RPTR RULL

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WHAT IS THE FEDERAL GOVERNMENT DOING TO COMBAT THE OPIOID ABUSE EPIDEMIC?

FRIDAY, MAY 1, 2015

House of Representatives,

Subcommittee on Oversight

and Investigations,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 9:02 a.m., in Room 2322, Rayburn House Office Building, Hon. Tim Murphy [chairman of the subcommittee] presiding.

Present: Representatives Murphy, McKinley, Burgess, Griffith, Bucshon, Flores, Brooks, Mullin, Collins, Upton (ex officio), DeGette, Schakowsky, Tonko, Clarke, Kennedy, Green, and Pallone (ex officio).

Staff Present: Noelle Clemente, Press Secretary; Jessica

Donlon, Counsel, O&I; Brittany Havens, Oversight Associate, O&I; Charles Ingebretson, Chief Counsel, O&I; Alan Slobodin, Deputy Chief Counsel, Oversight; Sam Spector, Counsel, Oversight; Chris Knauer, Minority Oversight Staff Director; and Una Lee, Minority Chief Oversight Counsel.

Mr. Murphy. Well, good morning. Welcome here to the Oversight and Investigation Subcommittee hearing.

I just want to say it's mental health month, so it's fitting that we are here today on this issue. This is a third in a series of hearings examining the growing problem of prescription drugs and heroin addiction that is ravaging our country. This is our Nation's single biggest public health concern.

Over the past 5 weeks, this subcommittee has heard from addiction experts working with local communities and our leading and academic and research centers. Dr. Robert DuPont, the former White House Chief of Drug Control Policy and the first director of the National Institute on Drug Abuse, testified that Federal programs lack direction and standards on treating addiction as a chronic condition, and noted what is being done to follow up with patients to prevent relapses and put them on a path of real recovery? He challenged us to even ask the most fundamental question, "What is recovery?"

Dr. Anna Lembke of Stanford Medical School provided critical testimony on how we must revise our healthcare quality measures to reduce overprescribing, reform medical privacy regulations, and incentivize the use of prescription drug monitoring programs.

We know that those with opiate addiction disorders need a broad range of treatment options that may -- and that many with substance abuse disorders have co-occurring psychiatric disorders, but we need

to tear down Federal policy and funding barriers that keep us from treating both simultaneously.

About 3 weeks ago, one of today's witnesses, Mr. Michael Botticelli, the director of the Office of National Drug Policy, presented a slide -- I'm going to show it here -- at the national RX summit on major causes of death from injury from 1999 to 2013. Quite a revealing slide. While the trends of other major causes of death, such as auto accidents went down, drug poisoning continued to go up 21 percent from 2008 till 2013. In many States, these numbers are soaring at high double-digit rate increases. As Mr. Botticelli has indicated to me privately and at the RX summit, we must do better, and we have much work to do.

Today, we will hear from Federal agencies charged with providing guidance, direction, and leadership in our Nation's public health response to the opiate epidemic. No Federal agency is more central in this ongoing epidemic than the Department of Health and Human Services or HHS. HHS and its substance abuse and mental health service administration, also known as SAMHSA, are responsible for leading our Nation's public health response to the opiate heroin abuse and addiction crisis.

SAMHSA regulates our country's 1,300 opiate treatment programs, and SAMHSA is responsible for certifying the 26,000 physicians who prescribe the most commonly-used opiate maintenance medication,

buprenorphine. According to testimony provided by SAMHSA before this subcommittee in April of last year, there were nearly 1.5 million people treated with these opiate maintenance medications in 2012, which is a fivefold increase in the last 10 years.

Has SAMHSA defined the goal of recovery for what these federally subsidized treatment programs are supposed to accomplish? Is SAMHSA collecting and evaluating meaningful data at an individualized level that would hold grant recipients individually accountable for effective results? So far, preliminary examination indicates the answers are no. And when you don't define where you're going, every road you take still leaves you lost. So we're hoping we can get some direction today.

The numbers indicate we are failing as a Nation, and we darn well better come to terms with that. The 43,000 lives lost last year, the thousands of babies born addicted to opiates tell us the terrible toll this epidemic has taken. You've heard my thoughts about the government-sponsored promotion of what I've characterized as addiction maintenance, and I refer to buprenorphine as heroin helper, not because the medication is altogether lacking, because it is helpful, but rather, because infrastructure the Federal Government has created for the use of this highly potent and important medication is not fully working and, worse yet, in many cases, contributing to the growing problem. This has to be fixed, and I hope we'll find some solutions,

and that is what we need to discuss today openly, honestly and humbly.

If we do not reverse the current trend, where is this going to end? How many millions of citizens do we want to have on opiate maintenance? How many more must die? And how many more lives and dreams must be shattered before we recognize the depth of this national scourge?

Now, I don't believe in better living through dependency. And, again, please do not misconstrue this critique as a general indictment of opiate maintenance. It is not. For some people, opiate maintenance is the most appropriate bridge treatment, and there should be no shame or sigma associated with it. But opiate maintenance therapy should not be the only treatment offered to the opiate-dependent individuals, and it is not the only goal.

What patients on opiate maintenance can be successfully transition off of these medications? What protocols are best for affecting this transition? What are the best practice for prevention of relapse for those patients who end opiate maintenance treatment? There are nonaddictive medications approved for this use, but are these medications widely available and how well do they work?

The diversion of buprenorphine for elicit nonmedical use is a related problem because this is how the opiate epidemic can be spread. According to the DEA, buprenorphine is the third most often seized prescription opiate by law enforcement today. Where is a call to

modernize our existing opiate addiction treatment system to ensure that the right patient gets the right treatment at the right time? Why aren't we hearing about expanding access to nonaddictive narcotic treatments that have zero potential for abuse or diversion, such as Naltrexone and evidence-based counseling? These are all incredibly important tools, and we want to make sure HHS talks more about these.

Last week, Dr. Westley Clark, the former Director of SAMHSA Center for Substance Abuse treatment and the man who oversaw the growth of buprenorphine over the past decade declared before the American Society of Addiction Medicine that many buprenorphine practices have become pill mills where doctors and dealers were increasingly indistinguishable and physician negligence and alleged laboratory fraud prevailed. The problem is not with buprenorphine, however. The problem lies with current practices, and this is what we need to discuss.

I consider opiate maintenance as a bridge for those with addiction disorders to cross over in the recovery process. And as I said, it is not a final destination. We seek to lay out a vision for recovery that includes complete withdrawal from opiates as an option. For cancer, for diabetes, for AIDS, we want people to be free of the diseases, not just learn to live with it. We need to commit the same sorts of things through our research and clinical efforts that boldly declare what we must change here.

I thank our witnesses for being here today. And I now recognize the ranking member of the committee, Ms. DeGette, from Colorado for 5 minutes.

Ms. DeGette. Thank you so much, Mr. Chairman.

I think it's really important to hear from our witnesses today about the work the Federal Government is doing to address this serious public health issue, and I know all of the agencies represented before us do critical work to prevent and treat this epidemic.

In March, Secretary Burwell announced an initiative to combat the opioid crisis. I applaud the Department's actions, and I'm gratified to hear that this is one of the Secretary's top priorities. I want to hear more about this initiative today and how all the agencies before us are working together to accomplish its goals. But at the same time, I have some hard questions about our approach to caring for those who have substance abuse disorders.

Last week, we heard from a panel of medical experts who have vast experience in treating opioid addiction. Unfortunately, as the chairman said, they gave us a fairly bleak view of the opioid treatment landscape in this country. For example, one witness, Dr. Adam Bisaga, a psychiatrist at Columbia University and a research scientist at the New York State Psychiatric Institute, told the committee that the majority of patients being treated for opioid addiction received treatment that is both, "outdated" and "mostly ineffective." He

described this approach of rapid detoxification, followed by an absence-only method without the use of important treatment medications. Dr. Bisaga added that this is potentially dangerous because it raises the risk of an overdose if a patient relapses.

As troubling as this testimony from our last hearing was, today we have Dr. Volkow on our panel, who is one of the world's top experts on addiction research. And she notes -- I'm sure you'll talk more about this, Doctor -- in her written that, "Existing evidence-based prevention and treatment strategies are highly underutilized across the United States."

Why is that, Mr. Chairman? Why do we have experts week after week telling us that the bulk of the treatment Americans are receiving for this devastating disease are ineffective, outdated, and not evidence based.

We need to be asking ourselves some tough questions. For example, Dr. Westreich, the president of the American Academy of Addiction Psychiatry, told us last week, "Patients and their families need to know that detoxification treatment and drug-free counseling are associated with a very high risk of relapse." Are patients enrolling in treatment getting sufficient data so they can make medically informed choices? Are families and loved ones being told what approaches have high failure rates before choosing an approach to treatment? Frankly, this is not a decision that should be taken

lightly. Getting ineffective treatment may not only be financially costly, but it may result in a fatal relapse.

Finally, Mr. Chairman, recent testimony, including some I saw in the written statements for today, raises important questions about whether taxpayer dollars should fund certain approaches for combating this opioid epidemic over others. This is an issue I've been talking about week after week. We all agree that we need the most effective treatment, and our experts agree that this treatment needs to be a broad menu of options that is different from patient to patient.

So we might not have a silver bullet to cure opioid addiction at this point, but we do know what treatments work better than others. Evidence tells us -- and all the medical experts we heard from last week agree -- that for most patients a combination of medication-assisted treatment and behavioral treatment, such as counseling and other supportive services, is the most effective way to treat opioid addiction. If that's the case, we should pursue more policies that encourage this approach as a clear option and steer away from any efforts that are not evidence based. It's costly, and it's dangerous to the patient.

So I hope we can all work together to fight this epidemic, and I do look forward to hearing from all of our witnesses. I'm glad Secretary Burwell and the department are devoting serious attention to addressing both the prevention and treatment sides of this problem.

And, Mr. Chairman, this has been a really great series. I'm happy to have a whole investigation like this in this committee. There's one group that we haven't heard from yet, I'm hoping --

Mr. Murphy. States.

Ms. DeGette. Good. The States. We haven't heard from the States yet. It's critical we hear from them because that's where the rubber is hitting the road. We need to hear what the States are doing to address this problem and understand the reasoning between -- behind some of the choices being made. Some choices -- some States are picking effective treatment methods and others are not.

So I think we need a multifaceted approach that this is what -- this is what our research has showed, and I know we can work together to continue this important investigation.

I just want to add one more note. The witnesses and the audience may see members jumping in and running out. We have another hearing in Energy & Commerce Committee going on down on the first floor, so people will be coming and going. But I know certainly, from my side of the aisle, people recognize this is a very serious issue. Thank you.

Mr. Murphy. Thank you. And I know that they'll be calling votes at 9:30 for first vote series.

Ms. DeGette. I thought it was at 11:00

Mr. Murphy. Something has changed. First and only vote series

of the day. I'm here for the duration, so we want to hear from you and hopefully the members.

And now we recognize Mr. Upton.

Mr. Upton. We really are going to have votes at 9:30?

Mr. Murphy. That's what it says now.

The Chairman. Well, I'm going to -- I'm going to submit my statement for the record then.

Mr. Murphy. Okay. All right.

The Chairman. Yield back.

Mr. Murphy. All right.

Mr. Pallone, 5 minutes.

Mr. Pallone. I'll do the same, Mr. Chairman, because we both have to go to the other hearing.

Mr. Murphy. Okay.

The Chairman. It's his bill. It's his bill we're talking about.

Mr. Murphy. See how much we get along.

Is there anybody else on either side that needs recognition? Go right into this.

Okay. Let me find my --

Ms. DeGette. No. Wait, wait. Mr. Kennedy.

Mr. Pallone. Oh, he wanted a minute. Can I -- Mr. Chairman, can I yield just 1 minute to Mr. Kennedy?

