

In 2015, my mother was assigned to hospice care. She had taken pain medications for severe back pain for more than 20 years. The hospice doctor refused to renew her prescriptions saying, because she had dementia, she couldn't feel any pain. I

know that to be untrue. I appealed on her behalf to no avail. She died a year later suffering an extremely painful death—literally—TORTURED TO DEATH.

If I did not have access to my medication, I would deteriorate rapidly and end up in bed most, if not all, of the time due to extreme, unrelenting pain and fatigue. I would not be able to work part-time. I would not be able to care for myself, my family, or my home. Already, I am depressed just worrying each day might be the day I lose my medications. My husband works full-time; he is not in great health so he would not be able to take care of me and we could not afford in-home care. If he had to stop working to care for me, we would lose our home and God knows what would happen to us.

In all the years I have taken pain medications, never once have I broken my pain contract. I have always been a compliant patient. Besides the ridicule, I have been subjected to pill counts, urine tests, etc. the entire time. My current pain specialist says I have been a model patient—one that she considers "low-risk" even though I am prescribed more than 90 MMEs/day. My condition will not likely improve and the effects of added pain will only result in more doctor visits and costs to the health-care system. Opioids and pain management are what keeps me functioning as a contributing member of my community and they are a low-cost, effective modality in dealing with my incurable issues.

Thank you for listening.

Carol Efaw

LETTER SUBMITTED BY SONYA HUBER
Member, Connecticut Pain Advocacy Group, C–50

U.S. Senate
Committee on Finance
Dirksen Senate Office Bldg.
Washington, DC 20510–6200

Re: "Tackling Opioid and Substance Use Disorders in Medicare, Medicaid, and Human Services Programs," Thursday, April 19, 2018

Dear Senators,

Prescribing of opioids has declined. Instead, people are dying from cheap heroin and illegal fentanyl. I know this as an informed member of the C–50/ Coalition of 50 State Pain Advocacy Groups, a grassroots national organization, not funded by pharmaceutical companies and run by patients advocating for a revision of the CDC guidelines and a National Pain Policy program.

I know from personal experience that laws targeting the prescription of all kinds of painkillers have spooked doctors, leading to drastic decreases in medication for legitimate and painful life-long conditions, such as my own of rheumatoid arthritis, fibromyalgia, and Hashimoto's Thyroiditis. I have been living with these conditions for 9 years. I use Cognitive Behavioral Therapy, I meditate daily, I ride an exercise bicycle, I use topical muscle relaxing creams, I use a Quell TENS unit, and a variety of supplements such as turmeric and fish oil. None of these even comes close to chipping away at the pain. One of the important things to know about pain is that it builds to an exhausting level, and occasionally without a relief from it, a person in pain is not able to sleep and to get the rest and physical repair necessary to continue. I took one Tramadol a day for sleep, and that has been discontinued by my doctor as the result of the opioid scare.

I was recently in the ER for a related pain condition, and surgery was recommended. I saw how high my blood pressure was spiking because of pain. I am afraid to have surgery for fear of what the pain treatment situation would be like afterward. The current environment in the medical community with regard to opioids means that there is a great deal of shaming if a patient confesses to any pain. Anyone who tells a doctor they are in pain is branded as a suspected drug seeker. This shame in addition to having multiple chronic conditions is unbearable.

I am a model patient. I use one pharmacy and coordinate my care with multiple doctors. I have always followed prescription instructions exactly—and in fact when given pain pills, I usually take less than prescribed. I take the minimum I need to function. In addition I have a med safe at home in which I keep all opioids and anything else that might be dangerous locked up, and I turn in my old medications to a drop-box at the fire station near my house. I am not able to drink any alcohol

due to negative interaction with an injectable non-opioid chemotherapy drug I take weekly for my condition, which is at this point incurable.

I work full time as a college professor, I am a mother to a 14-year-old son, and I'm as active as I can be. Knowing there is no help today for chronic pain patients makes contemplating my future to be a crushing exercise. If you don't know what it is every day to get up in excruciating pain, you don't fully understand how punishing an overly aggressive and wrongly targeted law can be.

