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COMBATING THE OPIOID ABUSE EPIDEMIC: PROFESSIONAL AND ACADEMIC PERSPECTIVES

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTEENTH CONGRESS

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THURSDAY, APRIL 23, 2015

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:17 a.m., in room 2322 of the Rayburn House Office Building, Hon. Tim Murphy (chairman of the subcommittee) presiding.

Members present: Representatives Murphy, McKinley, Burgess, Blackburn, Bucshon, Brooks, Mullin, Hudson, Collins, Cramer, DeGette, Schakowsky, Tonko, Clarke, Kennedy, and Green.

Staff present: Leighton Brown, Press Assistant; Noelle Clemente, Press Secretary; Brittany Havens, Legislative Clerk; Graham Pittman, Staff Assistant; Chris Santini, Policy Coordinator, Oversight and Investigations; Alan Slobodin, Deputy Chief Counsel, Oversight; Sam Spector, Counsel, Oversight; Jean Woodrow, Director, Information Technology; Jeff Carroll, Democratic Staff Director; Ashley Jones, Democratic Director, Outreach and Member Services; Christopher Knauer, Democratic Oversight Staff Director; Una Lee, Democratic Chief Oversight Counsel; and Elizabeth Letter, Democratic Professional Staff Member.

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. MURPHY. All right, good morning. We are here at the Oversight and Investigations Subcommittee hearing on Combating the Opioid Abuse Epidemic: Professional and Academic Perspectives. Welcome.

Less than 1 month ago, on March 26, we held the first in a series of hearings to examine the growing problems of prescription drugs and heroin abuse. During that brief span of time, according to the best estimates from the Department of Health and Human Services, at least 3,374 Americans will have died from drug overdoses, with opioids being the most common cause. That is 3,374 overdose deaths in less than 1 month. Indeed, during the time we spend in this hearing, another 10 lives will be lost.

The headlines out of Pittsburgh last week sent shockwaves throughout my district with 10 heroin overdoses in a single 24-hour period. Of the two who died, they were found with stamped bags

marked either "Chocolate" or "Chicken/Waffle." And this is what we are up against. This is what is killing our sons and daughters, brothers and sisters, mothers and fathers.

Let me state clearly so as to leave no room for doubt: Our current strategy just isn't working, and I am not going to stop until we start moving in the direction of success, defined not just as getting individuals off of street drugs and onto a Government-approved opioid, but getting them to the point of drug-free living.

About 3 weeks ago, on the very same day this committee held our first hearing on this issue, the Department of Health and Human Services released its long-awaited three-part plan to reverse this epidemic. Elements of the plan made sense; however, I am puzzled and amazed to read one particular priority included in their press release, and I quote, "Exploring bipartisan policy changes to increase use of buprenorphine and developing the training to assist prescribing."

We are in desperate need of innovations to reverse the current trend and not merely maintain it. Why would we focus only a single opioid replacement program rather than the full range of FDA-approved treatments for opioid addiction? Why the fixation on one pharmaceutical product? According to testimony presented to this committee last year by the Director of SAMHSA's Center for Substance Abuse Treatment, nearly 1 million people were prescribed buprenorphine in 2011. We know that number is much higher today, probably closer to 1.5 million people or more. Think about that. Success by Federal Government standards for addiction disorders is 1.5 million people prescribed synthetic opioids. Yet, consider the sad fact that States have not seen their investment in prescription clinics reverse this opioid epidemic. States like Maryland, Vermont, Massachusetts and others that have made massive investments in buprenorphine maintenance have not seen reductions in overdose deaths. On the contrary, things have gotten much much worse.

According to the DEA, buprenorphine is the third most confiscated drug in law enforcement activities in our country today. More than morphine, more than methadone, more than codeine. Patients are routinely getting buprenorphine prescribed as "heroin helper", meaning they get a month's supply of buprenorphine to use whenever they can't get heroin. It tides them over, enabling them to remain in their active addiction. This should more accurately be called addiction maintenance, not just the euphemistically called, opioid maintenance.

Some addicted to methamphetamines go to local bupe mills and get a 30-day supply that they promptly sell to buy their drug of choice. In the field of addiction treatment, the enabler is part of the problem. Helping intentionally or unintentionally to keep a family member as an alcohol or drug addict is enabling. Here, the U.S. Government is the biggest enabler of them all.

Some clinics operate cash-only businesses for writing 30-day supplies of buprenorphine at the highest permissible doses; usually 32 milligrams, knowing full well patients will sell at least of half of the pills in order to pay for their treatment or other illicit drugs.

At our last hearing, Professor Sarah Melton at East Tennessee University noted that that there are methadone clinics operating

on a cash basis, handing out methadone without any other treatment, or buprenorphine pill mills. It is not acceptable that Federal taxpayer money be used to support programs that hand out these drugs for cash. Worse, Professor Melton testified that there was a dearth of good treatment programs. And what happens after the patient leaves the treatment program? What is being done to follow-up with patients to prevent relapses and put them on a path of real recovery? I fully recognize the importance of medication-assisted treatment as a transition from street drugs and to prevent overdose from heroin, but relying on this as the one and only solution shouldn't be the strategy.

As I recently heard Dr. McLellan, the former Deputy Director of ONDCP say, while there is an appropriate place for medication-assisted treatment, we should not turn a blind eye to the fact that there is also a tremendous amount of medication-assisted addiction. It is not acceptable for Federal taxpayer money to be used to support treatment programs that lack evidence of effectiveness, or that define success merely as an individual with an addiction disorder using heroin fewer times per week than before treatment.

I am calling for a patient-centered initiative with a goal of matching patients with the most appropriate care, coupled with a focus on transition not just off street drugs, but eventual transition from opioids altogether. I hope to modernize our existing opioid addiction treatment system to ensure that the right patient gets the right treatment at the right time. It simply isn't true to present buprenorphine and methadone as opioid-free treatment. We do a tremendous disservice to those living with addiction disorders when we advance disingenuous double-talk and not state outright that buprenorphine and methadone are highly potent opioids.

We are not going to end this opioid epidemic by increasing the use of opioids. We need an exit strategy that enables Americans to become opioid-free altogether. We can do better than addiction maintenance. We can and we must.

I look forward to working with my colleagues and HHS as we explore new innovations for detoxification and treatment models to transition individuals off of all opioids and into evidence-based counseling with non-addictive, non-narcotic behavioral and medication treatments. We don't do enough to help those addiction disorders. I believe in recovery. I believe in lives being restored so that every individual may live to their full God-given potential and do so drug free. I consider opioid maintenance as a bridge to cross over in addiction recovery, not a final destination. At this point, the Government simply stopped building the bridge. We have not yet fully helped move those with addiction disorders beyond opioid maintenance, and I seek to lay out a vision for recovery that includes complete withdrawal from opioids as an option. Once we lay out those goals, we can then move forward with research and clinical efforts, and boldly declare that we are no longer satisfied with the status quo of opioid maintenance only.

To assist us today, the subcommittee will hear from some of the Nation's foremost professional and academic experts in the field of opioid addiction. Among these questions we hope these experts will address are, What can be done to incentivize individual compliance with prescribed treatment plans and reduce the risk of relapse?

What should be the aim of treatment for opioid addiction: reduce the intake of illicit drugs by these individuals to more moderate levels, or should the aim be to place patients on a path to detoxification and ultimately a full recovery, ending all illicit uses and removing the need for lifelong opioid maintenance recovery? To what extent is the increased prescribing of methadone for pain contributing to more overdose deaths? Are Medicaid and Medicare payments for the treatment of pain incentivizing doctors to prescribe the opioids like candy for the treatment of pain?

Today we have assembled some of the leading opioid addiction experts. We welcome you to get your thoughts on dealing with this epidemic. And I thank you for your expertise and look forward to hearing your testimony.

[The prepared statement of Mr. Murphy follows:]

PREPARED STATEMENT OF HON. TIM MURPHY

Less than one month ago, on March 26, we held the first in a series of hearings to "Examine the Growing Problems of Prescription Drug and Heroin Abuse." During that brief span of time, according to the best estimates from the Department of Health and Human Services, at least 3,374 Americans will have died from drug overdoses, with opioids being the most common cause. That's 3,374 overdose deaths in less than one month. Indeed, during the time we spend in this hearing, another 10 lives will be lost.

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• Exploring bipartisan policy changes to increase use of buprenorphine and develop the training to assist prescribing.

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Think about that. Success by Federal Government standards for addiction disorders is 1.5 million people prescribed synthetic opioids. Yet, consider the sad fact that States have not seen their investment in prescription clinics reverse the opioid epidemic. States like Maryland, Vermont, Massachusetts and others that have made massive investments in buprenorphine maintenance have not seen reductions in overdose deaths. On the contrary, things have only gotten much much worse:

• According to the DEA, buprenorphine is the third most confiscated drug in law enforcement activities in our country today. More than morphine, more than methadone, more than codeine.

• "Patients" are routinely getting buprenorphine prescribed as "heroin helper"—meaning they get a month's supply of buprenorphine to use whenever they can't get heroin. It tides them over,enabling them to remain in their active addiction. This should more accurately be called " addiction maintenance" not just the euphemistic, "opioid maintenance."

• Some addicted to methamphetamines go to local "bupe mills" and get a 30-day supply that they promptly sell to buy their drug of choice.

• In the field of addiction treatment, the "enabler" is part of the problem—helping intentionally or unintentionally to keep a family member as an alcoholic or drug addict. Here, the U.S. Government is the biggest enabler of them all.

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Today we have assembled some of the leading opioid addiction experts to get your thoughts about how to reverse this epidemic. We thank you for your expertise and look forward to hearing your testimony.

Mr. MURPHY. I now recognize Ms. DeGette for 5 minutes.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you so much, Mr. Chairman. Before I make my opening statement, I want to announce today is Take Your Daughter to Work Day. My daughters tragically have grown up, but I have my daughter-for-the-day today, Paula, who is with us. Paula is a sixth-grader at Howard Middle School, and she is going to be with me today. She just told me she thought it would be really boring to come to the Capitol, but actually, so far she has found it to be fascinating. So I think she has a career ahead of her in politics, and we are glad to have her.

I am also glad, Mr. Chairman, that we are having this hearing today. This is our second hearing in the series on this very important issue.

This is a problem that touches all parts of the country and is growing. In 2013, 50 percent of all drug overdoses in this country were related to prescription pharmaceuticals. In Colorado, my home State, the rate of prescription overdose deaths has quadrupled in the last 10 years.

I am happy to have this distinguished panel today who I hope can actually talk about, Mr. Chairman, what you suggest which is science-based treatments, and the best practices for treating this disease. All of our panelists have years of experience treating patients struggling with addiction, and I want to hear what all of you think is the most effective treatment.

In our last hearings, we received considerable testimony from experts who told us that medication-assisted treatment, or MAT, can play a vital role in treating opioid addiction. Experts tell us that a combination of MAT and behavioral treatment, such as counseling and other supportive services, is the best way of treating opioid addiction. And, of course, there are several FDA-approved medications that have proven effective in treating opioid addiction.

Now, Mr. Chairman, in your opening, you talked about science-based treatments, and I completely support that. You also talked about patient-oriented treatments, and I support that too. But in doing that, we need to recognize that while it is the goal to get everybody off of these drugs if possible, it is not always the case, and we need to look and see at the treatments that should be available for every patient. And so in an ideal world, we would have all the options available to every patient, and we should strive for that, but right now, MAT is not an available option for all patients. Dr. Bisaga, for example, will testify today that very few patients with opioid addiction receive treatments that have been proven the most effective, which includes access to MAT. What many Americans receive instead is a form of rapid detoxification from the drug, followed by an abstinence-only approach. Dr. Bisaga and others have called this method outdated and mostly ineffective, and even worse, I suppose, it could be dangerous because patients face a significantly elevated risk of dying by overdose if they relapse. So I want to ask questions about that today. Is it true that most Americans with opioid addictions don't receive the most effective treatments? Do they and their loved ones understand that? Is it true that many patients receive treatments that some experts suggest may be inef-

fective or dangerous? And finally, why is not MAT available as an alternative to all patients seeking treatment?

From the perspective of the Federal Government, it is important to have science-based policy so that we are expending our resources on efforts that actually have a chance at success. And patients seeking treatment for opioid addiction should be apprised of the benefits and risks of alternative treatment approaches.

Now, I understand that we need more study to predict which treatment alternatives will be effective for any given patient, and that is why I look forward to hearing from Dr. Seppala about the work he is doing at the Hazelden Betty Ford to collect data on factors. And by that way, in that vein, I want to recognize our former colleague, Mary Bono, who is here with us today, and a former member of this wonderful committee. So we are glad to have you here, Mary.

I also recognize that we need more study regarding how to best treat opioid-addicted patients for the long-term, particularly people who want to taper off of the medications. And I certainly understand and support the desire to move toward medication-free recovery, but we also need to make sure that patients understand the risk.

Finally, Mr. Chairman, much of what is being done to prevent and treat the opioid epidemic is happening on the State level. I am hoping in one of our future hearings that we can have witnesses come from the States to talk about their approaches. In Colorado, for example, we have the Colorado Consortium for Prescription Drug Abuse Prevention, which is a statewide coalition, and which is designing targeted programs. So when we have our hearing, I would like to have someone from Colorado.

I think that this hearing will give us more information, and information and science-based decision making is really what we need to make effective use of our resources to combating this very, very serious problem of opioid abuse.

And I yield back. Thank you.

Mr. MURPHY. Thank you.

I now recognize the vice chairman of the full committee, Mrs. Blackburn, for 5 minutes.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. Thank you, Mr. Chairman. And it is indeed Take Your Daughter to Work Day. And after I get to Nashville this afternoon, my daughter will go to an event with me. But she is an adult and, of course, has two children of her own, and we will not take them to that event.

It is so good to see our former colleague, Mary Bono, here and I appreciate the good work that she continues to do on this issue.

And, Mr. Chairman, I thank you for the hearing because this is a critical public health issue, and it does need our attention and our best efforts. And we are going to continue to look at this problem of prescription drug and heroin abuse because it has skyrocketed. And since '97, the number of Americans seeking treatment for addiction to painkillers has increased by 900 percent.

That should give us all pause. Deaths related to heroin abuse increased 39 percent from 2012 to '13. That is a 2-year period of time. And while heroin use in the general population is still low, the number of people beginning to use it has steadily increased since 2007. And according to the National Institute on Drug Abuse, part of the explanation for the trend is a shift from the abuse of prescription pain relievers to heroin as a more potent, readily available and cheaper alternative to prescription opioids.

Addiction and deaths due to overdose are just the tip of the iceberg in terms of medical consequences of this problem. One tragic consequence of the problem is neonatal abstinence syndrome. According to Dr. Stephen Patrick at Vanderbilt, in 2013, Tennessee became the first State to make NAS a publicly reportable condition to the Department of Health. From information reported to our Tennessee Department of Health, we know the overall rate is 13 cases out of 1,000 births in the State of Tennessee. We can and we must do better for these babies. Our goal is to improve the Federal Government response to this crisis.

Recently we heard from witnesses who expressed the State and local perspectives on this issue. Last year, we heard from a Federal panel of witnesses, including CDC, DEA, SAMHSA, NIH, and the Office of National Drug Control Policy, and today, we are rounding out this focus by hearing from you all who will give us the professional and academic perspectives. And we look forward to your testimony today, and we welcome you.

And I yield back.

Mr. MURPHY. And nobody else on this side seeking final 2 minutes, then I will turn towards Ms. Schakowsky for 5 minutes.

OPENING STATEMENT OF HON. JANICE D. SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Ms. SCHAKOWSKY. Thank you, Chairman Murphy and Ranking Member DeGette, for calling this very important hearing on prescription drug and heroin abuse in the United States. Also thanks to our witnesses for coming here today to shed more light on this issue.

This hearing could not be timelier. Increasingly, we are hearing reports of the toll this crisis is taking in communities across the country. And like myself, I am sure that every member of the subcommittee has heard stories from their constituents about the toll of prescription drug abuse and heroin abuse, the toll that it has taken in their districts.

I have mentioned previously before this committee that I have a constituent, Peter Jackson, who tragically lost his 18-year-old daughter, Emily, after she consumed a single Oxycontin tablet that she received from her cousin while visiting family. I look forward to hearing from our witnesses about the most effective ways to combat prescription drug abuse, to learn what additional steps we can take together to stop this crisis, and to prevent the further tragic loss of life.

I also want to call attention to the impact that reducing discretionary spending will have on access to treatment and research on addiction. Just yesterday, House republicans approved budget allo-

cations that will further cut discretionary spending for vital programs like SAMHSA and the National Institutes of Health. We have already heard—and we have already seen devastating cuts to these same programs. For example, the Substance Abuse Prevention and Treatment Block Grant within SAMHSA when adjusted for inflation has actually been cut by 25 percent in the last 10 years.

While we are here today to discuss the most effective methods of treating addiction, without Federal funding for programs, patients will simply not have access to these services, and research on addiction and treatment of addiction will greatly suffer. That is just a fact. If we are serious about combating the opioid epidemic, it is incumbent that we provide strong Federal funding for the programs that patients and researchers rely on.

And I want to yield the balance of my time to Representative Tonko.

OPENING STATEMENT OF HON. PAUL TONKO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. TONKO. I thank the gentlewoman from Illinois for yielding.