Mr. Murphy. Yes. You can yield your minutes to Mr. Kennedy of

Massachusetts.

Mr. Kennedy. Thank you very much for the consideration. I yield back.

Mr. Murphy. Okay. All right. Let me now introduce the witnesses on the panel for today's hearings. We have the Honorable Michael Botticelli, the director of the Office of National Drug Policy, which is part of the Executive Office of the President. Welcome here. Dr. Richard Frank, the Assistant Secretary For Planning and Evaluation at the U.S. Department of Health and Human Services; Dr. Nora Volkow, who is the director of the National Institute on Drug Abuse with the National Institutes of Health; Dr. Douglas Throckmorton who is the Deputy Director of the Center for Drug Evaluation and Research of the Food and Drug Administration. Dr. Debra Houry --

Dr. Houry. Houry.

Mr. Murphy. Houry, the director of the National Center For Injury and Prevention and Control of the Centers for Disease Control and Prevention; the Honorable Pamela Hyde, the Administrator for Substance Abuse and Mental Health Services Administration; and Dr. Patrick Conway, the Deputy Administrator For Innovation and Quality and the CMS chief medical officer at the Centers for Medicare and Medicaid Services. Welcome.

So you are aware that now swearing the witness that the committee is holding an investigative hearing and, when doing so, has a practice

of taking testimony under oath. Do you have any objection to testifying under oath?

None of the witnesses have objection. So the chair then advise you that under the rules of the House and the rules of the committee, you are entitled to be advised by counsel. Do any of you desire to be advised by counsel today? And none of the witnesses say so.

So, in that case, please rise. Raise your right hand. I'll swear you in.

Do you swear that the testimony you're about to give is the truth, the whole truth, and nothing but the truth?

Thank you. All the witnesses answered in the affirmative, so you are now under oath and subject to the penalties set forth in title 18, section 1001 format of the United States Code.

You may now each give a 5-minute opening statement. Please stick to the 5 minutes. If you don't have to fill it, that's okay, too. We'd like to get through.

STATEMENTS OF HON. MICHAEL BOTTICELLI, DIRECTOR OFFICE OF NATIONAL DRUG CONTROL POLICY; RICHARD FRANK, PH.D., ASSISTANT SECRETARY FOR PLANNING AND EVALUATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES; NORA VOLKOW, M.D., DIRECTOR, NATIONAL INSTITUTE OF DRUG ABUSE, NATIONAL INSTITUTE OF HEALTH; DOUGLAS THROCKMORTON, M.D., DEPUTY DIRECTOR, CENTER FOR DRUG EVALUATION AND RESEARCH, U.S. FOOD AND DRUG ADMINISTRATION; DEBRA

HOURY, M.D., M.P.H., DIRECTOR OF THE NATIONAL CENTER FOR INJURY PREVENTION AND CONTROL, CENTERS FOR DISEASE CONTROL AND PREVENTION; HON. PAMELA HYDE, J.D., ADMINISTRATOR, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION; AND PATRICK CONWAY, M.D., M.SC., DEPUTY ADMINISTRATOR FOR INNOVATION AND QUALITY & CMS CHIEF MEDICAL OFFICER, CENTERS FOR MEDICARE AND MEDICAID SERVICES.

STATEMENT OF HON. MICHAEL BOTTICELLI

Mr. Murphy. Mr. Botticelli.

Mr. Botticelli. Thank you, Chairman Murphy, Ranking Member DeGette, and members of the subcommittee for the opportunity to provide testimony to you today about the administration's efforts to address the opioid epidemic in the United States.

Mr. Chairman, as you recognized, in 2013 almost 44,000 Americans died of a drug overdose. That's one drug overdose death every 12 minutes. Using ONDCP's role as the coordinator of the Federal drug control agencies, in 2011, we published the administration's prescription drug abuse prevention plan to address the sharp rise in prescription opioid drug abuse in this country since 1999. As you know, the plan consists of action items categorized under four pillars: Education of patients and prescribers; increased prescription drug monitoring; proper medication disposal; and informed law enforcement.

With the work of our HHS partners here today, and other Federal partners as part of the interagency prescription drug workgroup convened by ONDCP, we have made some strides in each of these areas, but there is much more to be done.

Since time and graduate medical education programs devoted to the identification of treatment of substance abuse disorders is rare, we have worked with our Federal partners to develop continuing education programs about substance abuse, managing pain appropriately, and treating patients using opioids more safely. Many prescribers in Federal agencies, including HHS, are receiving this important training. Despite this, a large percentage of prescribers have not availed themselves of this training. Therefore, the administration continues to press for mandatory prescriber education, tied to controlled substance licensure. I am pleased that Secretary Burwell has expressed her support for working with Congress to set requirements for specific training for opioid prescribers.

Today, all States -- all States but one, Missouri, have prescription drug monitoring programs that allow prescribers to check on drug interactions as well as alert them to the signs of dependence on opioids. Missouri is also working to authorize a PDMP program. With almost all States implementing PDMPs, we are focusing on improving State-to-State data sharing, and improving access to PDMP data within the health record systems providers use every day.

In October, the Drug Enforcement Administration's final regulation on controlled substances disposal became effective. ONDCP and our Federal partners and stakeholders have begun to inform the public about these regulations and look to ways to stimulate more local disposal programs in partnerships with pharmacies, local government, community groups, and local law enforcement. And the work of our law enforcement partners at the Federal, State and local levels is ongoing. Those engaged in fraud across the drug control supply chain are being investigated and prosecuted.

Recent data shows we are seeing an overdose from prescription opioids leveling off in this country, but a dramatic 39 percent increase in heroin overdoses from 2012 to 2013. This is creating an additional need for treatment in a system where a well-known gap between treatment capacity and demand already exists. Therefore, we must redouble our efforts to address people who are misusing prescription opioids, since we know this is a major risk factor for subsequent heroin use.

Earlier this week, the administration held the inaugural meeting of the congressionally mandated interagency heroin task force. Mary Lou Leary, our deputy director for State, Local and Tribal Affairs, is one the cochairs for this committee. In addition, the President's FY '16 budget request includes $99 million in additional funding for treatment and overdose prevention efforts.

We have also been working to increase access to the emergency

opioid overdose reversal drug, Naloxone, and to promote good samaritan laws so that witnesses can take steps to help save lives. Many police and fire departments have already trained and equipped their personnel with this life-saving drug, and loved ones of people with opioid drug use disorders are equipping themselves as well.

And while law enforcement and other first responders have an important role to play, the medical establishment also must become more engaged to identify and treat heroin and prescription opioid use disorders. Every day, these people appear in our emergency departments and other medical settings, and more models and interventions are needed to get these individuals engaged in care.

We also need to expand availability of evidence-based opioid use disorder treatments. Medication assisted treatment, which uses FDA-approved medications, combined with behavioral and other recovery support, have been shown to be the most effective treatment for opioid use disorders. Decisions about the most appropriate treatment options and their duration need to be agreed upon by both the patient and the treatment provider.

We must also provide community supports, such as access to housing, employment, and education to give patients the functional tools they need to lead healthier lives and fully integrate into the community as part of their recovery process.

While we support multiple pathways to recovery, the literature

shows that short-term treatment, such as detoxification alone, is not effective and carries risk of relapse and overdose death. Because of the lack of availability of evidence-based maintenance treatments and the strong connection between injection of opioid use -- of opioid drugs and infectious disease transmission, we also promote the use of public health strategies that will help prevent the further spread of infectious disease. The HIV and Hepatitis C outbreak in Scott County, Indiana, is a stark reminder of how opioid use can spread other diseases, how comprehensive public health strategies, such as syringe exchange programs, need to be part of the response to the opioid use epidemic, and how rural communities that have limited treatment capacity may experience additional public health crises.

Finally, we are continuing our efforts to address neonatal abstinence syndrome. Research published just yesterday shows that the incidence of NAS has grown nearly fivefold between 2000 and 2012 and that 81 percent of the 2012 hospital charges for NAS were attributed to Medicaid. We must consider that the best interest of babies with NAS is often served by best addressing the interests of the mother. Therefore, we need to provide safe harbor for pregnant and parenting women seeking prenatal care and treatment.

In conclusion, we look forward to working with Congress and our Federal partners on the next stage of action to address this epidemic. Thank you.

Mr. Murphy. Thank you.

Dr. Frank, we're going to try and get your testimony and then we're going to run off and vote and we'll be back. Go ahead.

[The prepared statement of Mr. Botticelli follows:]

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

STATEMENT OF RICHARD G. FRANK

Mr. Frank. Okay. Chairman Murphy, Ranking Member DeGette, and members of the subcommittee, thank you for the opportunity to discuss how the Department of Health and Human Services is addressing the opioid abuse epidemic.

Containing the abuse and misuse of prescription opioids and heroin is a high priority for the HHS leadership team, and we're pleased to be here with you today. I would like to use my time today to give you an overview of how we view the challenge and describe how we are working to develop a multifaceted solution to this problem. It's going to take a lot of collaboration, and we are pleased to work with you and other stakeholders on this issue.

Addiction to an abuse of opioids, including both prescription painkillers and heroin and the terrible outcomes associated with them, are growing at an alarming pace. Just over a third of drug overdose deaths in 2012 and 2013 were from prescription opioids, while heroin-related deaths have spiked dramatically, almost tripling since 2010.

The sharp increase in the misuse and abuse of opioids places a great burden on the health system. There were 259 million prescriptions filled for opioids in the U.S. in 2012, a large increase

over just a few years prior. The Medicare program under part D spent $2.7 billion on opioids overall in 2011, 1.9 billion of that total, or 69 percent was accounted for by the top 5 percent of opioid users. Those spending patterns on these drugs reflect some of our concerns.

The cost of abuse and misuse of opioids shows up in preventible use of very expensive health care. Heroin presents an equally troubling, but different abuse and overdose pattern. We saw increases between 2002 and 2009 in a number of people using heroin, but that number has held fairly steady since 2009.

The striking new trend is that there's an increasing share of the users that are dying from heroin overdoses. So what I'm telling you is that we have a opioid prescribing problem, sitting alongside a drug abuse and misuse problem.

Secretary Burwell is committed to aggressively addressing the epidemic. She's driving us towards two main goals: One, reducing opioid overdoses and opioid -- and overdose-related mortality; and two, decreasing the prevalence of opioid use disorder. She directed us to use the best science and to focus on the most promising levers that can make a difference for the people who struggle with opioid addiction and their families.

HHS agencies have been collaborating on this problem for some time, and we hope you will agree after today that the sum is -- that the whole is greater than the sum of the parts.

Our actions informed by the evidence and discussions with States and other stakeholders fall into three general categories: One, addressing opioid prescribing practices; two, expending the use of Naloxone; and three, promoting medication assisted treatment.

Let me outline the plan in a bit more detail. First, PDMPs. We're increasing investments in prescription drug monitoring programs, which are among the most promising clinical tools to curb prescription opioid abuse. We're investing it through State grants and technical assistance and supporting best practices to maximize the impacts of PDMPs.

Second, Naloxone, which is the life-saving drug that can reverse overdose from both prescription opioids and heroin. We're supporting the development of user-friendly formulations and delivery mechanisms and are working with State and local governments to support training and other measures that get Naloxone into the hands of those that are in a position to reverse overdoses.

Finally, we have plans to support the appropriate use of medication-assisted treatment, or MAT. The enactment of the Mental Health Parity and Addiction Act opens up new opportunities to expand access to these evidence-based treatments.

We are also working on identifying best practices in primary care settings, increasing access to MAT through SAMHSA grant support and potentially increasing the supply of MAT providers by reviewing the

policy and regulations that limit the types of individuals certified to prescribe. Our commitment to halting this complex public health epidemic is set out in the President's 2016 budget that includes a $99 million increase for parts of our initiative.