We as a nation need a carve out for intractable pain patients under a Palliative Care exemption from CDC guidelines, Medicare restrictions and federal law. We need a National Pain Policy, which could include: mandated genetic testing for hyper-metabolizing (no patient metabolizes medications alike), standardized pain contracts (reasonable UAs, pill counts, one pharmacy), intractable pain diagnostic code re-defined so physicians are paid a higher fee for the extra time it takes to manage our complex cases, the Palliative Care definition clarified to include all incurable, progressive conditions and exempt from CDC guidelines/Medicare restrictions, and patients records protected for our lifetimes.

I worry every day about being disabled because of lack of access to effective pain treatment, and I worry about the depression and loss of functioning and career that might result. I urge you to take this huge segment of the population into consideration. Pain people are also voters, and we are human beings.

Sincerely,

Sonya Huber

LETTER SUBMITTED BY MARK IBSEN, M.D.

U.S. Senate
Committee on Finance
Dirksen Senate Office Bldg.
Washington, DC 20510–6200

Dear Senators:

My name is Dr. Mark Ibsen. Please know there is truly an epidemic in medicine: an epidemic of misinformation and disinformation. Someone has developed the idea that Percocet causes heroin overdose deaths. This is false.

The war on drugs and people has been a $2 trillion failure. Claiming that doctors have fueled an opiate epidemic is not proven. In fact opiate prescriptions have been decreasing since 2010 and yet overdoses have continued to skyrocket. Because of the scarcity of pain relief for pain patients, more people are turning to heroin. Therefore more complications from that drug, which is often contaminated by elicit Fentanyl from China, causes epidemics of death in various communities. In addition, street pills are now known to be mostly counterfeit. These counterfeit pills can look like an innocuous Percocet or hydrocodone tablets and contain deadly Fentanyl from China.

My promise is that you cannot arrest doctors expecting to change this dynamic. The consequence of restricting prescription opioids, and making it very difficult to obtain pain relief, is abandonment of the 25 million Americans who have been stable on their palliative opiate programs. Many patients metabolize opiates rapidly, requiring higher doses then the arbitrary doses given in the CDC guidelines. These guidelines have been misinterpreted as "rules," creating havoc for doctors and patients.

The key question to be asking is what is causing all these heroin overdose deaths? That would be heroin. Prince and Tom Petty both died of severe pain. They were treating their pain with counterfeit pills, resulting in death.

Please refer to the experience of the country Portugal, where opiates and other drugs were decriminalized, resulting in less crime, less rates of addiction, and less than 10 deaths a year in the entire country.

While there is a bandwagon of interested parties claiming that opiates prescribed by physicians are harmful, less than 1% of pain patients given an opiate develop an addiction. One way to sort this out is to collect better data. One way to get better data would be to put a marker on every pill that is manufactured legitimately. This will be like a fingerprint or a VIN number. I'm sure we have the technology to do this and we're already spending boatloads of money on this issue, but the data we are obtaining is inaccurate. Anyone who dies in America with any amount of opiate

in their system is listed as an opiate overdose. This gets us data which is "fake news."

We could actually do the research and find out what is the cause of the deaths that have been reported. Often these are suicides. Yet doctors get arrested and sent to prison when their patients use their medications to kill themselves.

Suicides are increasing in the pain population and veterans who suffer from pain and PTSD. Trying to arrest our way out of this problem has been unsuccessful for over 50 years.

Please review the Institute of Medicine report on Pain in America from 2011, which indicates that pain itself is present in 100 million Americans, causing a $650 billion impact on our economy. That's a lot of voters. That's also a lot of expense and drag on our economy. Please ignore bad data; only look at good data.

People are in agony, abandoned by their physicians who are too terrified to treat their pain.

Thank you,

Mark Ibsen, M.D.
Helena, MT

American Council on Science and Health, October 12, 2017

THE OPIOID EPIDEMIC IN 6 CHARTS DESIGNED TO DECEIVE YOU

By Josh Bloom

https://www.acsh.org/news/2017/10/12/opioid-epidemic-6-charts-designed-deceive-you-11935

I do not know Dr. Andrew Kolodny [1] personally, and, aside from one brief phone call last year, I have had no contact with him. Therefore I cannot know his motivation for becoming a driving force behind "opioid reform"—a concept which would border on hysterically funny if not for the tragedy that it is causing in this country.