Each and every year, I have spent Super Bowl Sunday in a soup kitchen, working alongside and serving individuals of the addiction recovery community. Why? Because I choose to land myself in the midst of real heroes. The individuals of the addiction recovery community, in my mind, through their courage, determination, and conviction are truly heroes. Bearing witness to the joy and rebirth that recovery has brought to their lives leaves me no doubt that complete recovery to a substance-free life is, and should be, our goal for every person who is struggling in the throes of addiction; a disease.

While recovery remains the goal, it is nearly impossible to achieve without access to effective treatments. Science tells us that the most effective treatment available for opioid addiction is a combination of medication-assisted treatments, commonly known as MATs, and behavioral therapy. MATs might not be the preferred treatment for everyone, but they constitute a vital tool in our toolbox for treating opiate addiction. Unfortunately, MATs were available in only 9 percent of all substance use facilities nationwide in 2013, according to SAMHSA. While I will acknowledge the concerns that a reliance on MATs can raise, the immediate tragedy here isn't that some individuals won't be able to taper off maintenance medications, it is that most won't even be able to access an evidence-based treatment modality that has proven to be their best chance of easing the burdens of addiction and saving lives. Across my district, there are hundreds on waitlists to access this treatment. Every minute we delay, needed treatment costs lives. In just the time that we are having this hearing today, 5 more people will die from am opioid overdose, and 4 out of 5 addicted to opioids will have no access whatsoever to treatment. This is totally unacceptable.

No treatment option is perfect, and I strongly support further research that will help us create more effective treatments and cures that can rid us of addiction once and for all. For now though, our focus has got to be on curbing the epidemic, expanding treatment,

savings lives, and giving people the stability they truly need to achieve recovery.

I look forward to hearing the perspective of our witnesses on these pressing issues. And I yield back, Mr. Chair, the balance of my time.

Mr. MURPHY. Thank you. The gentleman yields back.

And so we will go right into our witnesses and try and get all your testimony done before we have votes, and we will come back after votes too.

We have with us today Dr. Robert DuPont, the President of the Institute for Behavior and Health. Additionally, Dr. DuPont was the first director of the National Institute on Drug Abuse. Welcome. Dr. Marvin Seppala, the Chief Medical Officer at Hazelden Betty Ford Foundation. As acknowledged, Ms. Bono is here with you today. Dr. Westreich is the President of the American Academy of Addiction Psychiatry. Dr. Anna Lembke is an Assistant Professor of Psychiatry and Behavioral Science at Stanford University Medical Center. And Dr. Adam Bisaga is an Associate professor of Clinical Psychiatry in the Department of Psychiatry at the College of Physicians and Surgeons of Columbia University, and and a research scientist at the New York State Psychiatric Institute. Finally, Dr. Patrice Harris, Elected Member of the American Medical Association, Board of Trustees. Dr. Harris has served on the Board of the American Psychiatric Association, and was an APA delegate to the AMA. I feel like I should get continuing education credits today——

Ms. DEGETTE. I know.

Mr. MURPHY [continuing]. For being here.

I will now swear in the witnesses.

You are aware that the committee is holding an investigate hearing, and when doing so, has the practice of taking testimony under oath. Do you have any objections to taking testimony under oath? All the witnesses say they do not object. So the Chair then advises 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 during testimony today? All the witnesses decline. So in that case, will you all please rise, raise your right hand, and I will swear you in.

[Witnesses sworn.]

Mr. MURPHY. Thank you. All the witnesses have answered in the affirmative. So you are now under oath and subject to the penalties set forth in Title XVIII, Section 1001 of the United States Code. I will call upon you each to give a 5-minute statement. Just pull the microphone close to you, press the button, and make sure the light is on. And try and keep your comments under 5 minutes.

Dr. DuPont, you are recognized first.

STATEMENTS OF ROBERT L. DUPONT, M.D., PRESIDENT, INSTITUTE FOR BEHAVIOR AND HEALTH, INC.; MARVIN D. SEPPALA, M.D., CHIEF MEDICAL OFFICER, HAZELDEN BETTY FORD FOUNDATION; LAURENCE M. WESTREICH, M.D., PRESIDENT, AMERICAN ACADEMY OF ADDICTION PSYCHIATRY; ANNA LEMBKE, M.D., ASSISTANT PROFESSOR, PSYCHIATRY AND BEHAVIORAL SCIENCES, STANFORD UNIVERSITY SCHOOL OF MEDICINE; ADAM BISAGA, M.D., RESEARCH SCIENTIST, NEW YORK STATE PSYCHIATRIC INSTITUTE; AND PATRICE A. HARRIS, M.D., SECRETARY, BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION

STATEMENT OF ROBERT L. DUPONT

Dr. DUPONT. Thank you, Mr. Chair. It is a privilege for me to be with you.

And let me pick up on some of the things that were presented just now. I think one of the most counterproductive approaches to the problem is to pick drug-free against medication-assisted treatment, and I think every time we do that we undermine dealing with the problem at all. We undermine public confidence, and I think it is contrary to what the public interest is and public health. And let me be very clear that I believe that full recovery is consistent with continuing to take medications for opiate dependence; buprenorphine, methadone, and naltrexone. The issue to recovery, to me, is not whether they are taking the medicine, it is are they using drugs, are they using alcohol, are they still involved in drug-dependent behavior. And that is not compatible with recovery. And I am going to talk a little bit more about that issue about drug use in medication-assisted treatment, which I don't think is recovery, but I think that concept is very important, just like these patients taking psychiatric medicines is fully compatible with recovery. So I think that, to me, is a way to bring this together.

And I also point out what Dr. Marv Seppala is going to talk about on the Hazelden Program, which brings together medication and the drug-free programs as the way into the future.

And the last point I want to make before I really get started is to think about the elephant in the room when we are talking about recovery, and that is the 12-step programs; AA and NA, are an enormous part of what we are talking about, about getting well. We did a study, the first national study of physicians health programs, and we have now followed up with that 5 years after the mandatory monitoring. And 97 percent of those physicians were still in recovery 5 years after mandatory—and we asked them what part of the program was most helpful to you, and they were in very high quality treatment and many other services, by far the biggest percentage was participation in 12-step programs. That was what was most important to them. So I want to make sure at our hearing we understand the importance of that in terms of recovery.

Now, my focus is on the users, and I want to make one point very clear. Opiate dependence is not like the common cold; it does not go away, it is a lifetime problem. A person who has opiate dependence is going to deal with that problem one way or another for his or her lifetime. If you don't understand that then the concept of treatment is confusing because you think you are going to be

confusing because you think you are going to be fixed in treatment. People are not fixed in treatment with opiate dependence. Treatment can help them find their path to recovery, but treatment is not recovery, and it is really important that people are not fixed in any treatment, drug-free or medication treatment. It is a lifetime struggle, and that is a very important perspective on this.

Now, my concern is that treatment does not match up with the disease. The treatment is always short-term. Even medication-assisted treatment, which conceptually goes on for a lifetime, has very high drop-out rates, very rapid—patients drop out of the program for medication-assisted treatment. And the other thing is a high percentage of people in medication-assisted treatment continue to use opiates and other drugs while they are in the program. That is very important to notice that and pay attention to that. But even more important, and the thrust of my testimony, all of it is accountability for treatment. What are the results during treatment? What percentage of the patients are continuing to use drugs? How much retention is there? What is the retention curve of the program? How long do they stay in treatment? And when they leave, are they any better off than they were when they came in? Those questions need to be asked and answered in a systematic way.

The other thing I pick up on the chairman's statement about the standard. What we want is recovery. That means no use of alcohol and other drugs, including opiates, not just opiates but all drugs. That is what recovery is. It requires that. And what I am proposing and encouraging the committee to do is to look long-term, because the nature of the disorder is long-term. And I use the 5-year recovery standard. Start with a person who enters treatment. Where is that person in 5 years? And you can look at any program; drug-free or maintenance—or medication-assisted, and ask the question how good is this program at getting a person into a stable recovery. That is one standard for all treatments, and it gets you focused on the long-term. And when we do that in this country, including in the Federal Government, the whole game changes and we have a mechanism to improve treatment. Treatments can all compete on a level playing field to achieve that goal.

So that is my testimony. Thank you very much.

[The prepared statement of Dr. DuPont follows:]

STATEMENT OF ROBERT L. DUPONT, MD
PRESIDENT, INSTUTUTE FOR BEHAVIOR AND HEALTH, INC
BEFORE THE
HOUSE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
REGARDING COMBATTING THE OPIOID ABUSE EPIDEMIC: PROFESSIONAL AND ACADEMIC PERSPECTIVES

April 23, 2015

Dear Chairman and Members of the Committee;

I appreciate the opportunity to offer suggestions on the nation's response to the current opioid epidemic focusing on "demand reduction," the needs of the thousands of people who now are dependent on the nonmedical use of prescription pain medicines and heroin.

I was the second White House drug chief, under Presidents Nixon and Ford, and the first Director of the National Institute on Drug Abuse (NIDA). Prior to that I created and led the Washington DC Narcotics Treatment Administration (NTA) which treated 15,000 heroin addicts in the nation's capital between 1970 and 1973, mostly with methadone. Since 1978 I have been the president of the non-profit Institute for Behavior and Health (IBH), an organization devoted to research and to identifying and promoting better drug policies. I have served as a Clinical Professor of Psychiatry at Georgetown Medical School since 1980. My CV is attached.

My presentation encourages greater access to treatment for opioid dependent patients. However it goes further. It insists on greater accountability from treatment, including public reporting of both the continued drug use that occurs during treatment and the rates of program retention. This is important because there are high levels of alcohol, marijuana and other drug use today by patients in many opioid treatment programs, and virtually all of these treatment programs have high rates of dropping out. By asking what happens to patients after they leave treatment I am proposing a New Paradigm for treatment evaluation, one that is focused on long-

term results. A clear statement of goals of treatments for opioid dependence – both those using medications and those not using medications – is necessary for the programs to be evaluated or improved.

Several facts set the stage for my suggestions. The nation is in the midst of its third devastating heroin addiction epidemic, this one seeded by the explosive increase in opioid prescriptions beginning in the mid 1990's. The first was at the start of the 20th Century, the second started in the late 1960's. While there is much yet to be done to reduce the supply of prescription opioids for nonmedical use and the supply of heroin, I am focused today on what can be done to reduce the nonmedical use of opioids.

This Committee in this hearing, and in its subsequent actions, has the opportunity to critically assess the current state of the treatment for opioid dependence and to demand a much needed public accountability, even as it also encourages a similarly much-needed increase in treatment capacity. I focus on Medication Assisted Treatment (MAT) because that is the mainstay of the current treatment for opioid dependence. However, the concerns I have for the limits of the current MAT apply fully to the non-medication, Abstinence-Oriented Treatment (AOT), of opioid dependence. I have no interest in adding to the long-running war between MAT and AOT. It is a war that undermines public confidence in all substance abuse treatment. Worse yet this internecine battle fails to recognize the reality that all substance abuse treatment needs to be improved.

Let us start with a few facts that underlie all evaluations of treatment efficacy. First, opioid dependence is seldom a brief episode in a person's life. Rather, it is a chronic disorder that lasts a lifetime in the sense that even after a long period of abstinence the risk of relapse is substantial, as was tragically demonstrated last year by the fatal heroin overdose of Phillip

Seymour Hoffman after two decades of sustained abstinence. We know this about former cigarette smokers – even a single cigarette can prove disastrous to a previously dependent smoker. That risk is lifelong. Second, there are few opioid dependent people who do not also have problems with alcohol, marijuana, cocaine and other drugs of abuse. Opioid dependence uncommonly exists as a single substance dependence. Third, all substance abuse treatment, including opioid dependence treatment, is short-term compared to the lifetime nature of the disorder. This universal mismatch is crucial for public health policy.

Three medications are widely used in the treatment of opioid dependence: methadone, buprenorphine, and naltrexone. MAT works only when the medicine is taken. The standard evidence of efficacy is reduced opioid use. In addition, MAT can reduce overdose deaths and reduce infections related to intravenous drug use (such as HIV-AIDS and Hepatitis C) while the patient is using the medicine. Consider how an episode of care ends and what happens to opioid patients when they leave MAT. One scenario for the end of MAT is for patients to gradually lower their doses of medication to zero and then to be monitored while still in the program to establish that they remain opioid (or drug) free for a period of time before they are discharged. An alternative scenario for MAT is lifelong use of the medicine. The actual experience of MAT is clear. Only rare patients taper to zero and are monitored for a period of time and then discharged. The percentage of patients who stay in the programs for many years is also relatively small; although, these multiyear patients are very common in MAT programs. The large majority of MAT patients drop out while still taking medicines. This virtually always means that they return to nonmedical opioid use. In a high quality methadone program we have studied, about 60% of patients left treatment within less than a year and 18% either stayed with the program or were readmitted to it five years after entering treatment. In a similarly high quality treatment

program using buprenorphine to treat opioid dependent patients, only 5% of newly admitted patients were still in the program a year later. In addition to the problem of retention is the problem of continued use of drugs of abuse during MAT which I have seen ranges from a low of about 20% to a high of more than 50%

These concerns can be summarized in three questions. First, what percentage of patients who enter MAT either stay in the program for life or successfully taper off and are then monitored for relapse before discharge? Second, what percentage of patients are continuing to use alcohol, marijuana and other drugs while they are in treatment? Third, what happens to patients after they leave MAT? Are they better off than they were when they entered treatment?

The public widely expects substance abuse treatment to "fix" the addict. No treatment, with or without medication, can "fix" the addict because the risk of relapse is lifelong and treatment is brief. The public – and apparently those who pay for substance abuse treatment – do not understand this reality about the prognosis of addiction after any treatment. It is hard to imagine that any families bringing a patient into treatment would consider a 20% reduction in opioid use for a few months to be a reasonable outcome of treatment.

To move forward we must define the goal for substance abuse treatment. What is the standard against which all substance abuse treatments, both those using medicines and those not using medicines, can be measured? This question led me nearly a decade ago to conduct the first national study of the nation's state Physician Health Programs (PHPs). My colleagues and I looked at PHPs because I had treated many physician addicts in my own practice. I had seen their outstanding results. I had also participated with many others in the development of the Betty Ford Institute's[i] landmark definition of "recovery" from substance use disorders, including opioid dependence. Recovery includes no use of alcohol and other drugs. Our PHP study

demonstrated that recovery could be the expected outcome of treatment rather than relapse. This PHP study also emphasized the importance of long-term random monitoring after leaving treatment and participation in community support programs.

We recently extended our analysis of our PHP data to compare the outcomes for physicians who were dependent on opioids to those who were dependent on alcohol alone, and to the physicians who were dependent on other drugs with or without alcohol. The physicians in all three groups were randomly monitored for any use of alcohol, opioids or any other drugs for five years. The opioid dependent physicians did not receive buprenorphine or methadone but a few used naltrexone (in many cases because of problems with alcohol rather than opioids). The opioid dependent physicians did as well as the physicians in the other two groups with 75% to 80% of all three groups never testing positive for alcohol or other drugs including opioids.[ii] Of course, the physician addicts are different demographically from typical MAT patients. Nevertheless, these data demonstrate that the biological disease of opioid dependence can – in this situation at least – be successfully treated without substitution therapy.

We are now conducting a study of these physicians five years after their mandatory monitoring ended to assess the stability of their recovery. While the study is ongoing, preliminary analysis showed that 97% of the physicians were licensed to practice medicine and a similar high percent reported that they considered themselves to be in recovery. When asked to rate their PHP experiences on a scale from "extremely hurtful" to "extremely helpful" only 3% said it had been hurtful to any extent, the remainder reported their PHP experience was helpful with nearly 50% reporting "extremely helpful." When asked to rate which of the various components of the PHP program were most valuable to them the highest rating went to

participation in the 12-step fellowships, followed by their formal treatment experiences and their sustained random monitoring.

One controversial issue in defining recovery is whether a person can be considered to be in recovery while using medications including buprenorphine, methadone and naltrexone. I emphatically answer "yes" to that question – as long as the medication use is consistent with the prescribing physicians' instructions, and as long as the patient is not also using alcohol other drugs of abuse.

I recognize that the ultimate goal of sustained recovery is difficult to achieve, and even controversial. I also recognize that there are many interim goals of treatment along this path to sustained recovery that are worthy of evaluation and support. In addition, I recognize that some opioid dependent people achieve sustained recovery without treatment.[iii] Nevertheless, I am convinced that failure to define this (or some other ultimate goal of treatment) means that the entire treatment enterprise lacks focus. In addition, it is difficult to compare the outcomes of alternative treatments in the absence of a shared definition of the goal of treatment.

My hope is that this Committee will encourage all substance abuse treatment programs, both those that do and do not use medications, to keep track of two numbers and to routinely make them public: what is the retention rate of the treatment? And what is the drug use of patients during treatment? Beyond that, it is my hope that this committee will request that the National Institute on Drug Abuse (NIDA) and Substance Abuse and Mental Health Services Administration (SMHSA) fund several pilot programs to establish practical strategies to assess the Five-year recovery outcomes for various substance abuse treatments.