Finally, evaluation will help us identify the most effective activities, allow us to continuously learn. And inform future policy makers -- making in order to address this public health concern.

So, in closing, this is critical for HHS and for the Nation, and we can't do it alone. We need help. Thank you for encouraging an open discussion of this today, and we are committed to turning the tide on this scourge that has become the opioid epidemic.

[The prepared statement of Mr. Frank follows:]

******** INSERT 1-2 ********

Mr. Murphy. Thank you, Doctor.

Now, for the members -- so votes are in progress. And even though time is running out, just to let you know, I think only about 20 people voted so far. So, apparently, this is throwing everybody off in their schedules.

I apologize. This is what happens on Capitol Hill. But we're committed to hear from you. We know how important this is and we value your testimony. So we're probably going to be back in a little under an hour. So we look forward to hearing from you then and getting the rest of this testimony. Thank you.

RPTR HUMISTON

EDTR ROSEN

[10:55 a.m.]

Mr. Murphy. All right. Thank you for being patient.

All right. Dr. Volkow, you're recognized for 5 minutes.

STATEMENT OF NORA D. VOLKOW, M.D.

Dr. Volkow. Good morning, Chairman Murphy, Ranking Member DeGette, and other members of the subcommittee. I want to thank you for organizing and inviting me to participate in this important hearing.

The nonmedical use of prescription pain relievers is a particularly public health challenge, for it demands solutions, on the one hand, to prevent their diversions and misuse, while at the same time, it demands so many solutions that will not jeopardize access of these medications for those that need them.

Opiate medications are probably among the most effective pain killers that we have for the management of acute severe pain, and the proper use can actually save lives. They act by activating opioid receptors that are located in the areas of the brain that perceive pain, but there are very high concentration of opioid receptors in brain

reward regions, and hence, the problem. And it's activation of these receptors is what is associated with their addiction potential.

There are also high levels of receptors in areas of the brain that regulate breathing, which is why their use is associated also with a high risk of death from overdoses.

We have heard the devastating consequences from the escalation of the abuse of prescription medications in our country, the overdose deaths that transition to injection of heroin and associated infections with HIV and Hepatitis C, and increasing numbers that we are seeing on the neonatal abstinence syndrome.

NIDA's role in helping solve this epidemic is to support the research that will help develop solutions to prevent and treat abuse of prescription medications that could be implemented now, while, at the same time, funding research that in the future will provide transformative solutions.

There are already evidence-based practices that have been shown to be effective in the prevention of overdose death that include the use of medications for opioid addiction and the use of Naloxone to reverse opioid overdoses.

The three medications currently available to treat opioid addiction: Methadone, buprenorphine and naltrexone, which, when used as part of a comprehensive addiction treatment plan, have been shown to facilitate abstinence and reduce overdose and HIV infections.

Also, when coupled to prenatal care in pregnant women addicted to opioids, these medications reduce the risk of obstetrical fetal and neonatal complications. Yet, despite the strong evidence, less than 40 percent of those receiving treatment for opioid addiction get treated with these medications. Toward this end, NIDA is funding research on implementation strategies that facilitate the use of medications for opioid addiction in the healthcare system.

Another key component to decrease the overdose deaths is to expand the use of Naloxone, so NIDA has partnered with pharmaceutical companies to develop user-friendly, effective delivery systems for Naloxone that will facilitate their use by those that have absolutely no medical training.

In addition, NIDA supports research on the treatment of pain and on the treatment of opioid addiction that will offer new solutions for the treatment of these two disorders. Examples, for example, for the management of pain include the development of drug combinations or new formulations with less addiction potential; the development of analgesics that do not rely on the opioid system; and the development of nonmedication interventions, such as the use of transcranial magnetic or electrical brain stimulation for pain management.

Examples of research on the treatment of opioid addiction include the development of slow-release formulations that need only once-a-month or once-every-6-months dosing, which will facilitate

compliance and use -- and the development of vaccines against heroin, which will prevent the delivery of the drug into the brain, hence, interfering with its rewarding effects and adverse consequences.

Because the epidemic of prescription drug abuse resulted from a lack of knowledge by healthcare providers, the importance of developing curriculum to train both in pain and in substance abuse disorder is another priority for which NIDA has developed in partnership with the other institutions and NIH Centers of Excellence.

There are over 24,000 deaths from opioid overdoses in 2013, 24,000. This highlights the urgency to address this epidemic. Solutions are already available. The challenge is the implementation. This requires strong integration of efforts, and NIDA will continue to work closely with other Federal agencies, community organizations, and private industries to address this complex challenge.

[The prepared statement of Dr. Volkow follows:]

******** INSERT 2-1 ********

Mr. Murphy. Thank you.

Dr. Throckmorton, 5 minutes.

STATEMENT OF DOUGLAS THROCKMORTON, M.D.

Dr. Throckmorton. Mr. Chairman, Ranking Member DeGette, and members of the subcommittee, I am Dr. Douglas Throckmorton, Deputy Director for Regulatory Programs within FDA's Center for Drug Evaluation and Research. Thank you for the opportunity to be here today to discuss FDA's role in combating opioid abuse and encouraging the safe use of these important drugs.

Our goal is to find the balance between needing to treat patients with pain, including the use of opioids where appropriate, and needing to reduce opioid drug abuse. This work is being done together with other parts of the Federal Government, and we know that a successful and sustainable response must include Federal and State government, public health officials, opioid prescribers, addiction experts, researchers, manufacturers, and patient organizations.

For our part, FDA plays a central role in the regulation and use of drugs from their discovery and throughout their marketing. For example, when FDA reviews a drug for possible marketing, we also approve drug labeling for improved, which includes information about approved uses about the medicine, as well as information about potential safety

risks. FDA also follows drugs after they are marketed carefully, including opioid drugs. Where necessary, this enables us to take a variety of actions to improve their safe use, such as changes to approved labeling.

The first area of FDA activity I'd like to highlight is our work to support the development of abuse-deterrent formulations that make opioids harder or less rewarding to abuse. While this is not a silver bullet that will prevent all abuse, FDA believes abuse-deterrent opioids can help reduce opioid abuse. To incentivize their development, FDA recently issued final guidance on abuse-deterrent formulations, guidance we are using now to meet with sponsors interested in developing them.

To date, FDA has received some 30 investigational new drug applications from manufacturers. In addition, we have approved four opioid drugs with abuse-deterrent claims in their labeling.

Overall, then, while we are in the early stages of development, I am encouraged by this level of work. FDA envisions a day not far in the future when the majority of opioids in the marketplace are in effective, abuse-deterrent forms.

Next, with regards to prescribing opioids, we know that they are powerful medicines, and FDA believes that it is critically important to ensure that prescribers have high quality education about how to use them in pain management.

Over the past several years, FDA has done several things to improve educational materials on opioids. For example, we recently finalized required changes to the approved labels of extended-release, long-acting opioids, changing their indication to inform prescribers that these drugs should only be used for pain severe enough to require daily around-the-clock treatment when alternative treatments would not work.

At the same time, FDA strengthened significantly the safety warnings on these opioids. We want prescribers to use them with care, and today, the labels for extended-release, long-acting opioids are among the most restrictive of any drugs that we have in the center, and have clear language that calls attention to their potentially life-threatening risks.

FDA's also working to improve the information available for prescribers in other ways. Under certain circumstances, FDA can require manufacturers, as a part of a risk evaluation and mitigation strategy, to address safety concerns such as opioid abuse. In 2012, FDA required manufacturers to fund the development of unbiased continuing education programs on opioid prescribing practices for prescribers. In the first year since that program has been in place, approximately 6 percent of the 320,000 prescribers, around 20,000 prescribers of extended-release and long-acting opioids, have completed one of those courses. We believe this training for

prescribers is important. We also support mandatory education for prescribers of opioids, as called for by the administration in the 2011 Prescription Drug Abuse Prevention Plan, and reemphasized in the 2014 National Drug Control Strategy.

Finally, FDA has been working with many other stakeholders, including the agencies here today, to explore the best ways to prevent overdose deaths by the expanded use of Naloxone. As others have said, it can and does save lives. FDA is working to facilitate the Naloxone -- the development of Naloxone formulations that could be easier used by anyone responding to an overdose. First, FDA meets with manufacturers whenever needed, and is using whatever tools we can to expedite product development. We recently approved the first auto-injector formulation of Naloxone, which is intended to be administered by people witnessing and overdose, such as family members and caregivers. We completed that review and approved this product in 15 weeks.

Going forward, we continue to work on how best to use Naloxone. As a part of this work, FDA, and many of the others agencies at this table, are planning a public meeting in July to bring together key stakeholders to deal with questions of access, co-prescribing of Naloxone, and state and local best practices.

In conclusion, as a society, we face an ongoing challenge and a dual responsibility. We must balance efforts to address opioid drug

misuse, abuse, and addiction against the need for access to appropriate pain management. These are not simple issues and there are no easy answers. FDA is taking important actions we hope will achieve this balance. We welcome the opportunity to work with Congress, our Federal partners, the medical community, advocacy organizations, and the multitude of interested communities and families to turn the tide on this devastating epidemic.

Thank you for this opportunity to testify. I look forward to answering any questions that I can.

[The prepared statement of Dr. Throckmorton follows:]

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

Mr. Murphy. Thank you, Doctor.

Dr. Houry.

STATEMENT OF DEBRA HOURY, M.D.

Dr. Houry. Chairman Murphy, Ranking Member DeGette, I would like to thank you for inviting me here today to discuss this very important issue. I would also like to thank the committee for your continued interest in the prescription of opioid abuse and overdose. My name is Dr. Debra Houry, and I am the director of the National Center for Injury Prevention and Control at the CDC.

As a trained emergency room physician, I have seen firsthand the devastating impact of opioid addiction on individuals and their families, as well as the importance of prevention. Together, we have witnessed a deadly epidemic unfolding in states and communities across the country. The overdose epidemic is driven, in large part, by fundamental changes in the way healthcare providers prescribe opioid pain relievers. Enough prescriptions were filled in 2012 for every American adult to have their own bottle of pills. As the amount of opioids prescribed increased, so has the number of deaths.

In alignment with the Department's initiative, I want to highlight CDC's work in developing evidence-informed opioid prescribing guidelines for chronic pain and providing direct support

to States to implement multi-sector prevention programs.

CDC is currently developing guidelines for the prescribing of opioids for chronic noncancer pain. This undertaking is responsive to a critical need in the field. These new guidelines will redefine best practices around opioid prescribing for chronic pain and make important advances in protecting patients. The audience for these guidelines are primary care practitioners, who account for the greatest number of prescriptions for opioids compared to other specialties. The guidelines process is underway, and our goal is to share a draft for public comment by the end of this year. We have plans in place and purge uptake and usage of the guidelines among providers, which is key for improving prescribing practices.

The second activity I would like to highlight is our major investment in State-level prevention. States are at the front lines of this public health issue, and CDC is committed to equipping them with the expertise they need to reverse the epidemic and protect their communities. Utilizing the newly-appropriated $20 million, we recently published a new funding opportunity called Prescription Drug Overdose: Prevention for States. It builds upon existing CDC-funded State programs, and targets States that have a high drug overdose burden and those that demonstrate readiness needed to combat the epidemic. It requires collaboration across sectors for a truly comprehensive response.

The goals for this program are to make prescription drug monitoring programs more timely, easier to use, and able to communicate with other State PDMPs, to implement Medicaid or Workers' Compensation interventions to protect patients at risk, and to bring data-driven prevention to the communities struggling with the highest rates of drug abuse and overdose. States also will be given the flexibility to use the program to respond to emerging crises and develop innovative interventions so they know what works to reduce overdose and save lives in their community.