Dr. Kolodny, a psychiatrist, is the executive director of Physicians for Responsible Opioid Prescribing (PROP)—a group that played a significant role in creating the disastrous CDC Guideline for Prescribing Opioids for Chronic Pain *(https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm)* (2016). The CDC ended up incorporating much of PROP's recommendations, which were supposedly designed to help the U.S. mitigate the damage done by opioid (1) drugs, despite the fact that the "evidence" contained in the recommendations had been carefully scrutinized and found unsupportable by FDA scientists *(http://paindr.com/wp-content/uploads/2013/09/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf).*

Since I cannot read his mind, I have no way of knowing whether Kolodny's efforts are an honest, but misguided, attempt to help, or something else.

But I can read his writings, and based on "The opioid epidemic in 6 charts," recently published *(https://theconversation.com/the-opioid-epidemic-in-6-charts-81601)* in *The Conversation,* honesty is not the word that first pops into my mind. Yes, Dr. Kolodny does present 6 charts to explain his version of what I will now call "The Fentanyl Crisis," (2) but even a quick read of his editorial reveals that it appears to be designed to confuse rather than clarify matters. Let's take a look.

Trick #1: Manipulative and misleading statistics.

"Drug overdose deaths, once rare, are now the leading cause of accidental death in the United States, surpassing peak annual deaths caused by motor vehicle accidents, guns and HIV infection."

This sentence, the very first of the editorial, doesn't pass the sniff test. Why?

- The term "drug overdose deaths" (there are about 60,000 annually) is now standard jargon used to characterize fatalities from *all drugs* of all sorts, anticoagulants, antidepressants, aspirin, cocaine, etc. But most people will read what Kolodny wrote and arrive at the conclusion that 60,000 people were killed

[1] *(https://www.phoenixhouse.org/news-and-views/news-and-events/phoenix-house-appoints-dr-andrew-kolodny-as-chief-medical-officer/).*

by prescription pain medications. *They were not.* All opioids *together* (including heroin) killed 30,000 people. The number of deaths from prescription opioids—the target of the current crusade—was about 17,000—half the number killed by accidental falls *(https://www.cdc.gov/nchs/fastats/accidental-injury.htm).* Are we having an "accidental fall epidemic?" Why not? Accidental falls are killing twice as many people as prescription pain medicines.

- The figure 60,000 is, of course, inaccurate, but so is 17,000. This is because opioid overdose deaths are frequently the result of *combination with other drugs,* especially benzodiazepines, which potentiate the effect of the opioid action. In 2015 *almost half* (7,500) of the overdose deaths from opioids also involved benzodiazepines (Figure 1). When you include other drugs that are taken with opioids, especially alcohol and cocaine, it can reasonably be assumed that the number of deaths from opioid pills *alone* will be much lower, perhaps in the neighborhood of 5,000—10 times lower than the 60,000 that Kolodny implies, and roughly the same as bicycle and bicycle-related deaths *(http://www.pedbikeinfo.org/data/factsheet_crash.cfm). This* is what the hysteria is about?

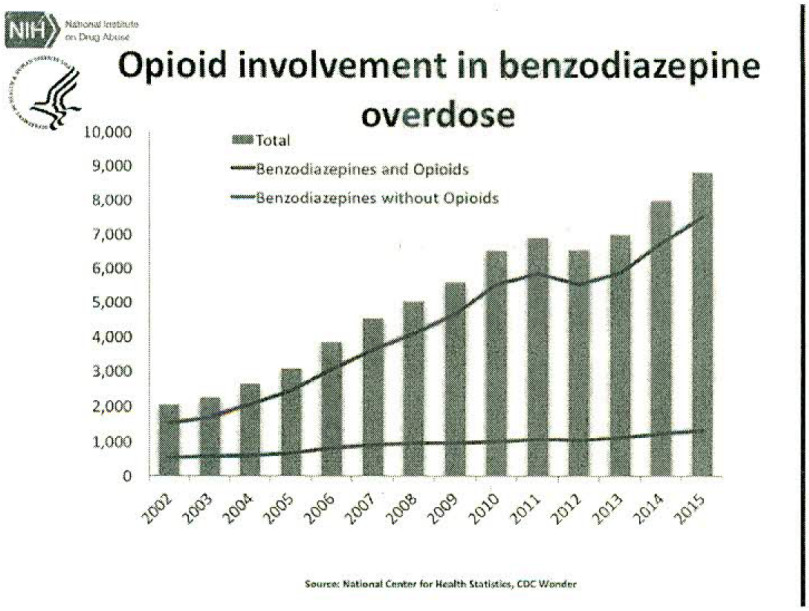

Figure 1. Opioid involvement in benzodiazepine death, and also benzodiazepine involvement in opioid deaths.