My testimony today is focused on the need to improve substance abuse treatment, especially but not only the treatment for opioid dependence. In this context I return to our decade long study of the state PHPs which I believe set the standard for achieving sustained recovery. This is a standard toward which all substance abuse treatments can usefully aspire. While the PHPs use high quality treatment, the treatment itself is brief, often one to three months of residential treatment or several months of intensive outpatient treatment. The PHPs also address other issues which contribute to addiction including comorbid mental and physical disorders. They insist on active, sustained participation in community support programs, mostly but not only Alcoholics Anonymous and Narcotics Anonymous. This unique system of care management also includes continuous random monitoring for any alcohol or drug use linked to serious consequences for even a single use. The PHP model is a not a model of substance abuse treatment. It is instead a model of care management. The PHPs do not themselves do any treatment or monitoring, all of that is done by others under the supervision of the PHPs.

PHP care management could hardly be more different not only from MAT but also from typical abstinence-oriented treatment. Skeptics say the PHP model is utopian and thus irrelevant. But the fact is that some treatment programs, including the Caron Foundation, are now experimenting with PHP-like contracts for patients leaving treatment that include active random monitoring and vigorous supervision of the patient participation in community support as well as early identification of any relapse. I see similar new thinking in the courageous model being developed at Hazelden, the distinguished source of all modern AOTs, as it has added buprenorphine and naltrexone to its armamentarium for opioid dependent patients. This experiment holds the promise of helping to break down the counterproductive wall between MAT and AOT. Our study of an exemplary methadone program asked about the experiences of

patients with Alcoholics Anonymous and Narcotics Anonymous because one of my colleagues complained of the harm done by the 12-step fellowships to patients in MAT. What we found surprised me. "More than three quarters of respondents (77.2%) currently participating in NA said that it was very or extremely helpful to them; 72.4% of current AA participants rated this activity as very or extremely helpful. Only about 3.5% of each group said that NA or AA was not helpful."[iv] This methadone program staff had not known of this widespread involvement with AA and NA until our study. This too is an example of new thinking about treatment, thinking that is outside the old paradigm of MAT vs AOT.

Once the goal of sustained recovery is established for opioid treatment and once the disorder of opioid dependence is defined as a serious, chronic and often fatal disease there is new hope for the widespread application of the PHP-like long-term care management in the new direction of health care. Health-care is moving away from brief and expensive episodes of care to long-term, even lifelong, disease monitoring and management. This effort is devoted to the prevention of relapse and to early intervention when relapses do occur. This is increasingly the case for diabetes, coronary artery disease, and asthma. In the not too distant future, I expect that opioid dependence will be added to that list of serious chronic – and high cost – diseases. When that happens the PHP model of care management or opioid dependence will become the standard of care.

In conclusion, the concerns I have expressed for MAT are no different from my concerns for AOT. Both need to shift their focus away from relatively brief episodes of treatment to the long-term goal of sustained recovery. That means shifting the focus from only what happens to the patients in treatment to include what happens to them when they leave treatment. There is plenty of room for improvement in all forms of substance abuse treatment. Having a measurable

goal will help all treatments achieve their full potential as important parts of the nation's response to the current, devastating opioid epidemic.

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[ii] McLellan, A. T., Skipper, G. E., Campbell, M. G. & DuPont, R. L. (2008). Five year outcomes in a cohort study of physicians treated for substance use disorders in the United States. *British Medical Journal, 337*:a2038.
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Other Relevant Publications

1. DuPont, R. L. (1990). Saying 'no' to heroin use: A dilemma in a free society [Foreword]. In W. H. McGlothlin & M. D. Anglin (Eds.), *The Compulsory Treatment of Opiate Dependence*. New York: Haworth Press.

2. DuPont, R. L. (1990). Benzodiazepines and chemical dependence: Guidelines for clinicians. *Substance Abuse, 11*, 232-236.

3. DuPont, R. L. (1990, October). Benzodiazepines and chemical dependence: Clinical guidelines. In *Practical Clinical Management: Drug Abuse Education for the primary Care Physician* (Monograph of Conference Proceedings, pp. 51-59). Baltimore Medical and Chirurgical Faculty of Maryland.

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5. White, W. L., Campbell, M. D., Spencer, R. A., Hoffman, H. A., Crissman, B., & DuPont, R. L. (2014). Participation in Narcotics Anonymous and Alcoholics Anonymous and abstinence outcomes of 322 methadone maintenance patients. *Journal of Groups in Addiction & Recovery, 9*(1), 14-30.

6. White, W. L., Campbell, M. D., Spencer, R. D., Hoffman, H. A., Crissman, B., & DuPont, R. L. (2014). Patterns of abstinence or continued drug use among methadone maintenance patients and their relation to treatment retention. *Journal of Psychoactive Drugs, 46*(2), 114-122.

Mr. MURPHY. Thank you. Thank you very much.

Dr. Seppala, you are recognized for 5 minutes.

STATEMENT OF MARVIN D. SEPPALA

Dr. SEPPALA. Chairman Murphy and Ranking Member DeGette, thank you very much for inviting me to participate in this important hearing, and for your leadership in addressing the crisis of addiction to opioids in this country.

My name is Marv Seppala, I am the Chief Medical Officer of the Hazelden Betty Ford Foundation. I attended Mayo Medical School, and have been practicing in the addiction field for 27 years. On a personal note, I have also been in long-term recovery from addiction since age 19.

The Hazelden Betty Ford Foundation is the Nation's largest nonprofit addiction treatment provider, and we have been around since 1949. We have 16 sites in 9 States. We offer prevention and recovery solutions nationwide for youth and adults. At our facilities, we have seen a pronounced increase in the number of patients with opioid use disorders, paralleling the grim stories you have probably been hearing about in your districts for some time now. At our residential youth facility, for example, opioid dependence rates increased from 15 percent of patients in 2011 to 42 percent in 2014. That is a dramatic rise, and this is an especially difficult addiction to treat. Individuals dependent on prescription pain medications and heroin often face unique challenges that can undermine their ability to stay in treatment and ultimately achieve long-term recovery. They are hypersensitive to pain and more vulnerable to stress. Their anxiety, depression, and intense craving for these drugs can continue for months, even years, after getting free from opioid use. They experience a strong desire to feel normal again, to escape what seems like a permanent state of dysphoria, which puts them at high risk for relapse. They are also at higher risk of accidental overdose during relapse because they no longer have the tolerance to handle the same doses they were taking prior to treatment. In other words, with opioids, unlike other drugs, relapse often means death.

In 2012, we launched a new protocol to treat opioid addiction, the Comprehensive Opioid Response with 12 Steps, or COR–12 as we call it. Our approach is grounded in the traditional 12-step facilitation model and based on abstinence, but it now also utilizes the safest live-saving medications that keep patients engaged in recovery long enough to achieve lasting sobriety.

We don't see a conflict in utilizing medications and pursuing abstinence, just as Bob described. Even when medications are part of our protocol, abstinence is still the objective. In fact, one might call it a third way because it strikes a reasonable commonsense balance between those who see medication assistance and abstinence as diametrically opposed.

Our COR–12 Program includes changes to traditional group therapy, additional patient education about opioids, and the option now of medication assistance. We utilize extended-release naltrexone, Vivitrol, as well as buprenorphine/naloxone, or Suboxone, to help engage patients long enough to complete treatment, and then become established in solid 12-step recovery. The highest risk period

for relapse is the first 12 to 18 months after treatment, so we prefer to have our patients involved and on medication in outpatient care throughout this extended period. And our goal is to discontinue medication as our patients become established in long-term recovery.

While our clinicians recommend which medication is appropriate, the final decision is up to the patient, and about ⅓ of our COR–12 patients elect to use no medication. Indeed, medication only addresses the biologic aspect of addiction. Our broader measures treat the psychological, social, and spiritual components to improve psychosocial functioning, enrich relationships, and foster a healthier lifestyle. And those are the keys to recovery that last.

Our COR–12 Program has resulted in more patients completing residential treatment, and a reduction in overdose deaths after treatment. While the research study of COR–12 is ongoing, and we do not have full results yet, we do know that COR–12 patients stay in treatment longer. Our atypical discharge rate, those who leave treatment early, for our general population is 13 ½ percent, and for those with opioid dependence who don't enter this program, it is over 22 percent. However, in this program, it is only 7.5 percent.

Now, based on our early positive results, we plan to continue paving the way for others to use both scientific and spiritual solutions to engage more people in treatment, save lives, and ultimately help more people get into long-term recovery.

I would also like to emphasize the need to educate a wider culture about the dangers of opioid overprescribing. The troubling trends began to emerge in the late '90's after the FDA approved Oxycontin and allowed it to be promoted to primary care physicians for treatment of common aches and pains. Education campaigns often funded by opioid manufacturers minimized risks, especially the risk of addiction, and exaggerated benefits to using these opioids long-term for common problems. When prescribing on a short-term basis to treat moderate to severe acute pain, opioids can be helpful, but when these are highly addictive medications that are taken around the clock for weeks, months, and years, they may actually produce more harm than healing. An increasing body of research suggests that for many chronic pain patients, opioids are neither safe nor effective. Over time, patients often develop tolerance, leading them to require higher and higher doses, which ultimately can lead to quality of life issues and functional decline.

It should be noted that doctors didn't start overprescribing out of malicious intent, but rather out of a desire to relieve pain more compassionately.

Now, we have a culture that seeks opioid medication for pain relief, not just for physical pain but also to numb psychic pain. Some of these patients have a significant risk for the development of addiction in a culture that promotes quick fixes, instant gratification, and escapism. Medical professionals need further education about the proper use of opioid medications and their risks. The general public also needs such education to prove recognition of risk, and limitations of these powerful, dangerous medications. It is time now to address opioid overprescribing and overuse without stigmatizing pain. This crisis deserves the attention you are providing today, and requires a substantial response.

Thanks again for having me here, and for your leadership. I look forward to answering your questions.

[The prepared statement of Dr. Seppala follows:]

Testimony of Marvin D. Seppala, MD
Before the Energy and Commerce Committee Subcommittee on Oversight and Investigations
April 23, 2015

Summary

My name is Marvin D. Seppala, MD, and I am the Chief Medical Officer at the Hazelden Betty Ford Foundation, the nation's largest nonprofit addiction treatment provider, with a legacy that began in 1949 and includes the 1982 founding of the Betty Ford Center.

My written statement below discusses the following main points:

- The Hazelden Betty Ford Foundation's experience with the epidemic of opioid misuse and how it drove us to develop a new treatment protocol called the Comprehensive Opioid Response with 12 Steps, or COR-12, program; and

- The dangers of opioid over-prescribing, which has unfortunately been fueled by a lack of prescriber and consumer education.

The misuse of opioids, the class of drugs that includes prescription pain medications and heroin, has reached crisis levels, with resulting overdoses ravaging families and communities throughout the country. This crisis deserves the attention you are providing today, and I am honored to offer my thoughts and expertise.

Written Statement

Chairman Murphy and Ranking Member DeGette, thank you very much for inviting me to participate in this important hearing. I am grateful to you and the other Members of the Subcommittee for your leadership in addressing the crisis of addiction to opioids in this country.

My name is Marv Seppala, and I am the Chief Medical Officer at the Hazelden Betty Ford Foundation. I attended the Mayo Medical School, and I have been practicing in the addiction treatment field since completing psychiatric training and an addiction fellowship at the University of Minnesota 27 years ago. On a personal note, I am also a person in long-term recovery from addiction; I've been sober since age 19.

The mission of the Hazelden Betty Ford Foundation is to help people reclaim their lives from the disease of addiction. We are the nation's largest nonprofit addiction treatment provider, with a legacy that began in 1949 and includes the 1982 founding of the Betty Ford Center. With 16 sites in nine states, we offer prevention and recovery solutions nationwide and across the entire continuum of care for youth and adults.

My testimony today will focus on two key points:

1. The Hazelden Betty Ford Foundation's experience with the epidemic of opioid misuse and how it drove us to develop a new treatment protocol called the Comprehensive Opioid Response with 12 Steps, or COR-12, program; and

2. The dangers of opioid over-prescribing, which has unfortunately been fueled by a lack of prescriber and consumer education.

The misuse of prescription painkillers and heroin has ravaged our nation's families and communities, to the point that the Centers for Disease Control and Prevention (CDC) has labeled the overdose deaths caused by these drugs an epidemic. Here at the Hazelden Betty Ford Foundation, there has been a pronounced increase in the number of patients with opioid use disorders. Opioid dependence among residential treatment admissions in our youth program, for example, increased from 15 percent in 2001 to 42 percent in 2014.

Individuals who are dependent on opioids face unique challenges that often undermine their ability to remain in treatment and ultimately achieve long-term abstinence. They are hypersensitive to real or imagined physical and psychic pain and are more vulnerable to stressful events, putting them at greater risk of relapse. They are more likely than other patients to leave treatment before completing it. And they are at higher risk of death from accidental overdose during relapse because of their reduced tolerance levels. Deaths can occur after treatment and a period of abstinence when people relapse and return to using the same doses they were taking prior to treatment, for which the body no longer has tolerance, causing respiratory depression.

Anxiety, depression and intense craving for these drugs can continue for months, even years, after getting free of opioid use. Those who are dependent on opioids experience a strong desire to feel "normal" again, to escape this seemingly permanent state of dysphoria, which puts them at a high risk of relapse, accidental overdose and death during relapse.

Our clinical response

In 2012, we launched a new treatment protocol designed to address this grim reality that more Americans were becoming addicted to opioids and dying from overdose.

Our new program – the Comprehensive Opioid Response with 12 Steps, or COR-12 as we call it – embraces the latest and best addiction treatment research and includes changes to traditional group therapy, additional patient education about opioids and the option of medication assistance. The research indicates certain medications improve recovery outcomes for people with opioid use disorders, so we integrated two medications – extended release naltrexone (Vivitrol®) and buprenorphine/naloxone (Suboxone®) – into our world-class Twelve Step Facilitation model to form the foundation of a unique new approach that we believe gives those with opioid dependence the best chance for lifelong recovery.

We use medications to engage our opioid dependent patients long enough to allow them to complete treatment and become established in solid Twelve Step recovery. The highest risk period for relapse is the first 12 to 18 months after treatment, so we prefer to have our patients remain on medication and involved in outpatient care throughout this period. Our goal is to discontinue the medication as our patients become established in long-term recovery.

Addiction is a complex brain disease that alters reward, motivation, memory and related circuitry. These alterations manifest in biological, psychological, social and spiritual dysfunction. Medication only treats the biological aspects of this illness, and patients using medication alone will not achieve the full gains of broad treatment using all the methods that we consider necessary for people entering recovery. Psychotherapies, abstinence from all addictive substances and a strong Twelve

Step orientation build a foundation that supports lasting recovery by improving psychosocial functioning, enriching relationships and fostering a healthier lifestyle. COR-12 attends to all of these aspects of recovery using a long-term approach for this chronic brain disease.

Our COR-12 team consists of medical, clinical and research professionals whose collective goal is to improve the lives of those suffering from opioid addiction. After thorough evaluation, they recommend to our admitting opioid dependent patients one of three COR-12 treatment paths: no medications, the use of Suboxone®, or the use of Vivitrol®. These evidence-based medications reduce the risk of overdose death, increase engagement in treatment and are extremely beneficial in preventing opioid use.

Those who opt for the non-medication pathway participate in all other aspects of the COR-12 program, including specialized group therapy and education that continues in the outpatient setting for 6-24 months. The Vivitrol® pathway includes the same psychotherapeutic endeavors with a monthly injection. Vivitrol® blocks opioid receptors in the brain, preventing the individual from experiencing intoxication from opioids. This medication has no euphoric effects and does not cause dependence, withdrawal or respiratory depression. The third group uses Suboxone® on a daily basis. Suboxone® is a partial opioid agonist, meaning it partially stimulates opioid receptors. It is used for opioid detoxification, as a maintenance treatment of opioid dependence, and for pain. It can be misused to get intoxicated and is sometimes diverted for nonmedical use, although most often to self-detoxify or to get by when the preferred opioid is unavailable.

While our clinicians make recommendations, the final decision on medication use is up to the patient. Of our COR-12 patients, approximately 33 percent choose the no medication pathway, 29 percent use Suboxone®, and 42 percent opt for Vivitrol®.

The COR-12 program has resulted in more patients completing residential treatment and a reduction in overdose deaths after treatment. While the research study of COR-12 is ongoing and we do not have full results yet, we do know our "atypical discharge" rates have dropped dramatically among opioid dependent patients. Many patients leave treatment earlier than recommended for a variety of reasons, which we call atypical discharges. The atypical discharge rate for our general population is 13.5 percent. For those with opioid dependence who are not involved in COR-12, it is 22 percent. Those in COR-12 are much more likely to complete residential treatment with an atypical discharge rate of about 7.5 percent, less than even the general treatment population.

Patients experience the same joy and heartache of early recovery, whether on medications or not, and in the treatment setting, it is not even perceptible which patients are on these medications. While a small group of our patients may need to remain on these medications for an extended period, our goal is to use the medications long enough to get patients solidly grounded in a Twelve Step lifestyle that ultimately allows them to discontinue the medication safely. Recovery is taking place every day in our outpatient settings as these patients dramatically change their attitudes, start to witness the real gifts of recovery and transition off medications.

Some see medication assistance and abstinence as diametrically opposed, and we have been criticized by those who support an abstinence-only approach for altering our program in this manner. We do not see a conflict. Even when medications are part of our protocol, abstinence is still the objective.