The development of opioid prescribing guidelines and our State prevention program are two key ways that CDC's broad work on the epidemic contributes to the Department's initiative.

We are also examining the increase in heroin use and overdose. Heroin overdose deaths have more than doubled since 2010, and prescription opioid abuse, a key risk factor for heroin use, has contributed significantly to this rise in heroin use and overdose. We will leverage our scientific expertise to improve public health surveillance of heroin and evaluate effective strategies to prevent future heroin overdoses.

Addressing this complex problem requires a multifaceted approach and collaboration among a variety of stakeholders, but it can be accomplished, particularly with the ongoing efforts of all of the organizations represented here on this panel.

CDC is committed to tracking and understanding the epidemic, supporting States working on the front lines of this crisis, and providing healthcare providers with the data, tools and guidance they need to ensure safe patient care.

Thank you again for the opportunity to be here with you today and for your continued work and support of us protecting the public's health. I look forward to your questions.

[The prepared statement of Dr. Houry follows:]

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

Mr. Murphy. Thank you, Doctor.

Pamela Hyde, welcome back.

STATEMENT OF HON. PAMELA S. HYDE

Ms. Hyde. Good morning, Chairman Murphy, Ranking Member DeGette, and members of the subcommittee. Thank you for inviting SAMHSA to be part of this hearing, and thank you for your interest in this important public health issue.

According to SAMHSA's National Survey on Drug Use and Health, the prevalence rate of nonmedical use of prescription opioids is high, approximately 4.5 million individuals in 2013. Heroin use is much lower, About 289,000 individuals reporting past month use, but that's doubled in 5 years.

Fortunately, the nonmedical use of pain relievers has actually decreased some from 2009 to 2013, especially among young people 12 to 17. However, as you know, overdoses and overdose-related deaths from both prescription drugs and heroin have risen dramatically among all ages. And as you've heard, few who need treatment are receiving the comprehensive community-based services they need to live lives in recovery, free of addiction.

SAMHSA believes prevention is the priority and recovery is the goal. SAMHSA's programs, data, practice improvement, public

education, and regulatory efforts are all designed to prevent addiction and overdoses, help provide the treatment and services needed for people with substance abuse disorders to achieve recovery, support their families, and foster supportive communities.

SAMHSA funds the American Academy of Addiction Psychiatry, together with six other medical societies, to train prescribers in the best approaches to pain management. SAMHSA also educates physicians on medication-assisted treatment for opioid addiction. SAMHSA's Addiction Technology Transfer Centers provide training and materials on opioid use disorders, and are co-funded with NIDA to distribute research-based best practices to the field of addiction treatment.

To help prevent opioid-overdose-related deaths, SAMHSA alerted States last year that substance abuse treatment block grant funds may be used to purchase and distribute Naloxone and increase education and training on its use. Also in 2014, SAMHSA updated its opioid overdose prevention toolkit to educate individuals, families, first responders, and others about steps to prevent and reverse the effects of opioid overdoses, including the use of Naloxone. This toolkit's one of the most downloaded resources on SAMHSA's Web site.

The President's 2016 budget includes $12 million in discretionary grants for States to purchase and distribute Naloxone, equip first responders in high risk communities, and support education on the use of Naloxone and other overdose prevention strategies.

SAMHSA also supports medication-assisted treatment as part of a recovery-oriented, person-centered care model. Medication-assisted treatment is not meant as a standalone approach, but rather is designed to include medication, counseling, behavioral therapies, and recovery supports.

In March 2015, SAMHSA issued revised Federal guidelines for opioid treatment programs which highlight this recovery-oriented care model, and encouraged the use of any of the three FDA-approved medications for the treatment of opioid use disorder based on an assessment of each individual's unique needs.

SAMHSA's also taking an integrated clinical care approach as part of a new 2015 grant program to expand and enhance the availability of medication-assisted treatment and other clinically appropriate services in States with the highest rates of opioid admissions. The President's 2016 budget proposes to double this program.

In collaboration with DOJ and ONDCP, SAMHSA added language to its 2015 treatment drug court grant requirements to ensure that drug court clients will not be compelled to stop or be prevented from using medication if it is prescribed or dispensed consistent with a licensed prescriber's recommendation, a valid prescription, or as part of a regulated opioid treatment program.

SAMHSA regulates opioid treatment programs, which are expected to provide a full range of services for their patients. In

collaboration with the Drug Enforcement Administration, SAMHSA provides waivers to physicians wishing to treat opioid use disorders with buprenorphine in a practice setting other than an opioid treatment program.

SAMHSA also funds efforts to help prevent prescription opioid misuse and heroin use. For example, in 2014, SAMHSA's Strategic Prevention Framework, Partnerships for Success program, made preventing and reducing heroin use one of its focus areas, along with prescription drug misuse and abuse, and underage drinking. For 2016, the President has proposed $10 million for the Strategic Prevention Framework RX, or SPF RX, to help States use data, including PDMP data, to identify and assist communities at high risk for the nonmedical use of prescription drugs.

We want to thank you, again, for taking on this issue and for allowing SAMHSA an opportunity to share some of its efforts with you. We look forward to answering your questions.

[The prepared statement of Ms. Hyde follows:]

******** INSERT 2-4 ********

Mr. Murphy. Thank you, Ms. Hyde.

Dr. Conway, you're recognized for 5 minutes.

STATEMENT OF PATRICK CONWAY, M.D.

Dr. Conway. Chairman Murphy, Ranking Member DeGette, and members of the subcommittee, thank you for inviting me to discuss the CMS's work to ensure that all Medicare and Medicaid beneficiaries are receiving the medicines they need, while also reducing and preventing prescription drug abuse.

As we have heard from other witnesses, opioid analgesics have increasingly been implicated in drug overdose deaths over the last decade. As a practicing physician, I understand the importance of this issue.

CMS recognizes our responsibility to protect the health of Medicare and Medicaid beneficiaries by ensuring that appropriate safeguards are in place to help prevent overuse and abuse of opioids, while ensuring that beneficiaries can access needed medications and appropriate treatments for substance abuse disorder.

Since its inception in 2006, the Medicare part D prescription drug benefit has made medicines more available and affordable, leading to improvements in access to prescription drugs and better health outcomes.

Despite these successes, part D is not immune from the nationwide epidemic of opioid abuse. CMS has broadened its initial focus of strengthening beneficiary access to prescribed drugs to also address potential fraud and drug abuse by making sure part D sponsors implement effective safeguards and provide coverage for drug therapies that meet safety and efficacy standards.

We believe that broader reforms that result in better coordinated care will help protect beneficiaries from the damaging effects associated with prescription drug abuse and to prevent and detect overutilization related to prescription drugs.

A centerpiece of our strategy is to strengthen CMS's monitoring of part D plan sponsors' drug utilization management programs, to prevent overutilization of these medications. To accomplish this goal, the Medicare part D overutilization monitoring system, or OMS, was implemented in 2013. Through this system, CMS provides reports to sponsors on beneficiaries with potential opioid overutilization identified through analysis of prescription drug event data and through beneficiaries referred by the CMS Center for Program Integrity. Sponsors are expected to utilize various drug utilization monitoring tools to prevent continued overutilization of opioids. Recent data has shown that from 2011 to 2014, the OMS has reduced the number of potential opioid over-utilizers by appropriately 26 percent.

CMS also utilizes the Drug Integrity Contract, or MEDIC, which

is charged with identifying and investigating potential fraud and abuse, and developing cases for referral to law enforcement agencies. In 2013, CMS directed the MEDIC to increase its focus on proactive data analysis in part D. CMS has also used our rule-making authority to create new tools to take action against problematic prescribers and pharmacies. We recently finalized a provision that requires prescribers of part D drugs to enroll or have a valid opt-out affidavit on file, and establishes a new revocation authority for abusing prescribing patterns.

State Medicaid agencies have also taken action to tackle the opioid abuse epidemic. Efforts include expanding the Medicaid benefit to include behavioral health services for those with addiction to prescription drugs and pharmacy management review programs. Although CMS does not determine what services are provided in each Medicaid program to prevent and treat opioid abuse, we are encouraged by the increasing efforts by States to develop effective strategies for designing benefits for this population.

We recently launched the Medicaid innovation accelerator program, or IAP, to provide States with technical assistance and other types of support to address this important issue.

CMS, in coordination with CDC, SAMHSA, and NIH, issued an informational bulletin on medication-assisted treatment for substance abuse disorder in the Medicaid program. This guidance outlines that

a combination of medication and behavioral therapies is the most effective combination of treatment. We issued a similar bulletin focused on these services in the pediatric and youth population.

CMS is dedicated to providing the best possible care to beneficiaries with opioid addiction, and is working with part D sponsors and State Medicaid programs to implement effective safeguards to prevent opioid abuse and treat patients effectively with substance abuse disorders.

CMS has made progress, but there is more work to be done. CMS is undertaking multiple policy initiatives and interventions to reduce the rate of opioid addiction and overdoses in both Medicare and Medicaid.

In previous testimonies, I've never had family here or the time to thank them, so I do want to thank my mother, Diane Conway, is here and my son, Jack, who's out of school, as well as my wonderful wife, Heather, and daughters Alexa and Savannah. And without their love and support, I would not be able to work on issues like this that are critically important to our Nation. So thank you.

[The prepared statement of Dr. Conway follows:]

******** INSERT 2-5 ********

Mr. Murphy. Thank you, Doctor. And thank you for recognizing Take Your Family to Testifying Day. Apparently everybody else did not get the memo, so --

I just want to start out by saying if talent and dedication alone could solve this crisis, we'd be there with the testimony of today and other days, but obviously, we still have problems. So let me start off with asking a few questions.

First, for Director Botticelli, for the Office of National Drug Control Policy, or ONDCP, uses the term "recovery," does it mean to include patients with opioid addiction in a buprenorphine or methadone treatment program and still using heroin or other illicit drugs, or would you say that's not recovery?

Mr. Botticelli. So I think, you know, from our perspective, and also as a person in recovery, clearly we want to make sure that people are continuing to progress in their recovery, and that kind of free from substances is the ultimate goal of recovery programs, and I think everyone would agree on that, but we also know that substance use, and particularly opioid use disorders, are a significant chronic disorder, and that oftentimes, and even my own experience show me, that people often will experience relapse and will often, I think, need multiple attempts at treatment to get to that final goal of long-term recovery and long-term abstinence.

And so we really want to make sure that we're continuing to engage

with patients that we're moving them toward better health, better recovery, and being free from substance abuse as part of long-term recovery.

Mr. Murphy. Well, let me ask in context of this, because we also heard from testifiers last week they felt there was not a uniform definition of recovery, but, I mean, this is the talent pool here, you're the ones that do these. Do you all meet on a regular basis to talk about these issues? And when was the last time you all got together to talk about policy issues? Was it within the last -- can someone answer that? Pam? Pam Hyde?

Mr. Botticelli. So let me start.

Mr. Murphy. Oh, you will start? Okay.

Mr. Botticelli. Let me start with that, because it's actually part of our statutory authority --

Mr. Murphy. Okay.

Mr. Botticelli. -- that we set in conjunction with, not just our HHS partners, but with all of the Federal agencies that have a role in substance use, and particularly in opioid use disorders. We have been engaged with the DOD and the VA and the Bureau of Prisons.

Mr. Murphy. So you all meet regularly?

Mr. Botticelli. We actually do meet regularly. So we have quarterly meetings to focus on where we are.

Mr. Murphy. Well, let me move on that too, because that's going

to be important.

Ms. Hyde, let me ask you a question here on -- in your response to our bipartisan letter of March 18 concerning the National Registry of Evidence-Based programs, you noted that, quote, "new submission and review procedures will improve the rigor of the registry and bring NREPP into closer alignment with other registries of evidence-based programs in the Federal Government."