- Comparing the number of drug overdose and motor vehicle deaths is pointless, arbitrary, and manipulative. What's more, these unrelated numbers can be interpreted in either of two ways. Annual deaths from auto accidents peaked in 1972—before seatbelt laws were in effect—and decreased by 41% as of 2011. What was responsible for the switch? Was it rising drug ODs? Decreasing auto accidents? Both? Does it matter? No, it doesn't. It's a stupid comparison.
- A comparison to deaths from HIV is similarly meaningless. HIV deaths have declined because of antiretroviral drugs.

This same sentence could be rewritten to be just as accurate, but send an entirely different, albeit, still pointless message:

"Life in the United States is now significantly safer. The number of annual deaths from automobile accidents, AIDS, and guns is now lower than that from drug overdoses, even when illegal street drugs, such as heroin, are included."

Trick #2: Telling a half-truth.

"The effects of hydrocodone and oxycodone on the brain are indistinguishable from the effects produced by heroin."

Yes, they are. But Kolodny omits a vital bit of information—potency. While the physiological *effect* of hydrocodone on the brain may be the same as heroin (the two drugs hit the same receptors), the functional difference between the two drugs is night and day. The *magnitude* of the effect is conveniently omitted from this "equation." Heroin packs a much more powerful punch than hydrocodone, especially at doses that are used by addicts. People can become addicted to heroin (or even die) from a single injection. It is virtually impossible for one hydrocodone pill to kill or addict anyone. The two drugs don't even belong in the same sentence, even though they happen to belong to the same class of drugs.

Trick #3: The absence of evidence is not the evidence of absence.

"In cases [of long-term use], opioids are more likely to harm patients than help them because the risks of long-term use, such as addiction, outweigh potential benefit. Opioids have not been proven effective for daily, long-term use."

- Trick #3 actually consists of a trick and maybe even a lie. Opioids may not have been proven to be effective for long-term use, but this is because such studies have not been done. This does **not** mean that opioids have been proven ineffective, even though the wording of this sentence implies this.
- The "lie" about addiction potential of opiates is perfectly obvious to anyone who has read the literature on addiction. The risk of addiction is very low for pain patients (less than 1% *(https://www.ncbi.nlm.nih.gov/pubmed/20091598)*) who take pain medicine to control their pain. Overwhelmingly, addiction arises from recreational, not therapeutic use of these drugs.

Trick #4: Blame the drug companies.

"The increase in opioid prescription was fueled by a multifaceted campaign underwritten by pharmaceutical companies. Doctors heard from their professional societies, their hospitals and even from state medical boards that patients were suffering needlessly because of an overblown fear of addiction."

- This tactic is appallingly unoriginal. There is no better way to shore up a weak argument than to introduce an "enemy." And if there is one failsafe enemy, it is the pharmaceutical industry. There is little doubt that there was malfeasance taking place, especially involving companies that were pushing the idea that certain drugs were safer than they really were. Purdue, the maker of OxyContin, was fined $653 million for its former actions. Other companies are now being investigated. *But this is now irrelevant.* Assigning blame may score some points with the readers, and provide fodder for trial attorneys, but does absolutely nothing to keep a single OD victim alive. Whatever certain companies did two decades ago is partly responsible for starting today's fentanyl OD epidemic, but it has *nothing* whatsoever to do with keeping it going.

Trick #5: Twist the truth.

"Why did this happen? A common misconception is that so-called 'drug abusers' suddenly switched from prescription opioids to heroin due to a federal government 'crackdown' on painkillers. There is a kernel of truth in this narrative."

Yes, there is, barely. But it is only a small part of the story. What Kolodny cites as a common misconception is probably a result of his twisting what I have written in previous articles (*see:* "No, Vicodin Is Not the Real Killer in the Opioid Crisis" *(https://www.acsh.org/news/2017/04/12/no-vicodin-not-real-killer-opioid-crisis-11123)* and "Heads in the Sand—The Real Cause of Today's Opioid Deaths" *(https://www.acsh.org/news/2017/08/16/heads-sand-%E2%80%94-real-cause-todays-opioid-deaths-11681)*). Except I never said this. The reasons for opioid abuse are multifactorial, but there is *no question* that epidemic began to escalate in 2010, not from any crackdown, but from an improvement in the formulation of abuse-resistant OxyContin and the unintended consequences that followed. This is indisputable.