The medication, in those cases, is simply a part of the path to abstinence. We call it COR-12. But one might also call it the "Third Way" because it strikes a reasonable, common-sense balance, grounded in the Twelve Steps and based on abstinence, while also utilizing the safest, life-saving medications to keep patients engaged in recovery long enough to achieve lasting sobriety.

We have chosen to use everything at our disposal to treat opioid addiction. We remain absolutely committed to Twelve Step recovery, in fact even more so, having witnessed our COR-12 patients reclaim their lives. We hope our research can inform the addiction field on how best to combine therapies and utilize the most appropriate medications. Based on our early positive results, we plan to continue paving the way for others to use both scientific and spiritual solutions to engage more people in treatment, save lives and ultimately help more people get into long-term recovery.

Overprescribing Opioids

I would also like to emphasize the need to educate our wider culture about the dangers of opioid overprescribing, use and misuse, as well as the perilous transition that many users make from pills to heroin. Over the past two decades, the use of opioids has escalated dramatically in this country, with enormous human and financial costs to individuals, families and communities.

The Hazelden Betty Ford Foundation sees the devastating effects of opioid addiction every day at our 16 locations, and our observations have been consistent with a wave of sobering statistics that reveal a public health crisis the CDC calls the worst drug addiction epidemic in U.S. history.

For starters, the CDC reports that prescription painkiller overdoses more than quadrupled in the U.S. from 1999 to 2011, and heroin overdoses more than doubled, leading to about a half million emergency department visits in 2010 alone. While CDC data show prescription drug deaths dipping slightly in 2012, heroin deaths shot up even more. And deaths from drug overdose still outnumber those caused by car accidents, with an average of 110 overdose deaths per day in America and more than half of those involving opioids, according to the CDC. If any other major medical illness caused such devastation, there would have been an unprecedented response from the medical community, but we are dealing with a poorly understood illness that remains overtly stigmatized.

Not surprisingly, opioid use disorders are also on the rise. Data from the Substance Abuse and Mental Health Services Administration (SAMHSA) in 2012 showed a 500 percent increase in treatment admissions for prescription drug disorders nationwide since 2001. The National Institute on Drug Abuse estimates 2.6 million Americans had an opioid addiction in 2012. Millions more, while not addicted, also reported nonmedical use of prescription painkillers, according to the CDC.

These alarming increases in overdose deaths, addiction and misuse parallel, as one might suspect, a skyrocketing rate of prescriptions for opioids. The CDC says prescriptions for opioid painkillers have tripled in the past two decades. In 2012, 259 million opioid prescriptions were written, enough for every American adult to have a bottle of pills. Today, despite having only 4.6 percent of the world's population, the U.S. consumes 80 percent of the world's supply of painkillers, according to the American Society of Interventional Pain Physicians.

These troubling trends began to emerge in the late 1990s, after the U.S. Food and Drug Administration (FDA) approved OxyContin and allowed it to be promoted to primary care doctors for treatment of common aches and pains. Physician organizations loosened standards governing opioid prescribing and then many began advocating for increased use of opioids to address what was perceived to be a widespread problem of undertreated pain.

Education campaigns, often funded by opioid manufacturers, minimized risks, especially the risk of addiction, and exaggerated benefits of using opioids long-term for common problems. In fact, there is no substantial evidence to support the long-term use of opioids for chronic pain. When prescribed on a short-term basis to treat moderate to severe acute pain, opioids can be helpful. In fact, they are the best medicines we have. But when these highly addictive medications are taken around-the-clock, for weeks, months and years, they may actually produce more harm than healing. An increasing body of research suggests that for many chronic pain patients, opioids may be neither safe nor effective. Over time, patients often develop tolerance, leading them to require higher and higher doses, which ultimately can lead to quality-of-life issues and functional decline, not to mention addiction. In some cases, opioids can even make pain worse, a phenomenon called hyperalgesia.

Increased opioid prescribing has established a new generation of opioid dependent individuals. Opioid prescription standards in the U.S. are so flexible now that patients sometimes get opioids even when they don't have significant pain. A 2014 study by the George Washington University School of Medicine showed a 10 percent increase in opioid prescriptions written for people visiting the emergency room yet only a 4 percent increase in people coming to the ER complaining about pain. Doctors need to become aware of the serious risk of overdose, dependence and addiction associated with opioid pain medications.

Many people associate prescription painkillers with older adults, and that certainly is a significant population affected by the current crisis, especially given the other sedating medications that older adults are sometimes prescribed.

Youth are increasingly at risk too, especially with opioids available in the medicine cabinets of so many homes. Young people are particularly vulnerable because their brains aren't fully developed until the mid-20s. Teens think the drugs are safe because a doctor prescribed them. But opioids can cause lasting changes to the brain. When abused, painkillers can be as life-threatening as heroin. According to the Foundation for a Drug-Free World, 2,500 American youths abuse a prescription pain reliever for the first time every day. In the 2012 National Survey of American Attitudes on Substance Abuse, 34 percent of teenagers reported they could get prescription drugs within a day. Furthermore, the National Institute on Drug Abuse (NIDA) says 70 percent of 12th graders reported obtaining prescription opioids from a friend or relative and that adolescent abuse of prescription drugs frequently is associated with other risky behavior.

According to Leonard Paulozzi, a physician and researcher with the CDC, about 75 percent of heroin users say they started out by using prescription opioids. That is consistent with what we hear from our young patients. They often report a relatively swift path from medicine bottle to heroin needle. As prescription supplies dry up and doctor-shopping options run out, heroin becomes the cheaper and more available alternative. That progression is scary considering that teenage abuse of prescription drugs has become so prevalent the Partnership for Drug-Free Kids refers to this age group as "Generation Rx."

Opioid problems are affecting every area of the country, devastating an entire generation in some hard hit communities like Staten Island, NY, where someone died of an opioid overdose every five days, on average, in 2012. Many of the lost are young people and some are parents. And many of those who escape death spend time incarcerated or are unfit to raise children because their addiction remains untreated.

This is a crisis that demands our attention and commitment, and at the center of this problem is overprescribing. Doctors didn't start overprescribing opioids out of malicious intent, but rather out of a desire to relieve pain more compassionately. The No. 1 reason people visit a physician is pain. Doctors were mistakenly informed beginning in the 1990s that treating all pain with opioids was safe. Physician visits are shorter. Non-prescription related health support services for pain patients have been fragmented and underutilized. Pressure to make decisions and provide quick solutions add to the doctor's dilemma. Reimbursement tied to patient satisfaction surveys also intensifies the pressure to prescribe opioid painkillers in hospital emergency departments. Often it is easier for a physician to write a prescription to maintain the 'status quo' than to ask the difficult question,

"Should I change how I am treating this patient?" Physicians need to limit opioid medication to the treatment of moderate to severe acute pain, and rarely use them for chronic pain.

We have a culture that seeks opioid medication for pain relief, and not just for physical pain, but also to numb psychic pain. Some of these patients have a significant risk for the development of addiction in a culture that promotes 'quick-fixes,' instant gratification and escapism.

Medical professionals need further education about the proper use of opioid medications and their risks. The general public also needs education to improve recognition of the risks and limitations of these powerful, dangerous medications. It's time for new education campaigns and new policies to help recalibrate and find a better balance – one that addresses opioid overprescribing and overuse without stigmatizing pain, in whatever imperfect but thoughtful ways we can. This crisis deserves the attention you are providing today and requires a substantial response not only from the federal government, but from all of medicine as well. The opioid crisis is too diverse for a single entity to solve; we need leadership and action from multiple sources.

We welcome your efforts to improve access to addiction treatment and improve the efficacy of treatment programs. The Hazelden Betty Ford Foundation will continue to do everything we can to contribute, but we need your help, we need physicians' help and we need the help of researchers and treatment programs across the country to develop a consensus regarding the solutions to this crisis.

Thanks again for having me here and for your leadership on this important topic. I look forward to answering your questions.

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Mr. MURPHY. Thank you, Doctor.

Now, Dr. Westreich, you are recognized for 5 minutes.

STATEMENT OF LAURENCE M. WESTREICH

Dr. WESTREICH. Mr. Chairman, members of the committee, thank you very much for inviting me to speak to you today about treatment for opioid addiction. Dr. Murphy, before I start, I would like to say that as a psychiatrist specializing in addiction, I am particularly appreciative of the clinical awareness you have imparted to the Helping Families in Crisis Act, which will focus resources on helping our patients. I am Board certified in general psychiatry, addiction psychiatry, and forensic psychiatry, and I serve as president of the American Academy of Addiction Psychiatry, which is a professional organization for psychiatrists who specialize in the treatment of addiction and other mental illnesses.

My primary professional focus is on the clinical treatment of addicted people. I trained at Bellevue, where I worked for many years and continue to teach, and I treat people addicted to opioids in my offices in Manhattan and in New Jersey, where I live. I know this committee understands very well the lethal nature of opioid addiction. You don't need us to tell you about that. My main goal in speaking with you today is to underline what you have already heard; opioid-addicted people need access to a broad range of treatments for opioid addiction. This must include access to medication-assisted therapy, and treatment for co-occurring psychiatric disorders. I have treated homeless, heroin-injecting senior citizens, college students who snort Oxycontin, and practicing attorneys who must take an opioid pill every few hours in order to continue seeing their clients. The death and destruction I have seen due to opioid addiction is profoundly disturbing, but thankfully with appropriate treatment, the more common return to health, the workplace, and family, is what keeps most of us doing the clinical work which helps addicted people in their search for recovery.

Part of that clinical work includes full treatment for what is ailing the addicted person. Research demonstrates that the opioid-using person often has a co-occurring mental illness, like major depression, bipolar disorder, or PTSD. Sometimes the opioid user is self-medicating uncomfortable mood states or anxiety, or just has difficulty soothing him or herself. All these circumstances can increase the risk for relapse, and require sophisticated and individualized psychiatric evaluation and treatment. Research makes it clear that prescribing the appropriate effective medication to help the patient with craving, along with talk therapy and treatment for a co-occurring psychiatric disorder, gives the addicted person the best possible chance for recovery.

That sophisticated treatment system must include access to well-trained clinicians who can select between the available psychosocial treatments like relapse prevention therapy, cognitive behavioral therapy, medications like buprenorphine, methadone, and naltrexone, and mutual support groups like Narcotics Anonymous. For many, mutual support groups like AA or NA can be extremely helpful, but they are not treatment, nor do they claim to be. They are support groups which can be lifesaving for some, and not so much for others. As you have heard, the available research has not

provided us with a silver bullet that works for all opioid addiction. Rather, the data tell us that some treatment works for some opioid addicts some of the time. Others may respond to a very different approach. That is one reason we clinicians must have all available arrows in our quivers. We must have the skills and training for a broad array of approaches to meet the treatment needs of each patient. Quite often, using a treatment—team approach that includes psychologists, social workers, nurses and counselors, is critical to therapeutic success.

The wide variety of personal choices addicted people make about treatment is yet another reason for supporting the full spectrum of treatment possibilities from medication-assisted treatments with buprenorphine and methadone, to opioid blockers like naltrexone, to relapse prevention therapy. Some patients demand to be treated without medications, while others clearly want and need medication to control their craving. And they also require more specific psychiatric treatment for any co-occurring disorders.

Use of buprenorphine and methadone, which are both opioids like heroin, can be controversial. When I talk to opioid-addicted people and their families, I sometimes, but not always, recommend tapering or maintenance with buprenorphine or methadone. The question is not whether the medication has side effects; all medications do, but whether the risk is worth the benefit. Patients and their families need to know that detoxification treatment and drug-free counseling are associated with a very high risk of relapse. As with other medical conditions, the relevant question about whether a medication is worth the risk is the following. Compared to what? Is taking buprenorphine or methadone better than dying from an overdose, better than contracting HIV or Hepatitis, flunking out of school, losing a marriage, losing a job? One-size treatment does not fit all, and different patients may need different treatments. But the very good news in this situation is that people who are able to stop their use of illicit drugs, whether through psychotherapeutic interventions, medications, and/or help from NA, or most likely some combination of the above, can return to vibrant and productive lives. It is that return to physical and emotional health, which I find so gratifying; it empowers me to help my patients to keep trying.

Before I stop, let me reiterate my main point, and what I know you have heard from many others. Opioid-addicted people need access to a broad range of treatments for addiction. This must include medication-assisted treatment, and treatment for co-occurring psychiatric disorders.

Thank you very much for inviting me today.

[The prepared statement of Dr. Westreich follows:]

Congressional Testimony

Laurence M. Westreich, M.D.

President, American Academy of Addiction Psychiatry

Combatting the Opioid Abuse Epidemic: Professional and Academic Perspectives," April 23rd 2015

Subcommittee on Oversight and Investigations

Mr. Chairman, Members of the Committee, thank you very much for inviting me to speak with you today about treatment for opioid addiction. Dr. Murphy, before I start, I'd like to say that as a psychiatrist specializing in addiction , I am particularly appreciative of the clinical awareness you have imparted to the Helping Families in Crisis Act, which will focus resources on helping our patients. I am board-certified in general psychiatry, addiction psychiatry, and forensic psychiatry, and I serve as President of the American Academy of Addiction Psychiatry, the professional organization for psychiatrists who specialize in the treatment of Addiction and other Mental Illnesses. My primary professional focus is on the clinical treatment of addicted people: I trained at Bellevue Hospital, where I worked for many years and continue to teach, and I treat people addicted to opioids in my offices in

Manhattan, and in New Jersey, where I live. I know this committee understands the absolutely lethal nature of opioid addiction, so you don't need me to tell you about that. My main goal in speaking with you today is to underline what you have already heard: ***opioid-addicted people need access to a broad range of treatments for opioid addiction. This must include access to medication assisted therapy and treatment for co-occurring psychiatric disorders.***

I have treated homeless heroin-injecting senior citizens, college students who snort OxyContin, and practicing attorneys who must take an opioid pill every few hours in order to continue seeing their clients. The death and destruction I have seen due to opioid addiction is profoundly disturbing but, thankfully, with appropriate treatment, the more common return to health, the workplace, and family is what keeps most of us doing the clinical work which assists addicted people in their search for recovery.

Part of that clinical work includes full treatment for what is ailing the addicted person. Research demonstrates that the opioid-using person often has a co-occurring mental illness like Major Depression, Bipolar Disorder, or PTSD. Sometimes the opioid-user is self-medicating uncomfortable mood states, or anxiety, or just has difficulty soothing him-or-herself. All of these circumstances can increase the risk for relapse, and

require sophisticated and individualized psychiatric evaluation and treatment. Research shows that prescribing the appropriate effective medication to help the patient with craving along with "talk" therapy and treatment for a co-occurring psychiatric disorder give the addicted person the best chance for recovery.

That sophisticated treatment system must include access to well-trained clinicians who can select between the available psychosocial treatments like Relapse Prevention Therapy and Cognitive Behavioral therapy, medications like buprenorphine, methadone and naltrexone, and mutual support groups like Narcotics Anonymous. For many, mutual support groups like AA and NA can be extremely helpful, but they are not treatment – nor do they claim to be. They are support groups which can be life-saving for some, and not so much for others. As you have heard, the available research has not provided us with a silver bullet that works for all opioid addiction. Rather, the data tell us that some treatments work for some opioid addicts, some of the time. Others may respond to a very different approach. That is one reason we clinicians must have all available arrows in our quivers - we must have the skills and training for a broad array of approaches to meet the treatment needs of each patient. Quite often using a team approach that includes psychologists, social workers, nurses and counselors is critical to therapeutic success.

The wide variety of personal choices addicted people make about treatment is yet another reason for supporting the full spectrum of treatment possibilities, from medication-assisted treatment with buprenorphine and methadone, to opioid blockers like naltrexone, to Relapse Prevention Psychotherapy. Some patients demand to be treated without medications, while others clearly want and require medications to control their craving, and may also require more specific psychiatric treatment for any co-occurring disorders.

The use of buprenorphine and methadone, which are both opioids like heroin, can be controversial. When I talk to opioid-addicted people and their families, I sometimes – but not always – recommend tapering or maintenance with buprenorphine or methadone. The question is not whether the medication has side effects (all medications do) but whether the risk is worth the benefit. Patients and their families need to know that detoxification treatment and "drug-free" counseling are associated with a very high risk of relapse. As with other medical conditions, the relevant question about whether a medication is worth the risk is the following:

"Compared to what?'

Is taking buprenorphine or methadone better than dying from an overdose? Better than contracting HIV or hepatitis? Flunking out of school? Losing a marriage? Losing a job? One

size treatment does *not* fit all, and different patients may need different treatments. But the very good news in this situation is that people who are able to stop their use of illicit drugs – whether through psychotherapeutic interventions, medications, and/or help from Narcotics Anonymous, or most likely, some combination of the above – return to vibrant and productive lives. It is that return to physical and emotional health, which I find so gratifying, and empowers me to help my patients keep trying.

Before I stop, let me reiterate my main point, and what I know you have heard from others: ***Opioid-addicted people need access to a broad range of treatments for addiction. This must include medication-assisted treatment and treatment for co-occurring psychiatric disorders.***

Thank you for inviting me today.

Mr. MURPHY. Thank you very much.

Dr. Lembke, you are recognized for 5 minutes.

STATEMENT OF ANNA LEMBKE

Dr. LEMBKE. Thank you for inviting me today to these hearings.

The main point I would like to make today is simple. We don't just have an opioid abuse epidemic or an opioid overdose epidemic, we have an opioid overprescribing epidemic.