Now, prior to entering into this July 2014 contract, did SAMHSA feel that the scientific basis of the rigor of NREPP needed to strengthened, yes or no? I mean, do you feel it needed to be strengthened?

Ms. Hyde. Thank you for the question. We thought the process that we used for determining what practices were reviewed needed to be strengthened, and in the process, we have also increased the rigor with which we look at them.

Mr. Murphy. Can you get us a list, not today, but can you get us a list of what you consider to be some of the models within the Federal registry that we can review as part of that, as evidence-based programs?

Ms. Hyde. Certainly.

Mr. Murphy. Okay. Thank you.

Your response also indicates an outside contractor will assume the role of gatekeeper for NREPP, determining which studies and outcomes are reviewed in the screening and review of an intervention,

with the aim of preventing bias in favor of the intervention developers.

Was SAMHSA's prior system for vetting and selecting interventions to be included in the NREPP prone to any kind developer bias or conflict of interest? Was that a concern?

Ms. Hyde. Yes, Mr. Murphy, it was a concern. It was pretty much developer driven. So a developer had to want their practice to be reviewed, and then they had some control over what research we looked at. We have changed that with the new contract, which began last year, and we will help decide priorities together with the public input, but the contractor will help us look more objectively at evidence.

Mr. Murphy. Thank you. I just pulled up here -- I just got a note, actually an article that, was this one of your constituents, Dr. Frank, from eastern Colorado? I don't want to take all your Colorado thunder, but it was fascinating article, because it made reference to the increased use of emergency departments associated with opiates. And it's interesting, they said that the reasons for this is -- first of all, they said there's 10-1/2 million estimated people with this, it's probably an underestimate, that people go to the emergency rooms for treatment for withdrawal, but also many trying to get more opiates; and that when you have users with opiate prescriptions from more than one physician, they're more likely to be involved in riskier practices.

I wonder if any of you could comment on if that's an area that

we're trying to address. I think, Dr. Volkow, you were also talking about issues with regard to prescribing practices, and Dr. Frank. Can some of you comment on those issues?

Dr. Volkow. Yes. And I think that that article, I think, that you're referring to the New England Journal of Medicine article that shows that there's been a very significant, quadruple number of cases of neonatal abstinence syndrome in the intensive care units, and this does reflect that the fact that there are -- many women are actually being prescribed opioid medications during their pregnancy itself. And, actually, based on another study, it was estimated that 21 percent of women that are pregnant are going to receive an opioid medication, which, again, highlights the need to enforce better that the guidelines on the management of pain need to be enforced in better ways. And this is also recognized by studies that have actually evaluated the extent to which physicians are following guidelines by the main medical organizations as it relates to the management of pain. So that is an area where there needs to be an aggressive increase in the education and enforcement of guidelines.

Mr. Murphy. Thank you. I'm out of time. I'd just ask unanimous consent that I can submit this research article for the record.

[The information follows:]

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

Mr. Murphy. Ms. DeGette, you're recognized for 5 minutes.

Ms. DeGette. Thank you, Mr. Chairman.

Dr. Volkow, as I mentioned in my opening statement, you're one of the world's top experts on the issue of treating addiction. Briefly, what does the body of scientific evidence show regarding the effectiveness of methadone and buprenorphine in this treatment of opioid abuse disorders?

Dr. Volkow. What the research has shown, and it has shown it not just for methadone and buprenorphine, but a more recent medication, naltrexone, that these medications when used as part of a comprehensive program for the treatment of opioid addiction are quite effective, and they significantly improve the outcomes of individuals being able to stay, on the one hand, abstinent from the drug or to decrease the likelihood of relapsing, but it also protects them against the adverse outcomes, such as overdoses.

Ms. DeGette. So in light of those studies, you also said in your testimony that existing evidence-based prevention and treatment strategies are highly underutilized across the United States. And last week we had an expert tell our panel that very few patients with opioid addiction today receive treatments that have been proven most effective. He was talking about this rapid detox followed by abstinence-based treatment.

I'm wondering, Dr. Volkow, if you can help understand this. Why

do we have a situation where people are not getting evidence-based treatment?

Dr. Volkow. Well, one of the problems has been, and it's a complex problem and there are many reasons why they're not getting the correct treatment, including the fact of adequate education as it relates to the proper screening and management of substance abuse disorder, including the healthcare system. Then you have a whole infrastructure that has developed because addiction is stigmatized, so, therefore, the likelihood of people accessing that medical care is much lower. So -- and then, of course, the -- there is a difference between States in the way that they implement the treatment. So all of these factors account for the current situation.

Ms. DeGette. Dr. Frank, do you have anything to add to that?

Mr. Frank. Yes, I do. I think that one thing that's very important to remember is that overall, we treat 10 percent of the people with these disorders, so it's not surprising that people aren't getting evidence-based treatment, because they're not getting treatment, period.

Second part is why aren't they getting evidence-based treatment among those who do? And I think that there are insurance dynamics that hopefully we're fixing, there are, as Dr. Volkow said, access to trained professionals who are trained in the best things, and then there's, in a sense, trying to kind of get the systems and the

infrastructures aligned so that they support the best practices.

Ms. DeGette. And, Dr. Houry, several of our witnesses, including you, mentioned the role of the States in this. Can you talk about that for a minute?

Dr. Houry. Absolutely. I think States have different populations, different issues, different prescription drug monitoring programs, and so tailoring these programs for States so they can best identify, whether it's their State Medicaid program, other high-risk programs or patients and how to best target them, and that's why the program at the CDC is really helpful, because we have the higher level view to work across the States for this.

Ms. DeGette. And do you think the States have work to do in terms of implementing these programs that are science-based and that work?

Dr. Houry. You know, I think we're starting to do that. Like, our program itself has only been in existence for 6 months, but we're seeing great progress. And if you look at some of the policies that States are implementing, we're seeing reductions in what we call doctor shopping and patient going, you know, to different doctors, because of utilizing prescription drug monitoring programs. So although it's early in the States, I'm very optimistic that we are making progress in the States.

Ms. DeGette. Okay. Dr. Volkow, I want to come back to you. Another -- one of our other experts last week said patients and their

families need to know that detoxification treatment and drug-free counseling are associated with a very high risk of relapse.

I'm wondering if you can -- if you can tell us what the science shows. Is this -- is this type of treatment generally effective or less effective? What does the research show?

Dr. Volkow. The research has shown that in general, fast detoxification of patients is associated with increased mortality, like what you just mentioned. And this reflects the fact that addiction is a chronic disease and the changes that occur in the brain persist months, years after you've stopped taking the drug.

So what they do in this fast detoxification is just remove the physical dependence and assume that the addiction is cured, and these are two independent process, and as a result of that, the patient feels that they are safe and then they relapse because they are still addicted --

Ms. DeGette. Thank you.

Dr. Volkow. -- and many times they overdose.

Ms. DeGette. Thank you.

Thank you very much, Mr. Chairman.

Mr. Murphy. I now recognize Mr. Collins for 5 minutes.

Mr. Collins. Thank you, Mr. Chairman. This is truly a fascinating topic we're discussing, and it's obvious there's no very easy solution. I mean, we've heard it's a chronic disease, 10 percent

are seeking treatment. I guess my question maybe for Ms. Hyde at SAMHSA is, you know, certainly with pregnant women, you know, that may have young kids at home, and inpatient treatment might be the preferred, and we just can't let perfect be the enemy of good, what other options are you looking at for people who can't get in, I mean, they're just not going to enter inpatient, so they may be part of the 90 percent not getting treatment at all? Some treatment better than no treatment, as frustrating as that might be? What are your comments to the young mother that's got kids at home and she's pregnant and she's dependent and she can't -- she just can't go into an inpatient center? What do we do for that patient?

Ms. Hyde. Thank you for the question. The issue of pregnant and parenting women is a big one in our field. We do have a small program to address that issue, but you're right, it's a residentially-based program.

We have increasingly been looking at ways to take what we learn in that program about the best ways to treat pregnant and parenting women and take it into other settings, so whether it's our opioid treatment programs or our -- the training that we do for physicians who are using medication-assisted treatment to deal with pregnant and parenting women. So we're trying in any -- in every way that we can to make those services available to those women.

Mr. Collins. So, again, with pregnant women, and we're looking

at other treatments, I guess, whether that's buprenorphine or methadone, are there studies that show whether that has an impact on the fetus and the baby?

Ms. Hyde. There -- you're right to be concerned about the child. What we see is that this prevents death, it prevents addiction of the baby, it prevents a lot of other issues that may come with allowing -- or the young woman to continue with the illicit drug use or the prescription opioid misuse. So definitely providing treatment helps both the woman and the child.

Mr. Collins. Now, as you've counseled these women, what kind of reaction are you getting? Are they recognizing -- and you would think the genuine concern they have for the baby. I mean, there's very much a complicated balancing act going on here. What kind of reactions are you getting from the women acknowledging the problem and wanting to treat it?

Ms. Hyde. You know, most pregnant and parenting women really want to do the best thing for their babies, and they want to do the best thing for themselves, but as you've heard, addiction is a chronic disease and it's very difficult; changes the brain, changes the ability to make decisions.

The women who are in the programs that we provide support for find it a very helpful program with the kind of supports, because we provide a range of programs, and we've recently introduced medication-assisted

treatment into those programs as well.

Mr. Collins. So are these women finding you on their own, or are their physicians guiding them to you?

Ms. Hyde. The women who come to our programs come from a variety of places; some from the correctional system, some from physicians, some from family, some from self-referral. So they come from a number of places, and we don't make a distinction between where they come from in terms of providing the care.

Mr. Collins. Well, it's something this committee's very concerned with. And, again, Mr. Chairman, thank you for holding this hearing and for all of your testimony. I wish there was an easy solution. There just doesn't appear to be one. So this is going to have to be addressed on a lot of fronts. And with that, I yield back.

Mr. Murphy. Mr. Tonko, you're recognized for 5 minutes.

Mr. Tonko. Thank you, Mr. Chairman. And let me join in welcoming the Conway family to the hearing, and let me compliment the Honorable Michael Botticelli for having the roots, origins in the 20th Congressional District of New York. So welcome all.

One of the biggest concerns I hear from individuals and families struggling with addiction is the difficulty they have accessing treatment. As you know, with the Mental Health Parity and Addiction Equity Act, as well as with our Affordable Care Act, millions more people have gained access to mental health and substance use services.

However, recent reports have laid bare the fact that these new treatments as options sometimes exist on paper only.

So my question first to Assistant Director Frank, Dr. Frank, what is HHS planning to do to increase the public disclosure of the Medicaid management practices insurers use both on the commercial side and on Medicaid and CHIP so that consumers can truly evaluate their health plans to make sure they are in compliance with parity?

Mr. Frank. Thank you for the question. We, too, view the Mental Health Parity Act as an incredibly important opportunity to increase the use of evidence-based practice and access to treatment.

We are doing a number of things. We work with both the Department of Labor on the ERISA side of the commercial health insurance side. We've trained the ERISA investigators in how to detect deviations from parity arrangements within insurance, and so they are out there fully trained now working on these issues. We have a group within HHS who regularly provides technical assistance to State insurance commissioners and works with them to resolve complaints as they arise. And we've done -- continued a series of forums and technical assistance around the country. And we're working with stakeholders, some of whom are in this room today, to improve our ability to ask for disclosure and to offer up consumers the opportunity to really make that evaluation that you referred to.

Mr. Tonko. Thank you, Assistant Secretary.

And Director Botticelli, I would like to talk about another barrier to treatment for some patients. And press accounts have suggested that some States are denying patients access to drug courts if they are receiving medication-assisted treatments, or MATs. I understand this has been a problem in Kentucky, at least according to some press accounts. So, Director, can you explain what is going on here? Given the importance of MATs, why are some judges attempting to cut patients off of medicines that can actually help them recover?