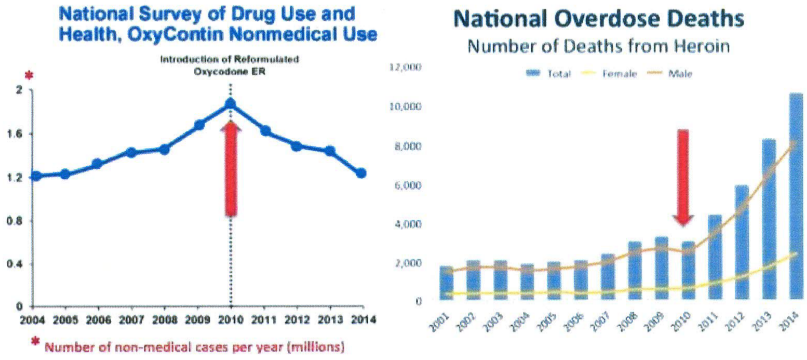

Figure 2.

From this point on, there was a "shortage" of pills, both because of market forces and government intervention. The difficulty in getting pills was clearly responsible for some/most of the switch to heroin. Koldony's statement itself was a "kernel of truth." And a rather small kernel at that.

Now let's look at what is *really* going on. Figure 3 makes this crystal clear. Despite 7 years of increasing "vigilance," the number of deaths caused by prescription pain medications remains *unchanged,* yet total opioid overdose deaths have increased dramatically. The reason is obvious. **Virtually all** of the additional overdose deaths since can be accounted for by increased use of heroin/fentanyl. Prescription pain medicines are much more difficult to get than 7 years ago, and the only result has been suffering by pain patients and no benefit. It could be no other way. Pills are not the primary driver of overdose deaths. *They never were.*

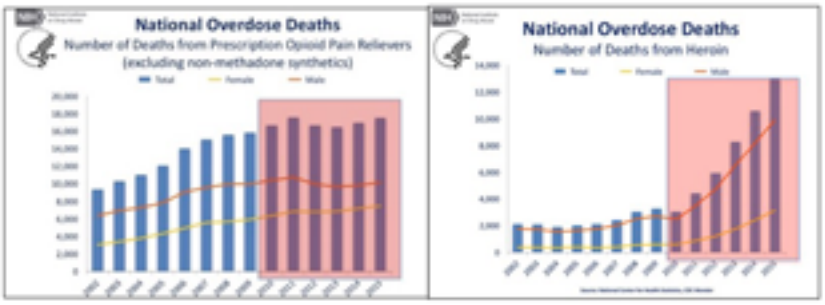

Figure 3. The futility of limiting prescription pain medication.
The result was more deaths from heroin/fentanyl and nothing else.

Trick #6: Ignore what doctors are saying.

"Here's another reason not to believe the narrative about a 'crackdown' on painkillers leading to a sudden shift to heroin: There hasn't been a crackdown on prescription opioids."

To say that there hasn't been a crackdown on opioid prescriptions is to ignore reality. Pharmacy chains are imposing bureaucratic barriers on filling prescriptions and denying prescription refills. The U.S. Association of Attorneys General is lobbying U.S. insurance *(https://ag.ny.gov/sites/default/files/final—naag—opioid—letter—to—ahip.pdf)* providers to revise their formularies to emphasize non-opioid medications in preference to opioids. The Veterans Administration has been directed by Congress to make the CDC prescription guidelines mandatory *(http://www.usmedicine.com/clinical-topics/addiction/cdc-guidelines-could-cause-problems-for-va-patients-clinicians/)* rather than voluntary. Hospitals and pain management practices all across America are discharging patients and forcibly tapering down the

dose levels *(http://www.statnews.com/2017/01/17/chronic-pain-management-opioids/)* of those they retain.

And Kolodny's statement also contradicts what *every single physician* I have spoken with has said (*see:* "Pain in the Time of Opioid Denial: An Interview With Arie Hausknecht, M.D." *(https://www.acsh.org/news/2017/07/30/pain-time-opioid-denial-interview-aric-hausknecht-md-11628)*). I'm not sure what Kolodny means by "crackdown," but when doctors are receiving "friendly" warning letters from departments of health and law enforcement agencies, that's not merely a crackdown. It's Kristallnacht.