Doctors are a major pipeline of misused and diverted prescription opioids, and contrary to what is commonly believed, doctors who treat addiction are not the main source of the problem.

The methadone that accounts for 40 percent of single drug opioid pain reliever death is almost entirely in the form of pills prescribed for the treatment of pain, rather than coming from methadone maintenance clinics that treat heroin-dependent patients. We, thus, need to think broadly about the problem with changing the behavior of all physicians and not just those who treat addicted patients.

I was pleased to see the education of providers was identified as one of three priority areas in the report issued last month from the Department of Health and Human Services, which called prescribers "the gatekeepers for preventing inappropriate access." But providing educational material on safe opioid prescribing, even if it is free and readily available, won't be enough. To change doctor prescribing behavior we need first to acknowledge the enormous incentive to prescribe opioids, and the disincentives to stop prescribing. Many doctors are afraid that a patient will sue them or complain about them if they don't prescribe opioids, even when the doctor knows the opioid is harming that patient. Also, no insurer questions me when I prescribe Vicodin for pain, but if I want to prescribe Suboxone to help an addicted patient stop taking Vicodin, I typically have to spend hours fighting an insurance company to get the prescription approved. Despite the Mental Health Parity and Addiction Equity Act that Congress passed by a huge bipartisan margin in 2008, many insurers still resist reimbursing for addiction treatment.

The solution to this problem lies in giving doctors tangible incentives to prescribe more judiciously, such that neither pain nor addiction is undertreated.

Today, I focused on three areas where I believe this Congress can make a positive difference. Number one, require revision of healthcare quality measures. Number two, incentivize use of prescription drugs monitoring programs. And number three, scrutinize accreditation organizations and regulatory agencies.

First, require revision of healthcare quality measures. The Centers for Medicare and Medicaid Services and the Joint Commission exert enormous control over how doctors practice medicine today. Their quality measures set the standard of care. In the 1990s, they urged doctors to prioritize pain treatment, and that is what we did. Prescriptions for opioids skyrocketed, not always to the benefit of our patients.

CMS and the Joint Commission need to link quality measures to treatment outcomes for patients with addictions. This will incentivize hospitals and clinics to create an infrastructure to screen for and treat opioid addiction.

Quality measures should also limit excessive prescribing of multiple drugs to the same patient, especially of controlled medications. A younger person with no objective evidence of disease should not be on 10 different medications, yet I often see this, and the medications frequently include an assortment of stimulants, sedatives, and opioids. Also, far too many patients are on a prescription of benzodiazepines at the same time as opioids, which greatly increases their risk of overdose.

Finally, CMS and Joint Commission quality measures should not be linked to patient satisfactions with opioid prescribing. Illness recovery, not patient satisfaction surveys should be the arbiter of quality care. Doctors are not waiters, and opioids are not items on a menu.

Second, incentivize use of prescription drug monitoring programs. Prescription drug monitoring programs allow doctors to see all the controlled medications prescribed to a patient beyond just the ones that they prescribe. When physicians make use of prescription drug monitoring programs, prescription drug misuse decreases. Monitoring programs don't merely limit access to opioids when they should not be prescribed. They allow for patients who really need them to get them. The question is how to get more doctors to use these databases. By some reports, only 35 percent of prescribers use these databases. Here are some ways to incentivize doctors to use prescription drug monitoring programs. Make it a billable medical service. Mandate education on use of PDMPs when physicians apply for DEA licensure. Amend privacy laws such as 42 C.F.R. so that healthcare providers can freely communicate with each other around issues related to prescription drug misuse.

Third, scrutinize accreditation organizations and regulatory agencies. The Joint Commission, the accreditation organization which sets standards for hospitals, was instrumental in socializing doctors to liberally prescribe opioids for pain. The Joint Commission's campaign on treating pain was funded in part by Purdue Pharma, whose main product is Oxycontin. I do not think Congress should allow a major healthcare accreditation body like the Joint Commission to take money from the pharmaceutical industry.

In 2012, the Food and Drug Administration wisely rescheduled hydrocodone products to Schedule II, but the very same week, the FDA approved the use of Zohydro, a longer-acting opioid with high abuse potential, similar to Oxycontin. The FDA's own advisory panel recommended not to approve Zohydro, yet it was approved anyway. Why? Do we really need one more high-risk opioid medication on the market? It seems to me like trying to empty a bathtub with a thimble, while filling it with a firehose.

Furthermore, the FDA should live up to its commitment to stop approving non-abuse deterrent formulations of opioids, which it did not do when it approved Zohydro. And doctors and patients need to understand that abuse-deterrent formulations make it harder to crush and snort and inject an opioid, but they do not prevent ingesting opioids orally at high doses, becoming physiologically dependent on and addicted to them, and overdosing on them.

To sum up, Congress can push back against the opioid epidemic by requiring revision of healthcare quality measures to reduce overprescribing, incentivizing use of prescription drug monitoring

programs, and scrutinizing accreditation organizations and regulatory agencies. All 3 approaches will save lives and improve the practice of medicine at the same time.

Thank you again for this opportunity to testify, and for your leadership in addressing this public health epidemic.

[The prepared statement of Dr. Lembke follows:]

Testimony of Anna Lembke, M.D.

Committee on Energy and Commerce

Subcommittee on Oversight and Investigations

"Combatting the Opioid Abuse Epidemic: Professional and Academic Perspectives"

April 23, 2015

Thank you Chairman Murphy, ranking member DeGette, and members of the Committee for holding these hearings and for inviting me to speak. My name is Dr. Anna Lembke, and I am on the psychiatry faculty at the Stanford University School of Medicine, where I direct the Addiction Medicine Clinic, treat patients, teach, and conduct addiction research. I've spent over a decade treating patients dependent on, misusing, and addicted to opioids, many of whom became addicted through a doctor's prescription.

The main point I would like to make today is simple. We don't just have an opioid misuse epidemic, or an opioid overdose epidemic, we also have an opioid over-prescribing epidemic.

Doctors are a major pipeline of misused and diverted prescription opioids. Contrary to what is commonly believed, doctors who treat addiction are not the source of the problem. The methadone that accounts for 40% of single-drug opioid pain reliever deaths is almost entirely in the form of pills prescribed for the treatment of pain, rather than coming from methadone maintenance clinics that treat heroin-dependent patients[1]. We thus need to think broadly

about the problem of changing the behavior of all physicians and not just those who treat addicted patients.

I was pleased to see that education of providers was identified as one of three priority areas in the report issued last month by the Department of Health and Human Services, which called prescribers "the gatekeepers for preventing inappropriate access"[2]. But providing educational material on safe opioid prescribing, even if it's free and readily available, won't be enough.

To change doctor prescribing behavior, we need first to acknowledge the enormous incentives to prescribe opioids, and the disincentives to stop prescribing[3]. Many doctors are afraid that a patient will sue them or complain about them if they don't prescribe opioids, even when the doctor knows the opioid is harming the patient. Also, no insurer questions me when I prescribe Vicodin for pain, but if I want to prescribe Suboxone to help an addicted patient stop taking Vicodin, I typically have to spend hours fighting an insurance company to get the prescription approved. Despite the Mental Health Parity and Addiction Equity Act that Congress passed by a huge bipartisan margin in 2008, many insurers still resist reimbursing for addiction treatment.

The solution to this problem lies in giving doctors tangible incentives to prescribe more judiciously, such that neither pain nor addiction is undertreated.

Today I focus on three areas where I believe this Congress can make a positive difference.

1. **Require revision of health care quality measures**
2. **Incentivize use of Prescription Drug Monitoring Programs (PDMP's)**
3. **Scrutinize accreditation organizations and regulatory agencies**

First, require revision of health care quality measures

The Centers for Medicare and Medicaid Services and The Joint Commission exert enormous control over how doctors practice medicine. Their quality measures set the standard of care. In the 1990s, when they urged doctors to prioritize pain treatment, that's what we did. Prescriptions for opioids sky-rocketed, not always to the benefit of our patients.

CMS and The Joint Commission need to link quality measures to treatment outcomes for patients with addiction. This will incentivize hospitals and clinics to create an infrastructure to screen for and treat opioid addiction.

Quality measures should also limit excessive prescribing of multiple drugs to the same patient, especially of controlled medications. A younger person with no objective evidence of disease should not be on 10 different medications a day, yet I often see this, and the medications frequently include an assortment of stimulants, sedatives, and opioids. Also, far too many patients are on a prescription for benzodiazepines (i.e., tranquilizers) at the same time as opioids, which greatly increases their risk of overdose.

Finally, CMS and Joint Commission quality measures should *not* be linked to patients' satisfaction with opioid prescribing. Illness recovery, not patient satisfaction surveys, should be the arbiter of quality care. Doctors are not waiters and opioids are not items on a menu.

Second, incentivize use of Prescription Drug Monitoring Programs (PDMPs)

Prescription Drug Monitoring Programs allow doctors to see all the controlled medications prescribed to a patient, beyond just the ones they themselves are prescribing. When physicians make use of Prescription Drug Monitoring Programs, prescription drug misuse decreases[4]. PDMP's don't merely limit access to opioids when they should not be prescribed, they allow for patients who really need opioids to get them. The question is how to get more doctors to use PDMPs. By some reports, only 35% of prescribers use these databases[5].

Ways to incentivize doctors to use PDMP databases include making it a billable medical service, mandating education on use of PDMPs when physicians apply for DEA licensure, and amending privacy laws, such as 42CFR, so that health care providers can freely communicate with each other around issues related to prescription drug misuse.

Third, scrutinize accreditation organizations and regulatory agencies

The Joint Commission, the accreditation organization which sets standards for hospitals, was instrumental in socializing doctors to liberally prescribe opioids for pain. The Joint Commission's campaign on treating pain was funded in part by Purdue Pharma, whose main product is Oxycontin[6]. I don't think Congress should allow a major health care accreditation body like The Joint Commission to take money from the pharmaceutical industry.

In 2012, the Food and Drug Administration (FDA) wisely rescheduled hydrocodone products to Schedule II. But the very same week, the FDA approved the use of Zohydro, a longer acting opioid with high abuse potential similar to Oxycontin[7]. The FDA's own advisory

panel recommended not to approve Zohydro, yet it was approved anyway. Why? Do we really need one more high risk opioid medication on the market? It seems to me like trying to empty a bathtub with a thimble while filling it with a firehose.

Furthermore, the FDA should live up to its commitment to stop approving non abuse-deterrent formulations of opioids, which it did not do when it approved Zohydro. And doctors and patients need to understand that abuse deterrent formulations make it harder to crush and snort/inject an opioid, but don't prevent ingesting opioids orally at high doses, becoming physiologically dependent on and addicted to them, and overdosing on them.

To sum up, Congress can push back against the opioid epidemic by requiring revision of health care quality measures to reduce over-prescribing, incentivizing use of Prescription Drug Monitoring Programs (PDMPs), and scrutinizing accreditation organizations and regulatory agencies. All three approaches will save lives and improve the practice of medicine at the same time.

Thank you again for this opportunity to testify and for your leadership in addressing this public health epidemic.

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Mr. MURPHY. Thank you, Doctor.

Now, Dr. Bisaga, you are recognized for 5 minutes.

STATEMENT OF ADAM BISAGA

Dr. BISAGA. Thank you, Chairman Murphy, Ranking Member DeGette, and members of the committee, both for holding this hearing and for inviting me to speak to you today.

My name is Adam Bisaga. I am a scientist, working on developing new medication strategies to treat opioid dependence. I am also educating physicians nationally with regards to safe and effective use of these mediations, and I have been practicing addiction psychiatry for the past 20 years.

I would like to speak on the opioid epidemic from the perspective of medical management. And I want to point out how our current drug treatment system in the United States is outdated; that it does not reflect the scientific progress we have made in the past 50 years. Our current system is built on the model for treating patients with alcoholism, and it is not capable of responding to the unfolding opioid epidemic.

Opioid addiction is manifested by the compulsive use of opioid painkillers or heroin. Patients have abnormal activity in several brain regions, and experience powerful urges to use that they find very difficult to control. This abnormal brain activity can persist for months throughout the abstinence, driving high relapse rates. Medications can stabilize opioid receptors in the brain; reducing craving, eliminating withdrawal, and blunting the patient's ability to feel the effects of heroin. These medications work best in conjunction with psychosocial therapies to produce long-lasting abstinence. This approach has success rates similar to treatments we have for many other medical and psychiatric disorders. However, in stark contrast, the treatment for most other disorders, very few patients with opioid addiction receive evidence-based treatment.

The traditional approach of a brief detoxification followed by therapy-only approaches has no evidence for treating effectively opioid addiction. In addition, this approach can be very dangerous. Patients that do not receive medications to block the effects of relapse face an elevated risk of dying when they relapse. Certainly, all of us have witnessed it on too many occasions.

So we have three FDA approved medications; methadone, buprenorphine, and naltrexone. Methadone activates opioid receptors in the brain and blocks the effects of heroin or painkillers. Methadone-treated patients use less heroin, have fewer medical complications, and have improved social and work functioning. In other words, they are able to lead a normal life. Methadone is the most effective medications we have, however, it is a potent medication, and can cause sedation or even death. Therefore, dispensing of methadone is highly regulated.

Buprenorphine works similarly to methadone, but only partially activates opioid receptors. It also protects patients from overdose risk. Because buprenorphine is safer than methadone, less monitoring is needed and it can be prescribed by the doctors in their offices.

Naltrexone, the last medication, is available as either a daily tablet or a monthly injection. Naltrexone works differently from meth-

adone and buprenorphine. It completely blocks opioid receptors, and it is used after detoxification to prevent relapse. It has no abuse potential, there is no withdrawal when it is stopped.

Treatment with medication works best as a maintenance intervention, without a predefined length of treatment. There is no scientific evidence showing benefits to limiting the time someone is treated with medication. Opioid addiction is a chronic brain disease, and that responds best to chronic treatment.

Methadone, buprenorphine, and naltrexone have all different mechanism of action. In this era of personalized medicine, patients respond best to medication that are tailored to their individual needs. All of these medications are needed to adequately address the opioid epidemic. Every American should have access to these medications, and with the help of a physician, help make an informed decision about their path to recovery. Regulations should be put in place to make buprenorphine and naltrexone available at every treatment center working with patients addicted to opioids.

More than 100 of individuals, many of them young adults, die of opioid overdoses every day. Medication-assisted treatment is the best way to reduce the number of deaths on a large scale. Addiction is a treatable disorder, and a joint effort of health professional, community advocates, and policymakers is urgently needed to reverse this tragic trend.

Thank you for the opportunity to testify.

[The prepared statement of Dr. Bisaga follows:]

Testimony before the House Energy and Commerce Oversight and Investigation Subcommittee U.S. House of Representatives

Hearing on

"Combatting the Opioid Abuse Epidemic:

Professional and Academic Perspectives."

Statement of

Adam Bisaga MD

Research Psychiatrist, New York State Psychiatric Institute

Professor of Psychiatry, Columbia University Medical Center

April 23, 2015

Introduction

Chairman Murphy and members of the Subcommittee, thank you for the opportunity to provide an academic perspective concerning the medical management of opioid use disorders as it relates to the current epidemic.

My name is Adam Bisaga. I am a Research Psychiatrist at the New York State Psychiatric Institute and a Professor of Psychiatry at Columbia University Medical Center. My research, supported by the National Institute on Drug Abuse, is focused on the development of new medications to treat opioid use disorder. I am also educating clinicians with regards to safe and effective use of medications to treat opioid use disorder. This effort is supported by SAMHSA with a national training program called Provider's Clinical Support System for Medication Assisted Treatment or PCSS-MAT. [1] Finally, I am also a physician, taking care of patients with substance use disorders and co-occurring mental health disorders for the past 20 years.

Addiction as a behavioral disorder

Substance Use Disorder, also known as addiction, is a brain disorder manifested by an abnormal behavior around the use of alcohol or drugs. At its core, it is the loss of control over substance use. When we examine brain function in a person who is addicted, we see unusually low or high activity in the brain centers responsible for pleasure, learning and memory, and motivation to perform and inhibit certain behaviors. As a result of these changes, individuals with Substance Use Disorders have intense responses to certain external stimuli, such as passing by the liquor store, and to internal experiences, such as feelings of sadness or anger. In response, they experience powerful urges to use the given substance, and cannot stop thinking

about it. Their ability to resist these intense urges is limited, even though they well know that using drugs can have catastrophic consequences. These exaggerated responses persist for a long time, even in people who were able to abstain from use, and as a result many individuals repeatedly relapse.

This set of abnormal responses and behaviors is at the center of the pathology associated with addiction. Some individuals with this problem, like those using substances every day, may also have unpleasant withdrawal symptoms when they do not take their daily dose. But the presence of withdrawal symptoms is neither sufficient nor necessary for a diagnosis of a Substance Use Disorder. As such, patients taking pain medicines every day as directed by physicians are not addicted, they still have control over their use, even though they will experience withdrawal if they miss taking the medication. A baby born to a woman treated with an opioid medication, a baby that is exhibiting signs of opioid withdrawal, is not addicted to opioids. Similarly, using psychoactive substances on daily basis is not sufficient for a diagnosis of addiction. Many people will have one or two drinks everyday after work and do not have any of the abnormal responses and behaviors that characterize addiction. They do not have an Alcohol Use Disorder, associated brain pathology, or the associated loss of control.