Mr. Botticelli. Thank you, Congressman. And as many of my colleagues have talked about today, increasing access to medication-assisted treatment along with other behavioral therapies is the best course of treatment for people with an opiate use disorder. Unfortunately, one of the access issues that we find in addition to issues around payment have been particularly lack of access within the criminal justice system, and we know that many people with opioid use disorders are ending up in our system.

Drug courts, some drug courts have not adapted policies that the National Association of Drug Court Professionals endorse in terms of ensuring that people who are on -- who do have an opioid use disorder get access to those medications as well as not predicating their participation that they get off these medications.

Part of what we've been doing on the Federal level is using our Federal contracting standards to ensure that people with opioid use

disorders, whether it's in a drug court or a treatment program or in other venues, are offered access to medication-assisted treatment and are not denied participation based on the fact that they are on physician prescribed medication.

Mr. Tonko. Dr. Volkow, on that same issue, do you agree with the assessment?

Dr. Volkow. Yeah, I agree very much. And at the same time, we are developing alternatives that may be more amenable for the criminal justice system, like prison or jail, like the naltrexone, so there is no reason why they should not get access to medication.

Mr. Tonko. Okay. And another barrier that patients face is the lack of available treatment providers who can prescribe MATs. Director Botticelli, can you comment on this dearth of providers who can prescribe buprenophrine, for example, what are some of the reasons for the shortage and what can we do to address it?

Mr. Botticelli. One of the other opportunities that we have is ensuring that all of our treatment programs either offer medication-assisted treatment or to refer to programs that have medication-assisted treatment. An analysis of our treatment programs show that a very low percentage of them have incorporated medication-assisted therapies into their programs. Some of this, Congressman, quite honestly, has been by myth and misunderstanding and this divide between abstinence-based care and medication-assisted

treatment, which I think is really unfortunate that we have here, so we really want to make sure that if a client is entering a treatment program that has particularly Federal funding needs to offer by way of its own offering or through referral medication-assisted treatment.

Mr. Tonko. All right. Thank you very much. And thank you to the entire panel for guiding us in this crisis situation.

Mr. Murphy. I just want to ask as a clarification for the question you were asking about the drug courts and the use of a medication-assisted treatment. So you're recommending medication-assisted treatment as part of an option package, although you say obviously we want to get people free from drugs all together, does it require a recommended practice from your agencies to get drug courts to do that? Does it require regulatory changes from one of your agencies to do that? Or does it require a legislative solution from us to do that?

Mr. Botticelli. Another panel could -- this is -- we've actually been doing that as a condition of their Federal --

Mr. Murphy. Okay.

Mr. Botticelli. -- drug court language.

Mr. Murphy. Okay.

Mr. Botticelli. You know, again, this is -- we want this to be decided by an expert in addiction services in consultation with the --

Mr. Murphy. Okay.

Mr. Botticelli. -- but we just didn't want to have categorical denial.

Mr. Murphy. Ms. Hyde, are you adding to that question?

Ms. Hyde. I did mention in consultation with ONDCP and also with the Department of Justice, we have changed the language in our request for applications for drug courts so that they can't require that someone either get off of or not be on medication-assisted treatment if it is prescribed appropriately by a physician or a certified program.

Ms. DeGette. So I just wanted to add, though, what you can do, you can make the Federal funding contingent on full programs, but that -- but we can't force the States or the -- or whatever regulatory agency is setting up the drug courts to offer this. They just can't get Federal money if they don't off offer it.

Mr. Botticelli. And this is where I'm glad the committee is actually going to be talking at State level, because as a former State administrator, States do play a crucial role. There are many, many programs out there that actually don't receive Federal funding, or drug courts that don't receive Federal founding. We hope that our policies and procedures are adopted by those nonfederally-funded programs, but States play a key role in licensing treatment programs.

Mr. Tonko. Thank you.

Mr. Botticelli. And they, I think, can look at the opportunities of increasing or ensuring that State licensing treatment programs also

the have same kind of language.

Mr. Murphy. Thank you. Speaking of States, go to the gentleman from West Virginia, Mr. McKinley, for 5 minutes.

Mr. McKinley. Thank you very much, Mr. Chairman, and thank you again for these hearings that we've been having on this topic.

As an engineer, I need to see things in perspective, and so I guess we've been following this over the last 4 years in Congress, and especially on this committee, been trying to look at this issue, and I think at one of the last meetings we just had, I tried to put it in perspective by saying from -- Botticelli, you said there were 44,000 overdose deaths. That -- I want people to understand, that's more than died in Vietnam in combat. I don't know that the American public understands that. And every day on the news, NBC or whatever, there was a -- they had body counts and they had that, and people were outraged over that.

I'm not getting the sense of outrage over every year we lose as many people to drug overdose as we did in a 10-year war in Vietnam. We just seem -- I'm concerned when I had affirmed that in West Virginia, one in five babies born in West Virginia, and I'm sure it may be one in four in other States or so, but one in five babies, they've been affected with drugs. I keep thinking this in perspective by saying in Europe, the overdose rate is 21 -- approximately 21 per million; in America, it's seven to ten times that amount.

Now, I get a little on the verge of outrage. You know, I'm the father of four and grandfather of six, and I see these are what we're giving our kids, this is what the future is. And I hear this testimony from this panel of seven and the seven before that and the seven before that, and quite frankly, I get confused, because I don't known what the priority is.

We -- from the business community and you all here in Washington, everyone loves to plan, but they don't carry out. Now, that may be insulting, and I don't mean it in an insulting fashion, but we still have 44,000 people who will die between now and next year because we don't have a prior -- I'd like to think that we could come up with one plan, one way, if you had at least one, prioritize it, what's the one thing, and then let's put everything we have into it, that Manhattan-type project, go after that one solution and see if that doesn't start the ball rolling in the right way, and then we can do two, three and four with it, but a focus; but I don't see a focus. I didn't see a focus from you. I heard seven, eight different ways that we might be able to approach this problem, because the planning -- everyone loves to plan, but the implementation falls short.

So could -- since you're meeting on a regular basis, couldn't you come up with one -- one idea to where we ought to begin to where we can really -- the metrics, we get the optics and everything, we can really dig into that, and then we can have plan B, C and D, but let's

achieve one instead of continuing to melt down as we do at this. I don't want to see another statistic of 44,000 more people die of overdose.

So I hesitate to ask, can you come up with an idea today in the time frame, is there one, just one idea that we should focus on? What's the best way? Is -- is that in the drug use, is that in real-time on purchasing the prescription drugs that it's a national database, is that the number one thing we should do? I mean, my God, the Federal Government just changed the sentencing guidelines for heroin and they said if you're caught with 50 hits of heroin, you get probation. What are we doing? Are we fighting heroin or not? I'm really frustrated with this, so I really -- give me some more guidance on plan one.

Mr. Botticelli. So, Congressman, I appreciate your --

Mr. Murphy. Microphone.

Mr. Botticelli. I appreciate your attention to this. And, you know, myself and many of our colleagues have been doing this work for a long time and, I think, are filled with a sense of tragedy in terms of where we are, and know that we can do better and know that we can work with Congress.

You asked for one. I think there are three areas, and some of these are articulated in the Secretary's plan, that we've got to do. We've got to change prescribing patterns in this -- in this -- we are prescribing way too much medication, and that's starting the

trajectory. We need to increase our capacity to treat the disease so that people who are -- go down that path have adequate access. And the third is that we really need to focus on reducing overdose deaths.

Those are three areas that I think we can work with Congress on to really look at how do we increase our efforts.

Mr. Frank. Let me add on to that on behalf -- it seems that people from West Virginia all sort of think alike that way. And our Secretary, who is -- shares the same experience you do has pushed us to focus and to take action in those three areas. And, you know, with it -- this year we more than quadrupled our funding in those areas, and we're going to triple that again if our plan goes through, and these are in those three focused areas, because that's where the evidence says we should be doubling down, and that's sort of what is guiding us.

Mr. Murphy. Thank you. Is the Secretary asking for legislation on this, then, to facilitate the answer to that question?

Mr. Frank. There are some legislative proposals, and some of it is just increasing some of the use of our discretionary funds, and we got some additional appropriations this year, and then in the President's budget, we have sort of some legislative proposals for --

Mr. Murphy. Could you please let this committee know if there's enabling language we have, and that would help address Mr. McKinley's question?

Mr. Frank. Yep.

Mr. Murphy. Thank you.

Ms. Clarke of New York, you're recognized for 5 minutes.

Ms. Clarke. I thank you very much, Mr. Chairman, and our ranking member, and thank you to all of our witnesses for giving the committee the benefit of your expertise and experience today.

I'd like to focus my questions on the prevention side of the equation, how do we prevent opioid addiction in the first place. So, Dr. Volkow, why -- picking up actually on a point that Mr. Botticelli made just a moment ago about way too many prescriptions, this is to you, why are so many prescriptions being written for opioids? Are physicians not getting the appropriate level of training and education in pain management for responsible opiate prescribing practices? What would you say?

Dr. Volkow. There are both. Actually, what had happened is we have to recognize that there's another epidemic of chronic pain in our country, estimated 100 million people, according to the Institute of Medicine. As a result of the pressure of needing to address this problem, the joint accreditation require that hospitals and physicians in hospitals demand -- ask questions about pain and treat them. This was in 2000. And the problem was that that was not associated with the education required in order to be able to properly screen pain, but also to manage it, and to manage it and use opioid medications

adequately. So there was a big gap between the need to implement better treatment for pain, but an inadequate education of that system, so that is a major problem.

I think that in terms of the prevention, we have to recognize two aspects of this epidemic that's different from the others. One of them, we do have individuals that start diverting and they get the medications because they want to get high, but then there's the other element that is as important, of individuals that are properly prescribed the medication because they have pain. And in the past, it was believed that you got an opioid and you had pain, you will never become addicted. Now the data shows us that that's not correct. We don't exactly now what percentage of individuals that will be treated for their pain will become addicted. The range goes enormously from none to something like 40/60, so we have no real idea. So what we need to -- and that's why I highlighted the notion of we need to be very aggressive in the education of healthcare providers on the screening and management of pain, but also be very aggressive on the treatment -- on the education of healthcare providers for the recognition of substance abuse disorder so that they can determine who's vulnerable, and when a person that's properly being treated is transitioning and how to intervene.

Ms. Clarke. Very well. Thank you very much.

Director Botticelli, does ONDCP believe that the Federal

Government should mandate continuing medical education on responsible opioid prescribing practices as a precondition of DEA registration to prescribe controlled substances? And can you elaborate on how that would work if that's the case?

Mr. Botticelli. Sure. We do support mandatory prescriber education. I think for all of the evidence that you've heard today, it's very clear that if we really want to prevent both prescription drug misuse and heroin use and overdoses, we need to stop prescribing these medications so liberally.

There was a recent GAO report that showed that physicians get little to no pain prescribing, and actually veterinarians get more pain prescribing than physicians in the United States. So we don't think that it's overly burdensome to require physicians in this epidemic to have education.

I think, as you talked about it, we'd have to work with the legislature to look at changes to the Controlled Substances Act to ensure that a certified continuing medical education program would be linked to the DEA licensure or relicensure process, and that we would monitor both the -- oversee those courses that we believe have the core competencies that we think are important and monitor who takes those.

RPTR RULL

EDTR SECKMAN

[11:53 a.m.]

Ms. Clarke. Very well. Thank you very much.

Dr. Throckmorton, manufacturers of opioid pain relievers are currently required to offer free voluntary education to physicians or responsible opioid prescribing practices. However, as I understand it, physician participation rates for these voluntary educational courses are fairly low. Is that correct?