In closing, although I have questioned whether the intentions of Kolodny and his acolytes are well-meaning or not, it really doesn't matter to the 6 million people who are cut off from pain treatment in this country. The resulting "opioid pain refugee crisis" is a national disgrace. As is the undue influence granted to a handful of ideologues, well intended or not. As public policy goes, this may be as cruel as it gets.

Notes

(1) The term "opioids" is scientifically meaningless. Technically, "opioid" means a drug that interacts with the same receptors as morphine etc., regardless of whether the drug is derived from a natural source, for example, poppy. Opiates are a subset of opioids; they are drugs that are found in plants (*e.g.,* codeine) or semi-synthetic derivatives of them. Heroin, which does not occur naturally, is considered to be an opiate because it is made from morphine, which does. Fentanyl is considered to be an "opioid" because it is not an opium derivative. These classifications are a distinction without a difference. The term "opiates" is more than sufficient to describe drugs with morphine-like properties. The word "opioid" should be dropped from the English language.

(2) There is no such thing as an opioid crisis. It is a fabricated term. People who are now dying from overdoses are now (most of the time) dying from fentanyl and its chemical cousins. A far better and more accurate term is "the fentanyl crisis."

LETTER SUBMITTED BY CHERRI O'KEEFE

May 2, 2018

U.S. Senate
Committee on Finance
Dirksen Senate Office Bldg.
Washington, DC 20510–6200

Re: "Tackling Opioid and Substance Use Disorders in Medicare, Medicaid, and Human Services Programs," Thursday, April 19, 2018

I am a 54-year-old wife, mother, grandmother, daughter and sister. I am also and have been for many years sadly a chronic pain patient. I have had 36 surgical procedures starting at the age of 16—four of my procedures have been to my brain due to a brain aneurysm. I suffer daily from severe osteoporosis, degenerative bone disease, osteoarthritis and numerous fractured disks in my back, seizure disorder and anxiety disorder. I have titanium in my brain, back and abdomen. The laws that have been changed allowing us to be treated with opioid medications have caused irreparable damage not just to us patients but to those who love us, care for us and pray for us. They now say it is an epidemic. For us patients who have worked so hard, have done everything asked of us, have subjected ourselves to at times feel like criminals by the way we are now treated, these laws are cruel and unusual punishment.

I sit and wonder how stupid the government must think we all are—most of us have worked jobs, paid taxes, raised children, been foster parents and law-abiding citizens. If we were just drug addicts, we would do what those with addictions do. We would just walk to any street corner and buy that crap—that is the real epidemic in this country—but we don't. We pay for insurance, we pay co-payments, we are subjected to signing contracts, UAs, pill counts, have one doctor, use one pharmacy and the list goes on. I have never met a chronic pain patient who enjoys their life. We need to take pain medicine on a daily basis so that we can just have a small amount of dignity, independence and the edge taken off the pain that never stops. We miss family functions, we miss our grandchildren's events—we miss our lives. We don't live, we just exist.

I have seen and dealt with cancer front and center. As a matter of fact, my first brain aneurysm was just 7 weeks after my mother died in my arms from breast cancer. I had taken care of her and we had made it 5 years. We were supposed to be in Hawaii celebrating but instead we were in a hospital for 11 days as she slipped away. It is a horrible disease, but it is not the only disease that can cause so much pain that we need to be medicated properly. The answer now is for us to just smoke pot. What happened to being an American with the Constitution and our rights? Since the CDC implemented their guidelines, chronic pain patients are bed ridden again, they are back in their wheelchairs, they've lost the hope we so desperately held onto, and many have chosen suicide. I have lots of pictures of my children and my grandchildren and my husband, but you know what's missing? Me! That breaks my heart and theirs.

If monitored prescribing of opioid medications to chronic pain patients was this epidemic then how do you explain the rise in ODs—30% rise since the policies were changed? Who is standing up for us who cannot stand for ourselves? What if it were any of you who had to live like we do or watch someone you love crying as they toss and turn in bed because of the pain. I hope with everything in my being that the government really stops, puts themselves in our shoes for just one moment—which by the way, I would not wish on my worst enemy—and see what they are doing and how wrong it is?