Our understanding of addiction as a chronic brain disorder is similar to our understanding of many other psychiatric disorders, in which symptoms and behaviors can be linked to abnormal brain function.

Like with many other disorders, vulnerability to addiction differs from person to person. The balance of risk and protective factors determines whether a person can drink everyday or be treated with painkillers on a ongoing basis with no subsequent problems, while another person will develop abnormal brain responses and over time causing the individual to lose control over

their substance use. We estimate that approximately half of the risk to develop these abnormal brain responses to substances is genetically determined. The remainder of the risk is related to life experiences, co-existing medical and psychiatric problems, and to the exposure to addictive substances.

Prior to the development of the current scientific understanding, addiction was seen as either a moral failing or a character weakness, as a criminal behavior, or as purposeful self-indulgence. However, research has now shown us otherwise. We developed strategies to more effectively treat addicted individuals that match the understanding of the nature or cause of the problem. At present, while there is a public recognition of the role of genetic and biological factors in the development of addiction, approximately one-third of Americans continue to view addiction as a sign of simple lack of will power. [2] This view has undermined efforts to implement the most effective and ethical strategies to reduce the impact of addiction on society.

Treatment

Research into mechanisms involved in maintaining addiction has led to multiple effective treatments. Informed by the scientific evidence, the most effective treatment for opioid addiction involves a combination of a medication that targets the brain, and psychosocial interventions (counseling, skills development) aimed at reducing abnormal behaviors. This combination of medicine and therapy has success rates similar to treatments for many other psychiatric and medical disorders such as depression or high blood pressure. However, in stark contrast to treatments for most other disorders, where using evidence-based medication assisted treatments is the standard of care, very few of the patients with opioid addiction receive treatments that have

been proven to be most effective. Instead, patients are treated with an outdated and mostly ineffective approach; a rapid detoxification of the substance followed by a so-called "drug-free" or "abstinence only" approach, a treatment that does not allow for medications to stabilize recovery. This approach is not only ineffective but can also be dangerous as patients face a significantly elevated risk of dying by overdose during the first month of abstinence. Tolerance, a resistance to drug effects after repeated exposure, is the main mechanism that the brain uses to protect itself against toxic effects of drugs. But during early abstinence, the "protective" effect of tolerance is lost and the brain becomes vulnerable to the effects of opioids. This rapid loss of established tolerance is one of the mechanisms contributing to post-detoxification deaths in patients that are not treated with medication.

Medications to treat Opioid Use Disorder

Three medications are currently used in the treatment of opioid use disorder; methadone, buprenorphine, and naltrexone. The FDA approved these medications, considering them safe and effective.

Methadone was approved over 40 years ago and was first widely used, with great success in the 1970s to treat returning veterans addicted to heroin. It works by stimulating opioid receptors in the brain which normalizes function in several key brain systems.[3] Compared to treatment without medication, methadone-treated patients show marked reductions in heroin and other drug use, have lower mortality, fewer medical complications, decreased criminal activity , and have improved social and occupational functioning. [4,5] Patients who respond to methadone report loss of craving for heroin and have no withdrawal symptoms. It is important to note that

when patients remain on the appropriate dose, they most often experience no sedation or euphoria from this medication and are able to live a normal life. However, methadone is a potent medication and if misused it can produce sedation, euphoria, and even death. To minimize these risks, dispensing methadone is highly regulated and occurs only in specialized treatment programs. However, these regulations can restrict access to methadone and there are waitlists to receive it in many areas of the country. Methadone is often misunderstood and stigmatized making access to treatment difficult.

Buprenorphine was approved in 2000 to treat opioid use disorder in primary care office settings by physicians who complete an additional training course. Buprenorphine works similarly to methadone but only causes partial activation of opioid receptors, limiting its risk of overdose. It also strongly binds to receptors blocking effects of heroin. Patients treated with buprenorphine experience similar reduction in drug use and have health benefits as seen with methadone, though methadone is generally more effective at retaining patients in treatment.[6] Patients on buprenorphine continue to benefit from ongoing treatment even though some may continue to use illicit opioids intermittently. Buprenorphine is safer than methadone; therefore less monitoring in needed. Nevertheless, buprenorphine, like methadone, is a controlled substance as it can be abused. Both methadone and buprenorphine stimulate opioid receptors and individuals taking them remain physically dependent. When these medications are stopped abruptly patients experience symptoms of withdrawal and discontinuation effects as is the case with many medications in use today like antidepressants or antihypertensives.

Methadone and buprenorphine are widely used around the world and are on the World Health Organization's list of essential medicines with the recommendation that they should "*... be available at all times in adequate amounts and in appropriate dosage forms, at a price the*

community can afford." [7] WHO recognizes that methadone and buprenorphine should be used in the setting of established treatment programs.

The third medication approved by FDA for treatment of Opioid Use Disorder is naltrexone. It was first available over 30 years ago as a daily tablet and was approved as a monthly injection in 2010. Naltrexone works differently from buprenorphine or methadone. It attaches to opioid receptors, and while it produces no effect on its own, it prevents heroin or opioid painkillers from exerting any effects. Naltrexone is used following detoxification to reduce cravings for heroin[8] and also block the impact of any relapse. Because it acts as a total blocker, it assures periods of abstinence where patients can learn to live without heroin and engage in therapy to learn new skills to regain control of their lives.

Given the challenge of treatment non-adherence in this population, a monthly injection assures longer periods of abstinence, compared to missing a daily dose of medication. Therefore the injectable form of naltrexone is now the preferred formulation by expert clinicians. Since this is a new form of medication, we have less experience with it as compared to methadone or buprenorphine, and fewer providers are aware of it. Naltrexone does not produce physical dependence so there is no withdrawal when it is stopped and it is not a controlled substance since it has no abuse potential.

Importance of Individualized Treatment

The response to medication-assisted treatments varies, similar to treatment in other medical or psychiatric disorders, such as hypertension or depression. Many individuals respond best to one of the three medications and it may take one or two attempts to determine the best fit. Occasionally, individuals may get better with treatment that includes only therapy and a self-help

group meetings (like Alcoholics Anonymous (AA) or Narcotic Anonymous (NA)). Such 12-step programs can be very helpful for patients who remain involved, but have very high drop-out rates. At this time we don't know how to predict which individuals will respond to a specific medication and which individuals will get better with psychosocial treatments alone.

Methadone, buprenorphine, and naltrexone have different pharmacological effects, they are not simply duplicative. Patients seeking treatment need all three available medication options. Hopefully, as all of these medications come into broader use, we will be able to carry out research to determine a process for matching the most effective medication to an individual patient based on drug use history, genetic factors, psychiatric profiles, and environmental exposures. However, as long as we are using one of the medications known to be effective, the odds of success will be greater than with a treatment approach without medication support. Unfortunately, treatment without medication support is currently the dominant approach in the United States. High quality evidenced-based medication-assisted treatment is only available at a few select programs or with high cost private practitioners.

Duration of medication-assisted treatment

The primary goals of treatment for opioid use disorder are similar to treatment goals for other chronic illnesses such as diabetes or hypertension. These are: 1) To reduce or eliminate the primary symptoms of the illness, in this case compulsive use of opioids, 2) To decrease the risk of illness-related complications, such as overdose, or incarceration, and 3) To improve the overall well-being of the patient to maintain a healthy life and contribute to society.

Treatment with methadone or buprenorphine works best as a maintenance intervention,

used at adequate doses without a predefined length of treatment duration. There is no scientific evidence showing benefits to limiting the time someone takes the medications. [3] Rather the evidence shows that the longer a patient remains in treatment, the more likely they are successful during treatment and after it is discontinued. [9] Opioid addiction is a chronic brain disease requiring ongoing treatment to achieve the best outcomes.

Aiming towards cessation of medications at some point in the future is important, due to concerns about costs and side effects that are always important to consider in medicine, but it should only be a goal of secondary importance, after all other goals were accomplished and patients have stabilized in their recovery. When it comes to using medications in the treatment of chronic medical problems, as long as the patient benefits from treatment, and benefits outweigh risks of continuing the medication, most physicians would advise against stopping it. For example, in management of hypertension, stopping medication is not a primary goal of treatment. The main objective is to maintain normal blood pressure and prevent complications such as stroke and heart attacks. If a patient lost weight, exercised regularly, and the dose of medication needed to maintain normal blood pressure was gradually decreased without problems, then stopping the medication could be a goal. But would we ever discontinue or refuse prescribing the medication because the patient is not willing to lose weight or exercise? Such an approach would be unethical and ineffective, not meeting the standard of care in medicine. Sadly, this situation is a common occurrence in the treatment of opioid use disorders.

Reduction in overdose deaths

The risk of death because of untreated opioid addiction is very high, approximately 1 in a 100 of individuals addicted to opioids dies every year as a result of this illness. This risk is greatly reduced in patients that are treated with medications. [10-12] Another important strategy to reduce the number of overdose deaths involves the distribution of overdose prevention kits with the opioid blocker naloxone. Reversing overdoses with naloxone can be certainly successful in saving lives, but this is not a treatment of opioid addiction. It should be promoted along side medications to treat this disorder. Unless these individuals enter treatment and receive medication to normalize their brain function, they will remain at very high risk of another overdose. Medication-assisted treatment is the best way to reduce the number of overdose deaths on a large scale. More than a hundred individuals, many of them young adults, die every day as a result of this devastating disorder. But unlike many other disorders with high mortality rates, opioid use disorder is treatable, and a joint effort of health professionals, community advocates, and policy makers is urgently needed to reverse this tragic trend.

Recommendations

Chairman Murphy and members of the Subcommittee, I respectfully submit the following recommendations for your consideration.

1) Encourage the expansion of medication-assisted treatments with methadone, buprenorphine, and naltrexone to maximize chances that every patient will have the best possible outcomes. Every licensed drug treatment program should offer these medications alongside evidence-based behavioral treatments and other supportive strategies.

2) Ensure that both public and commercial insurance companies pay for treatment that is evidence-based to encourage creation of new treatment programs that offer the most effective treatments.

3) Provide additional financial support, if insurance coverage is lacking, to lower the threshold for treatment entry and increase access to effective medications for all those that would like to receive help, including veterans, adolescents, and prisoners.

4) Provide funding for the education of a new generation of medical professionals: medical students, physicians, nurses, psychologists, social workers and counselors to be able to treat both mental health and substance use disorders. Include up-to-date training curricula in medication-assisted psychosocial treatments of substance use disorders.

5) Provide funding for research into developing new treatments and to improving the effectiveness of existing treatments such as protocols for patient-treatment matching to further maximize treatment effectiveness

I would like to thank the committee for the opportunity to testify on this very important issue.

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Mr. MURPHY. Thank you. Appreciate it.

We are going to try and get Dr. Harris' testimony in, then we are going to run to go vote and come back.

So you are recognized for 5 minutes.

STATEMENT OF PATRICE A. HARRIS

Dr. HARRIS. Thank you. Good morning, Mr. Chairman and Ranking Member, and esteemed members of the subcommittee. I am honored to testify today on behalf of the American Medical Association. My name is Dr. Patrice Harris. I am Secretary of the AMA Board of Trustees. I am also the Public Health Officer for Fulton County, which includes Atlanta, and I am a practicing psychiatrist with experience in addiction.

We are indeed in the midst of an epidemic. Physicians are deeply disturbed about the rise in overdoses and fatalities from prescription opioids, as well as the rapid increase in deaths from heroin-related overdoses. The numbers are sobering and unacceptable.

The AMA is working on a number of fronts with many other groups to develop recommendations and implement specific strategies to confront this public health crisis. Physicians are stepping up and taking responsibility to prevent and reduce abuse, misuse, overdose, and death from prescription opioids. We also need to make sure that our patients who experience pain receive the treatment they need. With opioids, if clinically appropriate, and that patients who have an opioid use disorder have timely access to affordable, comprehensive treatment.

These are complex problems and there is no one solution. A multifaceted, public health strategy is needed. There are key components to this strategy. First, physicians must continue to amplify our efforts to train and educate ourselves to ensure that we are making informed prescribing decisions, considering all available treatment options for our patients, and making appropriate referrals for our patients with substance use disorders. As part of the prescriber clinical support system for opioid therapies funded by SAMHSA and administered by the American Academy of Addiction Psychiatry, the AMA is developing new training materials on responsible opioid prescribing, including a focused educational module on opioid risk management for resident physicians.

Patients in pain deserve compassionate care, just like any other patient we treat. The dialogue must change to reduce the stigma that is associated with pain. We need to increase insurance coverage for evidence-based alternative, multidisciplinary, non-drug pain management therapies. At the same time, we need to support access to opioid-based therapies when clinically appropriate.

Opioid use disorder is a chronic disease that can be effectively treated, but it does require ongoing management. Physicians need more resources so that evidence-based treatments such as medication-assistant treatment in conjunction with counseling and other behavioral therapies and interventions are more available and accessible to all of our patients. There are not enough programs and many are not affordable.

We strongly support lifting the cap and expanding the number of patients that office-based physicians can treat with

buprenorphine and Suboxone, which are major tools in treating opioid use disorder.

Naloxone has saved thousands of lives across the Nation, and we strongly support increasing access to it. We encourage physicians to prescribe naloxone to their at-risk patients, but barriers still exist to using this effective drug to prevent overdose deaths.

Now, one way to reduce one of these barriers is passage of Good Samaritan laws so that healthcare professionals, first responders, friends, family members, and bystanders who see someone who had overdosed can help save a life without fear of liability.

Last, prescription drug monitoring programs can be a helpful clinical tool. However, to be most effective and used more often, PDMPs need to be real time, interoperable, and available at the point of care as part of a physician's workflow. In order to get to this point though, Congress needs to fully fund these programs so that States can modernize and fully fund and staff them.

So in summary, we know that it is up to our profession to provide the leadership necessary to confront this epidemic, and we commend this committee's leadership and look forward to working with you and other stakeholders to promote evidence-based solutions. Our patients deserve no less.

Thank you.

[The prepared statement of Dr. Harris follows:]

Statement

of the

American Medical Association

to the

Committee on Energy & Commerce
Subcommittee on Oversight and Investigations
United States House of Representatives

Re: "Combatting the Opioid Abuse Epidemic:
Professional and Academic Perspectives"

Presented by Patrice A. Harris, MD, MA
Secretary, Board of Trustees

April 23, 2015

Division of Legislative Counsel
(202) 789-7426

Summary of the American Medical Association's Statement

- There is no question that we are in the midst of an epidemic of prescription drug opioid misuse, abuse, overdose, and deaths from such drugs. At the same time, we are seeing an alarming related trend, with patients turning to illicit drugs such as heroin as the supply of prescription drugs decreases.
- The issues are complex and there is no one answer or solution, but we must approach the problems with a public health focus.
- As physicians, we need to take ownership and responsibility for prevention. We need to ensure that patients experiencing pain are appropriately treated, and that patients who abuse or misuse opioids are referred to and have access to treatment programs.
- The American Medical Association is providing leadership and working on a number of fronts to offer and implement specific strategies to deal with this epidemic. We are working with a diverse array of stakeholders at the federal and state levels to effect change.
- We have specific recommendations to address solutions. First, we support enhancing education and training of physicians, prescribers, and patients to ensure informed prescribing decisions to prevent and reduce the risks of opioid abuse. We are developing new training materials on responsible opioid prescribing through a SAMHSA grant.
- We need to ensure that patients in pain receive the care they need and reduce the stigma associated with many such patients. We must change the tone of the debate to pay more attention to multi-disciplinary, patient-centered approaches to pain management, including ensuring insurance coverage for evidence-based alternative pain management treatments.
- We need to recognize that opioid use disorder is a medical condition and increase coverage for and access to medication assisted treatment and other treatment programs. We need more resources devoted to ensure that evidence-based treatment is available and accessible.
- We need to increase access to naloxone and other overdose prevention measures, and enact Good Samaritan laws to provide protection from liability for bystanders who witness overdoses.
- We need to modernize and fully fund prescription drug monitoring programs. PDMPs can serve as a helpful clinical tool, but to increase their use, they need to be real-time, interoperable, and available at the point-of-care as part of a physician's workflow.
- Physicians want to be engaged and be part of the solution.

STATEMENT

of the

American Medical Association

to the

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

United States House of Representatives

RE: "Combatting the Opioid Abuse Epidemic: Professional and Academic Perspectives"

Presented by Patrice A. Harris, MD, MA
Secretary, Board of Trustees

April 23, 2015

On behalf of the American Medical Association (AMA), I commend the Subcommittee on Oversight and Investigations of the Energy & Commerce Committee for conducting this hearing to address "Combatting the Opioid Abuse Epidemic: Professional and Academic Perspectives." As the largest professional association for physicians and the umbrella organization for state and specialty medical societies, the AMA is dedicated to promoting the art and science of medicine and the betterment of public health. The AMA appreciates having the opportunity to testify at today's hearing.