Dr. Throckmorton. We do have those programs in place. They were put into place about 18 months ago, and so the initial year was spent putting into place a process to allow the education to be available, prescribers to make use of it. During that time, we saw about 20,000 prescribers of -- that are using extended-release long-acting opioids sign up for one course. That's true; 20,000 out of 320,000 prescribers that prescribe these medicines is not -- is not a large fraction. It is progress, but we hope is in the second year, which will end of July of this year, we'll see a larger increase in terms of uptake and use of this education. We have been working with the continuing education community to make better use of it, make it more available. We're optimistic. We hope that we'll see more use.

It's one of two pillars of education from our perspective.

Combined with the mandatory education that Mr. Botticelli just spoke about, we believe both of these things provide important opportunities to educate prescribers.

Ms. Clarke. Very well. I yield back. Thank you very much.

Mr. Murphy. Thank you.

Mrs. Brooks of Indiana, 5 minutes.

Mrs. Brooks. Thank you, Mr. Chairman, for continuing the focus on this critical subject for our country.

I want to start with you, Dr. Volkow. We talked about how the opioid addiction facing the country is, in large part, due to chronic pain. And you mentioned that 100 million people suffer from chronic pain. One in -- I've heard up to one in three Americans actually possibly suffer from chronic pain.

And one of the goals of this hearing is to try to focus on evidence-based treatment and new treatments in trying to find out what it is that is working. And, obviously, one treatment doesn't work for everyone, as we've heard.

But there is -- I learned about, in the course of examining this, that there are some technologies that are new, not completely new, but one being -- I was told about spinal cord stimulation, which targets nerves with electrical impulses rather than drugs, and that clinical studies have shown it to be safe: 4,000 patients have received this stimulator. And so it obviously is a -- a device, a technology that

can actually stop that stimulation and can help hopefully end that addiction, but yet NIH hasn't included that in its draft pain strategy. It didn't mention technologies like SCS.

Can you talk at all about why it wouldn't be promoting this FDA-approved type of technology? And are there other technologies we ought to be talking about other than medication for chronic pain?

Dr. Volkow. Yes. Thanks for the question.

And this -- this is an area that is rapidly evolving. And if it's not mentioned, it's because many of the findings are very way too recent. And the one that you're commenting in terms of stimulation is one of the strategies that we're also promoting research. And the same strategy can be utilized to be able to actually inhibit the emotional centers of the brain that react to pain.

So researchers are utilizing a wide variety of tools and technologies that have evolved as part of our work initiatives to understand the brain. That, again, highlights -- but it brings up something that, I think, that in these -- that is facing us in this epidemic, the need that we have to develop better strategies for the management of chronic pain because the physicians are forced -- patients in great suffering, they don't know what to do, and they give an opioid even though the evidence does not really show us they are very effective for the management of chronic pain. But there are not many out there.

So recognizing that this is an area where we require to invest resources for having alternatives for patients suffering from chronic pain is an extremely important part of an initiative of addressing --

Mrs. Brooks. How would you recommend we increase, then, patient access and educate more physicians about this type of technology?

Dr. Volkow. Well, this is a new technology, some of them. Actually, the evidence is just emerging. It will have to be submitted to the FDA for approval. And then physicians, as part of their training, should be exposed to them. And I would say -- I am just highlighting in the notion because Michael Botticelli very clearly delineated, I also think it's important that medical students, as part of their basic training, have an understanding of these technologies because pain is part of every medical condition, almost of every medical condition.

Mrs. Brooks. Thank you very much.

I'd like to ask you, Mr. Botticelli, my State, State of Indiana, recently passed a law allowing physicians to prescribe the naloxone to parents and to others and friends, giving them greater access to the reversal heroin drug.

Would you speak as to what's known about the impact of the naloxone programs and whether you have concerns about whether the naloxone might encourage actually more risk-taking? Because I met with law enforcement who said they had given people -- naloxone had saved their

lives and, a couple weeks later, saved their life again with the naloxone. And so I am somewhat concerned -- and I absolutely want to save lives, and we must. But yet -- and we know there aren't enough treatments. This is obviously a huge problem.

But might that encourage an addict, if they knew their mom, dad, or friend had the save right there? Can you talk to us about these naloxone programs?

Mr. Botticelli. Sure. So, to your first question, obviously, naloxone distribution by as many people who are -- who are -- have the potential to witness an overdose are particularly important. And law enforcement, particularly in rural counties, also play a key role in that -- in that effort.

I will tell you, by way of -- when I was in Massachusetts, we significantly increased access to naloxone and actually did a peer-reviewed study that showed when you introduced naloxone into a community, overdose rates go down. And the more naloxone you introduce, the better the scale effect.

I -- you know, one of the pieces that we are concerned about -- but there is absolutely no evidence to show that naloxone distribution actually increases drug use. Some of the issues that you mentioned become critically important, that overdoses are often seen as a significant motivator for people to seek care. But having treatment on demand is a particular issue. Treatment on demand, particularly

in some of our rural communities, is particularly an issue.

Interventions that are emergency departments to get people into care become critically important. So while we know that some -- addiction is a chronic disease and some people do continue to use, when you have these adverse events, but we also need to know we have to have a comprehensive response, not just saving someone's life.

Mrs. Brooks. Thank you. I completely agree, and I certainly hope the results in Indiana prove out to be the same as in your State.

And I yield back. Thank you.

Mr. Murphy. Gentlelady yields back.

Mr. Mullin from Oklahoma, you're recognized for 5 minutes.

Mr. Mullin. Thank you, Mr. Chairman.

Before I get to some questions, I have got a followup question for Ms. Hyde. The last time that you were in front of this committee, which I really appreciate you coming back, we had discussed your Web sites and if they were an effective use of taxpayer dollars. At that time, you stated that you were all in the process of evaluating that. Have you finished that process yet?

Ms. Hyde. That process continues. Thank you for asking the followup question. The process continues. I think the Web site that you indicated most concerns about was one of the Web sites that we were in the process of reviewing. It was originally developed based on data and knowledge from NIDA.

Mr. Mullin. Right. And which --

Ms. Hyde. And we have --

Mr. Mullin. Well, that was for the 3- to 6-year-old for suicide prevention. Have you finished that one yet?

Ms. Hyde. Yeah. Building blocks --

Mr. Mullin. Right.

Ms. Hyde. -- I think is the one you were concerned about. We have worked with our colleagues at NIDA and determined that the Web site hadn't been updated in a while, so it needed to be updated. So we have taken it down and are in the process of updating it.

Mr. Mullin. Could you give me some process reports on that, just so I can kind of know where you guys are at? We just want to make sure that taxpayer dollars are being used in an effective way.

Ms. Hyde. Certainly.

Mr. Mullin. To get to the questions, Dr. Throckmorton, just a simple yes or no. Does the FDA recommend that methadone be used as a first line of therapy for chronic pain?

Dr. Throckmorton. Methadone is approved for use for pain, yes.

Mr. Mullin. Is it -- but I am specifically speaking to the first line, for a first line of defense basically.

Dr. Throckmorton. It's one of the medications that we have approved for pain. I will say, however, that if you look at methadone, if you look at the labeling that we have for methadone, it calls it

out as far as a product that has particular characteristics that make it challenging to use for pain.

Mr. Mullin. So that would be -- that would be a no for the first line.

What is your recommendation for first line?

Dr. Throckmorton. Our recommendation is prescribers think very carefully before using methadone. There are things that make it a challenging product to use. It is approved for use in that setting, but I hope doctors think very carefully before they do it.

Mr. Mullin. Well, the FDA put out a warning about the drug safety and basically said that you guys -- that insurers should not -- should not be referred as a preferred therapy, unless special instructions and education was put onto it. So I would take that as the FDA would, by this statement, that it'd be a no, that you wouldn't recommend it unless there's a lot of consideration taken.

Dr. Throckmorton. Personally, what I just said is where I would be.

Mr. Mullin. Okay.

Dr. Throckmorton. I need to look at the statement and get back with you about the specifics of it.

Mr. Mullin. Okay.

Dr. Throckmorton. But it is a drug that has a very long half life that is variable patient to patient. It has unique cardiac toxicities.

There are other drugs that are useful for pain that don't have those characteristics and I --

Mr. Mullin. Sure. All we're -- all I'm really looking for is a yes or no because I'm really trying to get -- get to another -- further on down the line for questions. I do appreciate you being here. And I like the last name; that's my sister's last name. And I got some beautiful --

Dr. Throckmorton. A very good last name.

Mr. Mullin. I know. I've got three beautiful nieces. But the spelling usually gets messed up.

Dr. Houry, what about the CDC? Do you guys consider this methadone as being a first line of defense for pain?

Dr. Houry. At CDC, we just focus really on the primary prevention and not as much of the care, so I would defer to the sister agencies on that.

Mr. Mullin. Which would be?

Dr. Houry. The panelists here. FDA.

Mr. Mullin. Well, Dr. Throckmorton kind of gave his personal opinion. But the statement of FDA you heard about. So would you follow the statement, I'm assuming?

Dr. Houry. I would follow his statement. I don't have a personal opinion on methadone for pain. It's not something I did in my prior practice.

Mr. Mullin. Okay. Dr. Conway -- by the way, I'm always jealous when people have their family with them. I have got five wonderful kids. And if you ever want to see me cry, that's about the only thing that will make me cry. I miss them.

Voice. How are your kids doing?

Mr. Mullin. Thanks. I appreciate that.

I will take a deep breath and wipe the tear away.

Are you aware that methadone accounts for 30 percent of overdose deaths while only accounting for about 2 percent of the prescriptions that are prescribed for chronic pain?

Dr. Conway. I am aware that it's a higher percentage of deaths compared to prescriptions because of the long half life and risks described.

Mr. Mullin. Would you personally recommend it as a -- as a first line of defense for pain?

Dr. Conway. So I'm a practicing physician. I do not, as a practicing physician, typically use methadone as a first defense. However, I think it depends on the individual patient characteristics and would defer to the physician's judgment with that individual patient.

Mr. Mullin. Well, according to the Pew research, they put out a deal that said methadone is available in low-cost generic form and is considered a preferred drug in many States by the Medicaid programs,

despite FDA warnings about the drug safety and the statements by the American Academy of Pain Medicine that insurers should not be preferred this therapy unless it's especially educated and provided to the individual.

I just kind of wonder if -- overall, I would think, we're considering it not being there. Why is this still listed as a first line with Medicaid, I mean, when we're seeing so many deaths? It almost makes you think, is the cost of a life not more valuable than the cost of a low drug?

Dr. Conway. So I'd make a few points. Statutorily, the Medicaid programs have the ability to set their preferred drug list. However, we have taken a couple of actions that I think to try to address this issue. One, working with SAMHSA, NIH, and others on this panel, we have put an informational bulletin to the Medicaid programs talking about this issue and a complete array of pain, both on the medication side, the risks of methadone, and the other options and, also, importantly as others have said, the importance of both behavioral treatment and medication treatment.

I'd also call out, in our Medicaid Innovation Accelerator Program, the first area we're working on is substance abuse disorders. We have over 30 States involved, and they're taking a comprehensive approach to the Medicaid program to appropriate substance abuse treatment, including appropriate use of medications and also other

therapies.

Mr. Mullin. Dr. Conway, appreciate it.

Mr. Chairman, I yield back.

Mr. Murphy. Mr. McKinley has a followup question. Then I have a followup question, too, so --

Mr. McKinley. Thank you for the opportunity just to follow up because one of the questions or statistics I was giving you in talking about prospector is the model or the situation that they're facing in Europe. What do we have there in Europe? The average is 21 per million. And I was just looking at -- that's the average.

Italy, Italy is below that. Latvia, Netherlands, Belgium, Greece, France, Poland, Portugal, Bulgaria, the Czech Republic, Slovakia, Hungary, Turkey, Romania, all have less than that, significantly less. What are they doing right? What are they doing differently in Europe than we are in America? Are we learning anything from them?