We have done PT, TENS units, needles to try to block the pain, acupuncture, meditation. Please give us back our lives. Let us live, not just exist—even if it's just showing up for a brief period for our children, or our grandchildren's milestones and for us. That is our life and we accept it, but we continue daily to try to do better than we did the day before. We are trying to live not die!

Sincerely,

Cherri O'Keefe
Washington Pain Advocacy Group, C–50

LETTER SUBMITTED BY ELIZABETH POLSON

April 20, 2018

U.S. Senate
Committee on Finance
Dirksen Senate Office Bldg.
Washington, DC 20510–6200

After watching the Senate full committee hearing on April 19th ("Tackling Opioid and Substance Use Disorders in Medicare, Medicaid, and Human Services Programs") I felt the need to write and share my opinion on this topic. There are two types of patients in this issue: acute, temporary pain and chronic pain. The hearing and most of what I have heard in the news addressed the former. I am afflicted with the latter, chronic pain. I feel the patients suffering from chronic pain have not been heard and their needs are not being considered in the changes being made.

After a year of suffering with unexplained and widespread pain, and not knowing why, I was diagnosed with fibromyalgia in late 1996 at age 41. Unless a cure is found, I will live with this condition the remainder of my life. Fibromyalgia is a disorder characterized by widespread musculoskeletal pain accompanied by fatigue, sleep, memory, and mood issues. Researchers believe that fibromyalgia amplifies painful sensations by affecting the way your brain processes pain signals. Over the counter drugs like aspirin, ibuprofen, and acetaminophen do absolutely nothing to ease my pain.

The horrible pain and fatigue disrupted my daily life to a large degree and made working full time extremely difficult. My daughter had left for college and I was living alone and I found it almost impossible to complete daily chores, shop for groceries, etc. I was extremely lucky to have a supportive manager that allowed me to work from home for 2 years, otherwise I would not have been able to work and support myself. My life consisted of work and very little else. I was in too much pain to enjoy anything. In late 1998 I was prescribed an opioid for the pain, Tramadol, 50 mg once a day. It was a miracle for me and allowed me to function much better. The pain was not erased but was improved enough to give me a better quality of life and allowed me to continue to work until my retirement 2 years ago.

Shortly after, I went through specialized testing with a fibromyalgia specialist physician at Seattle's Harborview Medical Center. They had me try acupuncture, massage and homeopathy. The homeopathy did help to a degree but the other methods had *no* effect. Years later I discussed the new medications for fibromyalgia with my physician and was told my current treatment of Tramadol was probably best—the new drugs had too many side effects.

I would like to stress that in 20 years I have only seen three doctors for this condition. One was the specialist and the other two my regular physicians. My starting dose in 1998 remains the dose I still use today. I have never increased it over the years, I am not physically addicted, and I use the medication responsibly and under the constant care of my physician. I could easily stop using it tomorrow, but unfortunately I would be in constant pain.

When the mandates to reduce over-prescribing of opioids were put in place the last several years I cooperated with my physician. I discussed a Controlled Substance Agreement and we both signed it. I also agreed to a drug screen during my visit (with no prior notice). Nothing but my Tramadol was found and that was within the range of my current dose.

I am now 63 years old, retired, and terrified that the government will decide that I should no longer have the treatment that has worked so well for me for 20 years. I can live a relatively normal life with some joy and peace and even travel—my lifelong retirement dream.

Please consider the plight of people like myself when mandating the changes currently in work. I completely understand the crisis our nation is facing and know things need to be done, but not at the expense of my needs. Please let the doctors decide what is best for their patients. If it is found later that they misused that trust, then take away their license to practice medicine, don't inflict more pain and suffering on me because of their errors.

Opioid manufacturers most certainly should be held accountable for their efforts to get physicians to over-prescribe, providing incentives to prescribe, etc. They are one large piece of the cause of our current epidemic and I am all for suing them. It is reprehensible what they have done.

The pendulum is swinging from the extreme of over-prescribing opioids to the other on this issue. In my lifetime I've seen this phenomenon occur many times and in the end it typically swings back to middle ground eventually, the best answer. Neither extreme ends up being a good choice. Please take my needs and the needs of so many others in similar situations into consideration.