There is no question that we are in the midst of a public health epidemic. According to the Centers for Disease Control and Prevention (CDC), the rate of fatal prescription drug overdoses involving opioids almost quadrupled from 1999 to 2011. The rate of emergency department visits involving prescription drug misuse—primarily of opioid, antianxiety, and insomnia medications—more than doubled from 2004 to 2011. The CDC reports that while deaths involving prescription opioids declined for the first time in a decade in 2012, they once again increased in 2013, with more than 16,000 lives lost annually. More recently, there has been a substantial increase in deaths from heroin. The CDC recently reported that 8,257 people died of heroin-related deaths in 2013—a 39 percent increase from 2012. Total drug (illicit and prescription) overdose deaths in 2013 rose to 43,982, up six percent from 2012. We are deeply disturbed about the rise in overdoses from prescription opioids and that deaths from heroin-related overdoses are rapidly increasing. While public and media attention has focused on several recent overdose deaths of high-profile celebrities, communities across the U.S. have seen a tragic rise in heroin-related deaths. Some suggest this is due to restrictions on prescribing prescription opioids, or the lower

cost and easier accessibility of heroin. There may be other reasons as well, and we need the data to help guide our interventions, but it is clear that we need to act.

The numbers are sobering and the AMA is working on a number of fronts to implement specific strategies to reduce prescription opioid misuse, abuse, overdose, and overdose deaths. The AMA brings a critical perspective to this public health crisis as physicians are on the frontlines and fully understand the human cost and the toll it can take on patients and their families, as well as on whole communities. Physicians work hard to balance their ethical obligation to treat patients with legitimate pain management needs against their legal responsibility to identify patients who may be misusing or abusing drugs, and prevent abuse, misuse, overdose, and death from prescription drugs. Under the Controlled Substances Act (CSA), physicians have a legal responsibility to ensure that a prescription for a controlled substance is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." This legal responsibility underscores our ethical obligations to our patients, and the AMA is committed to helping physicians meet their responsibilities.

The AMA believes that it is up to physicians to be leaders in preventing and reducing abuse, misuse, overdose and death from prescription drugs through ensuring appropriate prescribing practices as one part of a multi-pronged public health strategy. At the same time, the AMA is strongly committed to ensuring that patients experiencing pain receive appropriate treatment with opioids, if necessary, and that patients with opioid use disorders have access to treatment.

We need a comprehensive public health approach to combatting the nation's prescription opioid abuse and growing heroin epidemic. These are complex problems, and the AMA is working with multiple stakeholders to effectuate change in how to address these issues. We believe the following critical components are necessary: enhancing education for physicians and patients about appropriate prescribing practices; increasing access to treatment programs for opioid use disorders, including medication assisted treatment programs (MAT); ensuring that patients in pain receive the care they need and reducing the stigma of pain; recognizing that opioid use disorder is a medical condition, reducing the stigma of this disorder, and increasing coverage for and access to medication assisted treatment and related services; increasing access to naloxone and other overdose prevention measures, and expanding Good Samaritan laws; and increasing funding and staffing for up-to-date, interoperable, at the point-of-care prescription drug monitoring programs (PDMPs) that are integrated into a physician's workflow. Each of these components is discussed in further detail below.

Enhancing education for physicians and patients

The AMA strongly supports physicians and other prescribers relying on the most up-to-date education and training when it comes to pain management, prescribing opioid analgesics, and other pain medications. We must take increased responsibility for solving this national epidemic. Enhanced education—beginning in medical, physician assistant, nursing, dental, and pharmacy schools and continuing throughout one's professional career—can help all prescribers, pharmacists, and patients identify and address the risks of prescription drug misuse and prevent diversion and overdoses. Physicians must take the lead in training and educating themselves and their colleagues to ensure they are making informed prescribing decisions, considering all available treatment options and data for their patients, reducing inappropriate prescribing of opioids, making appropriate referrals for patients with opioid use disorders, and taking other steps to address over-prescribing of opioids while ensuring

appropriate treatment of patients with acute or chronic pain. The AMA is working with the National Association of Boards of Pharmacy (NABP), National Association of Chain Drug Stores, Federation of State Medical Boards, and other associations on this effort.

In addition, the AMA, along with several other medical organizations, is a partner in the Prescriber Clinical Support System for Opioid Therapies (PCSS-O) funded by the Substance Abuse and Mental Health Services Administration (SAMHSA) and administered by the American Academy of Addiction Psychiatry. PCSS-O is a national training and mentoring project developed in response to the prescription opioid overdose epidemic. As part of this collaborative, the AMA is developing new training materials on responsible opioid prescribing and a focused educational module on opioid risk management for resident physicians, and is seeking to engage selected states and state medical associations on collaborative approaches to address opioid-related harms.

Ensuring that patients in pain receive the care they need and that they are not stigmatized as "malingerers" or "drug seekers"

Patients in pain deserve compassionate care just like any other patient physicians treat, and the AMA strongly opposes stigmatizing patients who require opioid therapy. In medicine, we do not use terms such as "malingerer" or "drug seeker" because these terms carry with them damaging psychological stigma. Patients who need care are simply "patients," and we should seek to change the tone of the debate toward more attention on multidisciplinary, patient-centered approaches to pain management and ensuring that evidence-based alternative pain management treatments and strategies are covered by insurance, while supporting opioid-based therapies when clinically appropriate and effective. For example, many patients must face step therapy, fail first, and prior authorization protocols by insurers that limit a physician's ability to prescribe a non-opioid treatment such as physical or occupational therapy. Despite the substantial burden of chronic pain in the U.S., access to multidisciplinary care and reimbursement for non-pharmacologic approaches is inadequate and needs to be addressed.

Furthermore, objective tests for the presence or absence of pain or pain intensity are still at a basic stage of development, and in most circumstances, the best clinical approach is to assume that the patient is reporting a true experience. While accepting a patient's complaint of pain as valid does not demand that a specific treatment be initiated, it does provide a foundation for assessment and the basis of developing an effective patient-physician dialogue and relationship, which is key to enabling the physician to provide the best possible care.

Recognizing that opioid use disorder is a medical condition and increasing coverage for, and access to, medication assisted treatment and related services

Similar to patients in pain, we should not use terms such as "addict" or "junkie" or "user" because these terms carry with them damaging psychological stigma. Patients who need care are "patients," and deserve our care and compassion. Opioid use disorder is a chronic disease that can be effectively treated but it requires ongoing management. However, more resources need to be devoted to ensure availability of, and access to, evidence-based treatment. A public health-based approach to harmful drug use requires having both broad-based treatment services available for those with opioid use disorders, as well as MAT, and insurance coverage for such treatment. MAT is the use of medications, commonly in combination with counseling, behavioral therapies, and other recovery support services to provide a comprehensive

approach to the treatment of opioid use disorders. Food and Drug Administration (FDA)-approved medications used to treat opioid addiction include methadone, buprenorphine (alone or in combination with naloxone), and naltrexone. Types of behavioral therapies include individual therapy, group counseling, family behavioral therapy, motivational incentives, and other modalities. MAT has been shown to be highly effective in the treatment of opioid addiction.

We are deeply concerned by the barriers faced by physicians in finding and placing patients in addiction treatment and recovery programs. Many physicians regularly face this dilemma because there is inadequate capacity to refer patients for treatment and recovery programs. A profound need exists to address the workforce limitations and the lack of accessible and affordable treatment programs.

Making certain prescription drugs less accessible, however, does not stop prescription drug misuse, abuse, diversion, overdose, and death. In fact, making these drugs less accessible without policies and strategies to provide treatment and recovery merely changes the drug of choice from legal prescription drugs to illegal drugs that have no legitimate medical use. If the ultimate goal is to provide comprehensive care to our patients and ensure we are doing everything we can as a profession and a society to stop addiction, overdose, and death, a far greater effort is needed to focus on the treatment and recovery side of this crisis.

For example, the AMA strongly supports increased access to treatment for drug addiction and physician office-based treatment of opioid addiction. The Drug Addiction Treatment Act of 2000 provided for an office-based option for opiate treatment utilizing buprenorphine (a potent synthetic compound that acts on the same opiate receptors as morphine and methadone). However, limits remain on the number of patients a physician may treat utilizing buprenorphine, a drug that can be used to facilitate recovery from opiate addiction. There is broad consensus in the medical community that buprenorphine is a major tool to fight addiction. Lifting the cap would enable physicians to treat more patients with this highly-effective drug.

In addition, suboxone, a combination of buprenorphine and naloxone (an inhibitor of the opiate receptor), is very safe to be administered on an outpatient basis and is available to be prescribed by any licensed practitioner after completing a training curriculum that focuses on the pathophysiology of opiate addiction, screening of patients, symptom identification and management, and prescribing of the medication. Becoming certified as a prescriber for suboxone requires a fee for completion of the training, registration with governmental entities, and after a waiting period, the ability to prescribe suboxone to 30 patients for the first year. The prescriber may submit a waiver request to treat up to 100 patients after the first year.

The regulatory process for becoming a prescriber and the patient limits serve as barriers to increase capacity to treat opiate addiction and the availability of suboxone to opiate-addicted patients, particularly those patients in jurisdictions that have adopted a law enforcement approach (as opposed to a public health approach) to combat prescription drug abuse. The advantages of reducing the regulatory burdens to prescribing suboxone would not only increase the availability of suboxone treatment for patients with opiate addiction, but would also increase clinical identification, awareness, and acceptance of opiate addiction as a disease and reduce the stigma associated with opiate addiction.

Several options exist to expand the current capacity to treat opiate addiction. First, suboxone training could be offered free-of-charge to prescribers with either renewal or initial application of a prescriber's DEA number. Second, the initial patient cap could be increased with a waiver option after 6 months instead of one year. In addition, Medicare reimbursement rates for suboxone treatment and counseling could be increased as an incentive for prescribers to treat opiate-addicted patients.

Increasing access to overdose prevention measures such as naloxone and enhancing Good Samaritan protections

The AMA strongly supports the national trend of states enacting new laws to increase access to naloxone, which is a safe and effective FDA-approved medication that reverses prescription opioid and heroin overdose and saves lives. Naloxone has no psychoactive effects and does not present any potential for abuse. AMA advocacy has supported new state laws to put naloxone into the hands of appropriately trained first responders and friends and family members who may be in a position to help save lives. The AMA encourages physicians to co-prescribe naloxone to their patients at-risk who are taking opioid analgesics. Since the mid-1990's, community-based programs have been offering naloxone and other opioid overdose prevention services to persons who use these drugs, their families and friends, and service providers (e.g., health care providers, homeless shelters, and substance abuse treatment programs). These services include education regarding overdose risk factors, recognition of signs of opioid overdose, appropriate responses to an overdose, and administration of naloxone. It is well documented that naloxone has saved thousands of lives across the nation. Despite this progress, however, barriers still exist to optimal use of naloxone in preventing overdose deaths. One way to reduce barriers to the use of naloxone is passage of Good Samaritan laws to protect from liability first responders, friends and family members, or bystanders who may witness an overdose and have access to naloxone.

Modernizing and fully funding prescription drug monitoring programs

We acknowledge that physicians and other prescribers must take charge of this epidemic by carefully examining prescribing practices. Physicians need to be sure that they are prescribing appropriately and taking necessary precautions, including consulting PDMPs when clinically indicated. PDMPs have the potential to serve as a helpful clinical tool in the fight against prescription drug misuse.

As a result of years of concerted advocacy from the AMA and other national medical specialty societies, the National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER) was signed into law. Although $52 million was authorized over a five-year period, it was not until 2009 that federal funds were appropriated to support the state adoption of PDMPs.

PDMPs can provide reliable and actionable information. It has been only in the past several years that almost all states (e.g., with the exception of Missouri) have finally passed state legislation establishing PDMPs. In order to increase the use of PDMPs, the AMA supports PDMPs that are real-time, interoperable, and available at the point-of-care as part of a physician's workflow. Currently, 28 states can share data through NABP's Pharmacy Interconnect platform. When PDMPs are available at the point-of-care, with up-to-date information, and integrated into physician workflow, their efficacy is remarkable. A growing body of evidence suggests that PDMP data can help inform sound clinical decision-making; however, there also is a growing body of evidence suggesting that PDMPs—by themselves—are not the panacea to reducing prescription drug abuse, misuse, overdose or death.

Modernized PDMPs can provide physicians with a basic tool to make treatment decisions based on patient-specific needs. This not only includes helping detect so-called "doctor shoppers," but also providing information on whether a patient might need counseling for a potential opioid use disorder. In short, PDMP data can be helpful to form a diagnosis and treatment plan, but it is not a stand-alone solution.

However, full funding for PDMPs is needed to ensure that physicians across the country have this effective tool at the point-of-care to combat prescription drug abuse while ensuring that patients with legitimate need for pain management continue to have access. Unfortunately, the appropriations to fully fund, modernize, and optimize the PDMPs have not kept pace with the rapid escalation in abuse and diversion of prescription drugs. We support full appropriations with a continued strong emphasis on the public health focus of NASPER.

Working with stakeholders at the federal and state levels

The AMA has worked closely with federal and state policymakers and with a diverse array of stakeholders for many years to address this growing public health crisis. At the federal level, the AMA is a founding member of the Alliance to Prevent the Abuse of Medicines (the Alliance), a non-profit partnership of key stakeholders in the prescription drug supply chain—e.g., manufacturers, distributors, pharmacy benefit managers, pharmacies, physicians—established to develop and offer policy solutions aimed at addressing the prescription drug abuse epidemic. In addition, the AMA participated in a diverse coalition of stakeholders convened by the National Association of Boards of Pharmacy (NABP), to discuss key issues and develop recommendations related to the safe prescribing and dispensing of controlled substances. The AMA Board of Trustees recently joined NABP and 15 medical, pharmacy, and other organizations to issue a consensus document, "Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances," that represents the culmination of several meetings and collaborative work by the stakeholder organizations.

Over the past year, the AMA has brought together representatives from more than 40 medical specialty and state medical associations, as well as the American Dental Association, to discuss strategies and develop recommendations to prevent and reduce opioid abuse and misuse. The AMA Task Force to Reduce Opioid Abuse is focused on ensuring that physicians and other prescribers take on an increased leadership role to address the nation's epidemic of prescription drug misuse, unintentional overdoses, and death, while also ensuring access to legitimate treatment for pain, as well as opioid use disorders.

At the state level, the AMA and our state medical societies have worked closely to ensure that new policies have a direct impact on this national epidemic. Nearly every state legislature is considering one or more pieces of legislation concerning prescription drug abuse, misuse, overdose, and death, including bills on PDMPs, continuing medical education requirements for licensing, restrictions on prescribing opioids, and electronic prescribing of controlled substances. It is important to note, as recognized by CDC, that different regions of the nation have different problems, and a one-size-fits-all approach is not the optimal method of attack. For example, the nation's heroin epidemic has gripped the Northeast in different ways than in other parts of the nation, and that region has made efforts to greatly expand access to naloxone. Similarly, states have begun to use county-level data to understand prescribing patterns, overdose and death patterns, and other key data to determine how to best target public health

interventions. The interventions needed in more rural parts of Kentucky and Tennessee, for example, might differ from what is needed in the Chicago, Philadelphia, or Denver suburbs.

One of the most promising interventions has been new laws focused on overdose prevention, increased access to naloxone, Good Samaritan protections, and treatment of opioid use disorders. The AMA has worked hand-in-hand with many state medical societies to help enact these laws throughout the nation, and our goal is for every state in the land to support this life-saving approach.

But we can't stop there. In addition to state legislative advocacy, the AMA remains engaged with the National Conference of Insurance Legislators (NCOIL), National Alliance for Model State Drug Laws, the National Governors Association (NGA), and other legislative-focused organizations. Outreach also continues with patient-focused organizations, including the HARM Reduction Coalition, National Safety Council, and others in an effort to balance the national discussion of prescription drug abuse, misuse, overdose, and death to one that appropriately emphasizes overdose prevention and treatment for opioid use disorders.

Conclusion

As the foregoing initiatives demonstrate, the AMA is strongly committed to combatting opioid drug misuse, abuse, overdose, and death while simultaneously ensuring access to treatment for pain and opioid use disorders. The AMA appreciates the opportunity to provide our comments on this critical health policy matter, and we look forward to working with the Subcommittee, Committee, and Congress to address the scourge of prescription opioid and heroin abuse and overdose, while ensuring that patients with legitimate pain management needs and opioid use disorders have access to treatment. Our patients deserve no less.

Mr. MURPHY. Thank you, Dr. Harris. And thank you to the panel.

We are in the middle of votes, so we are going to break here. It is going to take us about half an hour or so for votes. We will come back.

I just wanted to leave one sobering statistic I have here about this. In North America, the number of deaths from plane crashes between 1975 and today was 42,495. 1975 through today. For the United States, the number of drug overdose deaths last year was 43,000. If we were here having a hearing on plane crashes, we would need an arena to handle the media. What a sad day it is with 43,000 people died in this country last year. I feel that we need to have people understand the severity of that.

I thank this panel for your testimony. We will come back and ask you questions in a few minutes. Thank you.

[Recess.]

Mr. MURPHY. All right, we are going to return to our hearing here, and as members come in, we will put them in the queue.

So let me start off here. I want to ask a question here. Dr. Seppala, a Federal policy prohibits Medicaid matching funds being used at inpatient facilities with more than 16 beds whose patient roster is more than 51 percent people with severe mental illness, and for individuals between the ages of 22 and 64. Does this affect inpatient substance use disorders clinics as well when they have those limitations?

Dr. SEPPALA. It sure would, absolutely. Any population that is restricted in that manner is not going to get adequate treatment.

Mr. MURPHY. So again, making sure we have options available, that is a barrier that we need to eliminate.