Dr. Volkow. There is something that we're doing very differently. And, actually, you pick up exactly on the point. If you look at United States, from some of the medications we may be consuming 95 percent of the total production in the world.

So the question is, are we a Nation that is so much in pain that we require these massive amount of opiate medications? Or is there something that we are doing in terms of their access to them that is

inadequate?

And I want to, again, to reiterate the notion that, yes, we are overprescribing opiate medications, on the one hand. But, at the same time, which is not exclusionary, sometimes we are undertreating patients with pain. So we are in a situation that we have it bad in both ways. We over -- overprescribing, making these drugs available, which then can be easily diverted; and prescribing them to those that don't need them can also result in adverse consequences. You don't see that level of prescriptions in none of the European countries.

Mr. McKinley. So what's the -- why not? What are they doing? Are their doctors more sensitive to this issue than our doctors in America? Are they concerned about the trial lawyers? What's the difference between it?

If there are 10 to 15 times more people dying in America than there are in Europe, something is wrong. They're doing something differently, and I'd sure -- I'd like to know what it is.

Dr. Volkow. And that's one exactly -- the way that I say we have to aggressively institute the education of the healthcare providers on the proper screening and management of pain -- that's a crucial component -- while also educating them about the adverse effects as it relates to substance abuse disorders.

And we need to face the fact that we need to also provide with alternative treatments for the management of chronic pain that are

effective.

Mr. McKinley. Okay.

Yield back.

Thank you very much for that.

Mr. Murphy. Ms. Collins, you have a quick question?

Mrs. Brooks. Brooks. I'm sorry, I was looking at Collins' name. Where am I going? Where am I going?

Mrs. Brooks. Thank you. This is -- actually, I realize Mr. Botticelli mentioned it in his opening, and I wanted to have an unrelated followup if I might, Mr. Chairman.

Mr. Murphy. Yes, you may.

Mrs. Brooks. You mentioned -- and we are having a crisis in Indiana with respect to -- in Scott County, a community of 4,300 people, an outbreak of HIV due to needle exchange. And I would simply like -- and I hope that many of you have been following what has been happening and the number of citizens in Indiana who now have contracted HIV because of their, in all likelihood, heroin addiction, right.

Mr. Botticelli. Prescription drug.

Mrs. Brooks. Or prescription drug addiction and possibly heroin addiction as well.

I am very curious, since I have this incredible panel of experts here, what you might say to our State and to the health professionals, our public health professionals who are dealing with this crisis, to

our State and local government officials, what advice and thoughts do you have for our State? And I truly, if we could, this is a crisis in our State that I think could be in any State in the country.

Mr. Botticelli --

Mr. Botticelli. Sure.

Mrs. Brooks. -- and then anyone else who might comment, please.

Mr. Botticelli. So, first of all, just about the staff from all of the agencies on this table coordinate on a daily basis in tight coordination with the Indiana Health Department to make sure that we are giving Scott County the resources they need to do that.

Mrs. Brooks. Thank you. And I'm sure Dr. Adams appreciates that.

Mr. Botticelli. You're absolutely right that while we're seeing huge -- I think we're over 145 cases of HIV now -- one of the consequences we've seen nationally is increases in viral hepatitis as it relates to sharing needles. And I think it also points to some issues that we need to include about access to treatment services.

So I think what's happening in Indiana in Scott County is emblematic of the potential that we could see in other parts of the country but point to some of the issues that we've been talking about today in terms of making sure that people have access to good care, both infectious disease care and substance abuse care; they have adequate access to clean syringes so that they are not increasing

infection in this most poignant case of what we need; and that they're having timely access to treatment services, I think, are all areas to do that.

We'll continue to engage with folks in Scott County to make sure that whatever we can do on the Federal side can help alleviate the situation.

Dr. Houry. And I'd just like to add to that I'm really proud of all of the efforts CDC is doing on the ground in Indiana and in conjunction with agencies here, I agree completely with Director Botticelli about the access to medication-assisted treatment as well as the HIV therapy.

The other thing I would add is Indiana is number nine in the Nation for prescribing, and so there's a lot that can be done when you're looking at, again, trying to stop the epidemic before it even happens. So looking at, again, using the Prescription Drug Monitoring Program, having better prescribing guidelines, so that people don't get addicted to opioids, then inject them. So that's the third component, I think, we really need to add.

Mrs. Brooks. Dr. Volkow --

Dr. Volkow. Yes.

Mrs. Brooks. Or, I'm sorry, and Administrator Hyde. Maybe Dr. Volkow and then Administrator Hyde.

Dr. Volkow. There's another -- I mean, we got caught by surprise

with the Indiana epidemic of HIV, and I heard Tom Frieden say this is the fastest growing incidence of HIV cases that we've had since HIV entered the United States.

But there's been an extraordinary advance on HIV that has emerged really over the past 2 years -- past 2 or 3 years, which is that if you initiate someone on antiretroviral therapy, not only are you going to be improving their outcome, but you are actually going to dramatically decrease their infectivity.

So, in looking toward -- as one of the things I would have suggested to do is once you start to see a case, you immediately treat them with antiretroviral therapy. They'll do better, and their infectivity will dramatically increase. So this is another aspect, which actually relates to the issue giving of care -- to good infectious disease care to these individuals jointly with the interventions for substance abuse treatment.

Mrs. Brooks. Thank you.

Ms. Hyde. So I just wanted to add that we are working collectively on this issue and that we understand there may be some legal barriers that we've been talking to Indiana about in terms of developing opioid treatment programs, and there's not a lot of waivered physicians able to provide buprenorphine. I think the closest opioid treatment program is about 40 miles away. There may be some transportation barriers and some cost barriers and other things. So

we're collectively working with the State to try to help develop alternatives.

Mrs. Brooks. Thank you, Mr. Chairman, for allowing me to give that voice.

Mr. Murphy. Thank you.

I have two quick followup questions. First, Ms. Hyde, last week, the subcommittee heard testimony from Dr. Anna Lembke, the program director of the Stanford University Addiction Medicine Program that the 42 CFR part 2 is an artifact of the past. She told us the law's consent requirements are so stringent that two doctors seeking to treat the same patient for opioid addiction can't communicate with each other about the patient's medical condition. In fact, she cited that the subcommittee -- and we received subcommittee reports. The rule was based upon a 1972 law, and it's causing havoc in the age of electronic records. I guess sometimes the police would actually raid a methadone clinic and arrest people there.

Now -- so she has strongly recommend that we change that so we are not overprescribing people and we know who -- a physician can know who is in treatment.

Now my understanding is that SAMHSA is contemplating new 42 CFR part 2 rules. And I just want to know if you're committed that these rules will reflect the concerns that have been repeatedly voiced by so many in the medical community who treat patients with substance abuse

who want nothing more than to make sure patients aren't given double dose, so they can really communicate. Is that what SAMHSA is going to be working on?

Ms. Hyde. I really appreciate that question. It is a complex issue. And you're right; these laws and regs are decades old, before we had electronic health records, before we had collaborative care models and other things that we are now considering part of the practice.

We, a couple of years ago, put together some subregulatory guidance to try to help this issue, but that wasn't sufficient. So, last year, we held a listening session for stakeholders and have taken those pieces of input and are trying to balance the privacy concerns with the need for access to data. We hope that we will have something available for public input yet this year to try to address some of these issues.

Mr. Murphy. And please let the committee know. Thank you.

And, Mr. Botticelli, I wanted to follow up on this Kentucky drug court issue. Could the drug courts' decisions relate to the issue of diversion? I mean, at a previous hearing, we heard testimony from witnesses that Suboxone mills are popping up in Kentucky and West Virginia and these are high problematic States. And, when entering the drug court system, it's nearly impossible to determine if the Suboxone is from an illicit source or prescribed by a doctor.

Could this be part of the issue and the drug courts could make -- that the drug courts could really work and perhaps have some flexibility to deal with this on a case-by-case basis?

Mr. Botticelli. So I think there are a number of issues. The National Association of Drug Court Professionals actually did a survey of drug courts in the United States. And for those drug courts that were not referring, it was actually more about judicial bias than it was about fear of diversion that kept people from doing that.

I think the second piece that any -- any treatment, whether it's medication-assisted treatment or residential treatment, requires a level of collaboration and relationship between the court and the provider to ensure that courts who are referring to treatment are referring to high-quality treatment.

You know, we do need to pay attention to diversion. And drug courts, I think in combination with treatment programs, can ensure that these are appropriate -- appropriately prescribed and appropriately monitored medications. And they need to make sure that they're partnering with physicians who are implementing and dispensing medications in a high-quality way.

Mr. Murphy. Now, part of this -- I just got an article that was -- I'm not sure what newspaper it is. But it was talking about in some of these courts, they're using Vivitrol and for people in and out of incarceration trying to keep them off by maintaining Vivitrol.

So I just want to make sure I understand. They want to keep these people, after they're released from prison, drug-free. And so could you please clarify: Are you saying that unless they have some synthetic opiates, they're going to have Federal funding cut of -- Federal funding cut or they can still maintain Federal funding and then Vivitrol would be acceptable as another part of the program?

Mr. Botticelli. So we don't dictate to drug courts what medications. That actually should be a decision between the treatment provider and the patient.

I think our work here was just to make sure that there weren't categorical prohibition for drug courts either to not offer medication-assisted therapies and, if someone was on a recommended course of treatment, that they not have to get off the medications to do that.

We actually don't dictate what medications courts use to be able to do that. I think, like any treatment, you want to have an arsenal of medication.

Mr. Murphy. Dr. Frank, could you also respond to the Vivitrol question, too? Did you hear that, or is that -- I'm just wondering as that as an option for States as a diversion to be using Vivitrol, that that could be part of what we could be --

Mr. Frank. Well, I think that --

Mr. Murphy. Microphone, please.

Mr. Frank. I think that we are trying to have the full armamentarium available to the treating providers who are trying not to get between the provider and the patient as long as there is the opportunity to offer the most -- the richest menu of evidence-based treatments that are available.

Mr. Murphy. Mr. DeGette, do you have a followup?

Ms. DeGette. Mr. Chairman, I -- Mr. McKinley asked what -- asked the witnesses what one thing would you recommend that we could do to try to start reversing this epidemic and this problem. He got as far as Dr. Frank when he ran out of time. So I just ask unanimous consent, if we can ask each one of the other witnesses --

Mr. Murphy. Yes, please.

Ms. DeGette. -- to supplement their testimony. They don't have to say it right now.

Mr. Murphy. Get back to us. Thank you.

Ms. DeGette. But if you can get back to us with that recommendation. We recognize there is a problem, and we are really struggling with the issue of what we do as a Congress to remedy it. Thank you.

Mr. Murphy. And I think what you're also talking about, a partnership with the States -- says we should be looking at Kentucky and some others -- Indiana --

Mrs. Brooks. Indiana.

Mr. Murphy. -- Colorado, of course, and see what else is going on.

I want to thank this panel. We will follow up with the questions because we heard a number of recommendations from you, so we will ask for more clarifications of this.

Look, I want to thank you. As I said last time, too, you know, if this was about a single airplane crash, this room would be filled with media. But we have had more people die in the last year from drug overdose deaths than the combination of every airplane crash in North America from 1975 to the present. And we have to make sure we keep this on the front page. This is a serious crisis and one, whether it's education of physicians, mandatory education, whether it's options out there, we want to make sure the evidence-based care and that Federal funding is going in the right direction.

So I'd like to thank all the witnesses and members that participated in today's hearing.

I remind members they have 10 business days to submit questions for the record, and I ask that all the witnesses agree to respond promptly to the questions.

With that, this committee is adjourned. Thank you.

[Whereupon, at 12:22 p.m., the subcommittee was adjourned.]