Sincerely,

Elizabeth Polson

LETTER SUBMITTED BY AMANDA SMITH

U.S. Senate
Committee on Finance
Dirksen Senate Office Building
Washington, DC 20510–6200

Re: "Tackling Opioid and Substance Use Disorders in Medicare, Medicaid, and Human Service Programs," Thursday, April 19, 2018

To whom it may concern,

My name is Amanda Smith and I am the daughter of Kristi Becker. I am 25 years old and cannot remember a time when my mother DID NOT experience back pain. Her medications would keep it under control so she could live a somewhat normal life. Over the past few years her pain has increased to where sitting for any length of time causes her back to stiffen and cramp up.

She has been told that the medications she needs to control her pain are not going to be covered by her insurance any longer and she will have to pay out of pocket. She is unable to pay for her medications without the help of her insurance; without these medications her pain would become so severe and she will not have any kind of quality of life.

These medications are required so that her pain is under control.

Her back pain has affected our relationship a lot. We couldn't do a lot as a mother and daughter can normally do. Now I barely speak to her and never see her because of her pain.

Please, I'm asking to not cut production of these medications or cut funding away from these people in pain. As a daughter I should not be able to hear my mother in pain.

My mother is a very strong woman but I can hear the pain in her voice and it pains me to hear her like that.

Sincerely,

Amanda Smith

LETTER SUBMITTED BY REESE TYRELL
Member, Texas Pain Advocacy Group, C–50

U.S. Senate
Committee on Finance
Dirksen Senate Office Building
Washington, DC 20510–6200

Re: "Tackling Opioid and Substance Use Disorders in Medicare, Medicaid, and Human Services Programs"

I am writing to ask that chronic intractable pain conditions be exempted from CDC guidelines and Medicare/Medicaid policy on pain medication.

Background: I have an incurable autoimmune disease (IC/BPS) that causes lifelong, unrelenting cancer-level pain. Essentially, my body has its own tiny built-in torture device, punching holes in my flesh from the inside and dripping water on the razor wounds, 24/7.

For 20 years I have visited doctor after doctor, trying every known treatment from diet to meditation to electrical stimulation to pouring medicine into my own bladder through a catheter. I am a medical mystery, one of the 5% for whom no known treatments made any difference, including the alternative/experimental ones.

Science does not yet know how to remove my torture device. While research continues over the 40+ years I have left to live, treatment allowing me to work and contribute to society is my human right. That human right is being threatened.

My condition has been well controlled on pain medication for 20 years. Combined with other coping techniques, pain medication has allowed me to earn a doctorate, become an expert in my field, teach college, and raise a healthy, happy son with my loving husband.

Thanks to pain management, if you met me, the only difference you'd notice between me and a normal person is I pee once an hour. As a legitimate patient, I adhere to a narcotics contract and have never treated medication irresponsibly or taken more than prescribed. To keep my home and family safe, I do not publish medical information under my real name, but I do have 20 years of impeccable records in the state prescription database(s).

The medication I have thrived on for 20 years is suddenly not okay, because . . . why exactly? Because other people—people who are not me—fraudulently prescribed, abused, and overdosed on a similar substance?

I'm being told I have to cut back because the DEA and the state medical board are enforcing CDC guidelines. CDC guidelines do not say legacy patients have to cut back, they say "lowest effective dose."

There is a direct relationship between my medication and how long I can wait between bathroom visits. At or below the levels the CDC recommends, I have to pee every 10–15 minutes, around the clock. I know this for a fact.

That is not an "effective" dose. There are jobs that let you pee once an hour. There are no jobs that let you pee every 10 minutes. Not to mention, ever tried sleeping in 10-minute increments?

And . . . only legacy patients? If someone exactly like me was born in the 1990s instead of the 1970s, she just has to suffer? While the government has a responsibility to prevent diversion of drugs into the wrong hands, the government has no

business telling doctors what dosages to prescribe. Threats of DEA action have spread far beyond the agency mandate, affecting patients who need medication to work, parent, and live our lives. Americans with lifelong, incurable painful disorders need two things from our legislators:

(1) Within Medicare/Medicaid policy, please carve out an exemption to opioid prescribing guidelines for patients with intractable chronic pain conditions (such as IC/BPS, among others). This exception should be similar to the current exception for cancer pain. Treating cancer and non-cancer pain differently amounts to federal discrimination against people with disabilities.

(2) Please clarify to the DEA, CDC, and state medical boards that nonconsensual dosage reduction is not required. Finally, please help us in the chronic pain community educate the public on how unwarranted federal regulation damages the practice of much-needed medicine.

Thank you for your time.

Reese Tyrell
Austin, TX

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