Dr. SEPPALA. Yes, increasing options for addiction treatment is really necessary in this country. We don't have adequate treatment to address this problem, but we also have a public health information problem because, if you look at the data from SAMHSA, you will see that over 95 percent of the people with addiction don't even know they have it. So that is where the initial problem lies. And then of that small group that seeks treatment, the biggest problem is access.

Mr. MURPHY. Now, Dr. DuPont, I want to show you a poster here. According to the National Institute on Drug Abuse, for patients treated with opioid addiction with buprenorphine, there is a 92 percent of relapse with an illicit opiate within 8 weeks after stopping treatment. But look at the increases here—this line is buprenorphine—from 2003 to 2012, and it has gone up even higher now. Methadone rates have remained fairly flat, and heroin rates have increased slightly over this time. So I am wondering, given these statistics, and given the huge relapse rate with 92 percent, relapse with an illicit opiate within 8 weeks after stopping treatment, are we doing enough to hold treatment programs accountable to make sure that they are getting people the additional treatments to get them on the road to recovery?

Dr. DUPONT. Well, that is very important information, absolutely, and to me, it shows that buprenorphine or methadone are not magic bullets, but they are very attractive to many patients and they bring a lot of people into treatment, and that is a good

thing. I think the question, to me, is what happens to them then? And if they just go out and leave the program, nothing very good is happening. I am excited about the possibility of having a longer-term perspective on the buprenorphine patients, and helping them over a longer period of time. But the answer is, as you show there, that most stay a very short time and the outcome when they leave is that they relapse to the opiates.

Mr. MURPHY. And I want to make sure we are all on the same page, because what I am pushing for is I want to make sure we have a standard here that has hopes of getting people off of substances. And I recognize, like any other field, we can't reach 100 percent, but our goals should never be less than 100 percent. But there is a big overlap also with people with mental illness.

Dr. Westreich, so people with mental illness and severe mental illness who are actually seeking some substances to numb the effects or self-medicate. I see a lot of these in the military with folks, and of course, it makes a bad situation worse. But then when you have someone who is now addicted, and we are trying to wean them off, I would like to think that this is not just a matter of substituting an opiate with buprenorphine or methadone as a replacement as a road of treatment, but really thinking in terms of should they be on another medication, a psychotropic drug, something else to treat the underlying mental illness. Is this an appropriate hypothesis? And two, are we doing this, and if not, why not?

Dr. WESTREICH. First of all, I think it is absolutely an appropriate hypothesis, and I don't think we are doing it enough.

I think the point is that people who have addictive disorders as well as another mental illness need to have very sophisticated clinicians who are trained in being able to recognize psychiatric symptoms and what they mean. Do they mean that the person is simply medicating some uncomfortable symptoms? Do they mean that the person has got a freestanding psychiatric illness, which must be treated with psychotropic medications, or some combination of the above? And so this speaks to the training of psychiatrists, psychologists, social workers, counselors who need to be trained to recognize mental illness symptoms and treat them effectively.

Mr. MURPHY. And we have heard repeatedly in this committee that the huge shortage of psychiatrists, psychologists, especially child/adolescent ones, to deal with this issue. But another concern we have heard is from States that there are limitations on—they have funds for substance abuse, and they have funds for mental illness, and oftentimes they can't use those together.

Anybody want to comment on that of what we should be doing to make sure that they have maximum flexibility in the States? Can anybody comment on that? Dr. Bisaga?

Dr. BISAGA. I think those very often is more of a norm than an exception that they go together. So keeping them separate, in separate pools of money, doesn't really make sense from a clinical perspective. I think we are much more effective when we are integrating treatment for mental illness and substance abuse by the same provider in the same setting. This is the way to have better outcomes.

Mr. MURPHY. Thank you. Anybody else want to comment? Yes, Dr. Seppala?

Dr. SEPPALA. In our residential settings, in our youth settings, so it is about age 14 to 24, over 95 percent of our population enters treatment with a coexisting diagnosis of a mental illness. In our adult populations, again, a residential not outpatient setting, it is over 75 percent. So what we are seeing is comorbid psychiatric illness with addiction in our treatment settings. It is the norm. We have to treat both.

Mr. MURPHY. Thank you.

Ms. Schakowsky, you are recognized for 5 minutes.

Ms. SCHAKOWSKY. So I have never seen that chart before and, you know, you first look at the chart and you think that buprenorphine is a bad idea. I mean that is how it looks. So I wondered if anyone——

Mr. MURPHY. Yes, I am just saying we are doing more of it, but——

Ms. SCHAKOWSKY. So maybe Dr. Bisaga can speak to that?

Dr. BISAGA. Well, you know, obviously, this is a very complex problem. You know, we see increasing rates of buprenorphine prescribing because we have an epidemic and we are trying to expand the number of people that are treated with this medication. So it tells us a lot of things. It is true that not every buprenorphine treatment program is to the best standards, but that shouldn't really stop us from trying to expand access. We still have a shortage of providers that are trained to deliver this treatment. But if this chart had also a number of people addicted to painkillers, this line would probably go down, which I think speaks something about at least the beginning of making a——

Ms. SCHAKOWSKY. But it does it mean that methadone is better, or——

Dr. BISAGA. Well, you know, when you compare methadone with buprenorphine in a similar situation, methadone is a little bit more potent as a medication, but because it is such a, you know, difficult medication to use, it cannot be really widely, you know, as easily disseminated to the community as buprenorphine, and that is why we are pushing for the buprenorphine, again, as a first step of engaging people in treatment, protecting them from overdose, and then engaging them in the long-term psychosocial recovery-oriented treatment.

Dr. LEMBKE. Yes, I would just add that this is a really—I just would add a really important difference between buprenorphine and methadone is that the methadone—the overdose risk with methadone is very high, whereas the unique pharmacology of buprenorphine makes it very unlikely for people to overdose on it.

Ms. SCHAKOWSKY. Right.

Dr. LEMBKE. And so for that reason, there is a huge advantage in using buprenorphine, especially since one of the primary things we are trying to stop is the number of people who are dying due to opioid overdose.

Ms. SCHAKOWSKY. So also let me understand, on the panel, is there anybody who doesn't think that the combination of meds and psychosocial treatment, that one or the other itself is the way to go? No, oK.

So let me ask Dr. Lembke. Unfortunately, there are a number of barriers then for people to get medication, assisted treatment,

MATs, and one of the barriers is insurance coverage. And according to the American Society of Addiction Medicine, Medicaid coverage for MAT varies greatly from State to State, the chairman was talking about that, with some States not covering all FDA-approved medications, imposing prior authorization requirements, and fail-first criteria that require documentation that other therapies were ineffective. I wondered, Dr. Lembke, if you have experienced these issues in your practice, both of Medicaid and private insurers?

Dr. LEMBKE. So that is very common with both Medicaid and private insurers that when you try to get coverage for addiction treatment, they give you the huge runaround, you have to talk with somebody on the phone for hours regarding medical necessity, whereas that is not true if you are prescribing a pharmacologically identical medication, or a very similar medication, for the treatment of, for example——

Ms. SCHAKOWSKY. So what does that——

Dr. LEMBKE [continuing]. Pain.

Ms. SCHAKOWSKY [continuing]. Really mean for patients?

Dr. LEMBKE. Well, what that means is that you want to get addiction treatment for patients who are struggling with the disease of addiction, and you can't get insurance companies to pay for it, which means that patients don't access the treatment. All you are left with is non—you know, interventions outside of the infrastructure of medical institutions, which is primarily just the 12-step movements. So it is a huge problem.

Ms. SCHAKOWSKY. And so in your opinion, and anybody else can weigh-in on this too, would increased coverage of MATs help more individuals to remain in recovery?

Dr. LEMBKE. Well, what happens now is that—what I see with private insurers is that they say they cover MATs, but then, basically, they have all kinds of loopholes whereby they can deny that coverage, and they just make it so incredibly bureaucratically cumbersome in real time, you know, in the trenches, that you end up throwing up your hands. And once you start somebody on buprenorphine, you don't want to just suddenly not have it available to them, but that happens frequently because all of a sudden, you have been denied coverage. It is insane.

Ms. SCHAKOWSKY. Anybody else want to comment on that?

Dr. SEPPALA. Yes, I could speak to it.

Ms. SCHAKOWSKY. Yes, Dr. Seppala.

Dr. SEPPALA. We have had to increase our own infrastructure just to have enough people involved to get these medications approved.

Ms. SCHAKOWSKY. You are talking about people who spend time on the phone and——

Dr. SEPPALA. Yes. Yes.

Ms. SCHAKOWSKY. OK.

Dr. SEPPALA. So trying to limit our doctors' involvement and have other people do that, usually nurses, but it really has required adding FTEs to what we do. So increasing our expenses just to get these medications approved by insurance companies.

Ms. SCHAKOWSKY. And eventually you do get them approved usually?

Dr. SEPPALA. I would say usually is a good description. Not always.

Ms. SCHAKOWSKY. Yes. OK.

Dr. HARRIS. And I also would like to add that it is increasing coverage for MAT, but it is also increasing coverage for the other interventions; the behavioral interventions, the therapies, cognitive behavioral therapies, the other therapies that we know compliment MAT and work well.

Ms. SCHAKOWSKY. And those are hard to——

Dr. HARRIS. It is very difficult to——

Ms. SCHAKOWSKY [continuing]. Get approved?

Dr. HARRIS [continuing]. Get coverage for that, yes.

Ms. SCHAKOWSKY. Thank you. OK, I don't know, can Dr.——

Dr. BISAGA. Can I—yes, on the other hand, another trend is that insurance companies know that this saves them money. Evidence-based treatment saves money. So we also see a trend of them declining to pay for the programs that do not offer evidence-based treatment; psychotherapy and the medication and on the 12-step. So that is another good trend. So hopefully we, you know, we can use the data to inform how we should actually invest in the public healthcare.

Ms. SCHAKOWSKY. Thank you so much. Thanks, Mr. Chairman.

Mr. MURPHY. Well, I want to follow up on what she is saying. It is very important, especially in light of the mental health parity. So we want to make sure that evidence-based care is there. Medication-assisted treatment is there as part of a protocol, psychosocial therapy is part of a protocol, using the proper things. Just talk therapy in a general concept isn't going to work, it has to be very focused with someone who understands addiction. And part of our challenge here is, we had previous testimony from some places just talking about pill mills where doctors are just cranking out lots of medication, and since 90 percent of people we found weren't in any kind of treatment, and of those getting treatment, only 10 percent of that were getting the evidence-based treatment. It sounds like what you are saying the insurance companies are kind of throwing the baby out with the bathwater here, responding to Ms. Schakowsky's questions, making it very difficult to get proper treatment. And since most people aren't getting treatment anyway, shouldn't they be focusing on something else? Dr. DuPont?

Dr. DUPONT. A point about that—that the evidence of what—what is the evidence we are talking about, and the evidence for evidence-based is what happens to the person while they are taking the medicine. It is not what happens to them later. Where do they go? And what I am encouraging is to have evidence-based assessment of what the consequences are—what the long-term outcome is of all of these treatments. Which treatments are getting people into stable recovery, which are not. And that is not what we are doing now. Our evidence is what happens while they are there, in the face of the fact that you have very rapid cycling through these programs. If we are talking about dealing with an epidemic, we have to deal with those people as individuals for their lifetimes, for long periods of time. That is why I say 5 years. So evidence-based of while they are in the treatment is good, but it is not what we

really want. Is it evidence of getting them into stable recovery or not——

Mr. MURPHY. Thank——

Dr. DUPONT [continuing]. That is the question that has to be asked.

Mr. MURPHY. Thank you.

Ms. DeGette, 5 minutes.

Ms. DEGETTE. Thank you very much.

Dr. Lembke, I am listening with interest to this discussion, and others might have also input on this, but why is it so difficult to get insurance companies and others to pay for these appropriate treatments?

Dr. LEMBKE. My belief is that essentially insurance companies do not want people on their panel who have chronic lifetime diseases that will need chronic lifetime care, and they essentially view the addicted population wrongly as folks who cannot get better and will always need lots of medical care. And it is really an untrue bias that insurance companies have that mirrors a bias that society has, because the truth is when you get addicted persons into quality addiction treatment, they have about 50 percent response recovery rates, which is on par with recovery rates for depression and many other chronic illnesses——

Ms. DEGETTE. So——

Dr. LEMBKE [continuing]. With a behavioral component.

Ms. DEGETTE. So you think that they don't want to—they are reluctant to get—pay for a treatment plan if they think that it could be a chronic long-term plan?

Dr. LEMBKE. Yes, that those people are going to be——

Ms. DEGETTE. Yes.

Dr. LEMBKE [continuing]. Costly for them. They don't——

Ms. DEGETTE. Right. And——

Dr. LEMBKE. They don't want to——

Ms. DEGETTE. And you think one of the solutions might be putting more patients on those boards?

Dr. LEMBKE. Patients on——

Ms. DEGETTE. People who have dealt with recovery and so on, is that what I am hearing you saying?

Dr. LEMBKE. On what boards?

Ms. DEGETTE. On the insurance review boards.

Dr. LEMBKE. You know, it is a weird group thing that happens even when you have physicians who you have to talk to who are representing insurance companies, their mandate is to withhold care. Their mandate is to pay for as little as humanly possible. I mean I can tell you horror stories about hour-long conversations I have had with physicians representing insurance companies who then denied care in cases where care was——

Ms. DEGETTE. So——

Dr. LEMBKE [continuing]. Obviously needed.

Ms. DEGETTE. So, Dr. Bisaga, I want to follow up with that because in your testimony, you said that very few of the patients with opioid addiction receive treatments that have been proven to be effective, and you said the treatment most of them were receiving is outdated and mostly ineffective. What kind of treatment is that that people are receiving that is just not working?

Dr. BISAGA. Right, so we just had a wonderful example from Dr. Seppala talking about kind of the best possible treatment that marriages very efficiently 12-step with the medications. This is really, really exception. This is 1 of the 1 percent. Majority of people, the treatment consists of going to the hospital, getting detoxified, and then trying to be encouraged to go to the 12-step meetings without being told even that there are evidence-based medications.

Ms. DEGETTE. So what it is, it is kind of a truncated treatment. It is like we are——

Ms. BISAGA. Again——

Ms. DEGETTE [continuing]. We are going to give you some—maybe we are going to give you some medication, we are going to make—we are going to tell you to go to this treatment, then you are on your own.

Ms. BISAGA. Right. So we only going to detox you, and we expect you—that you going to stay abstinent. There is no information about the evidence-based medications. After detoxification, opiate blocker could be a way to maintain——

Ms. DEGETTE. OK. So there is not—there is not even medication involved in most of these.

Ms. BISAGA. No. Many inpatient detoxifications do not put people on medication. It——

Ms. DEGETTE. They just detox them——

Ms. BISAGA. Yes.

Ms. DEGETTE [continuing]. And then they——

Ms. BISAGA. Detox them and sell them to 12-step groups.

Ms. DEGETTE. OK.

Ms. BISAGA. It is changing, but slowly.

Ms. DEGETTE. And do all of the rest of you agree with that, that that is what is going on for the most part? Yes? OK.

Now, Dr. Westreich, you said in your testimony, patients and their families need to know that detoxification treatment and drug-free counseling are associated with a very high risk of relapse. So it is sort of the same question that I was asking Dr. Bisaga, do you think that patients enrolling in programs that employ this approach are being given adequate information to make informed decisions about their treatment?

Dr. WESTREICH. Well, I think that is exactly the question. At the middle and end of that treatment episode, they should be given information about their particular case and what their likelihood for relapse is, and what possible treatments are, including medications, including abstinence models, and be able to make an informed decision based on having those treatments available to them. And my concern is when they are not available, the person cannot make an informed decision.

Ms. DEGETTE. Right. If you never have MAT offered as an alternative, you can't have a complete program.

Ms. WESTREICH. Exactly.

Ms. DEGETTE. And this is not just your idea or the other esteemed members of this panel, this is like scientifically proven, right?

Dr. WESTREICH. Yes.

Ms. DEGETTE. Yes.

Dr. LEMBKE. Can I just add one thing?

Ms. DEGETTE. Please.

Dr. LEMBKE. You know, MAT works for some people, it doesn't work for everybody——

Ms. DEGETTE. Right.

Dr. LEMBKE [continuing]. And what some people who are in the acute crisis of the disease of addiction need is to be put into a hospital so they can detox, and hopefully then get routed to some kind of behavioral or residential treatment. And that is also very hard to get insurance companies to pay for.

Ms. DEGETTE. Right, and if you can find a program to put them in.

Dr. LEMBKE. Even to put them in the hospital——

Ms. DEGETTE. Exactly.

Dr. LEMBKE [continuing]. I mean, even to put them in the hospital for 3 or 4 days is very hard.

Ms. DEGETTE. And, you know, let me just say, Mr. Chairman, I really appreciate this hearing because this is exactly what I have been trying to say is, it is not a one-size-fits-all solution for these patients, there are different types of solutions, but if you take out one of the programs that really works, like MAT, or the MAT plus the intensive long-term counseling, not only are you going to have a failure rate, but you are also going to have deaths. So thank you.

Mr. MURPHY. And even that is difficult for them to get.

Dr. Burgess, recognized for 5 minutes.

Mr. BURGESS. Thank you, Mr. Chairman. And I do have a number of questions for Dr. Harris. Thank you for being here today. I may end up submitting those to you in writing and ask for a written response because I do want to use part of the time that I have available to get on my soapbox. That is what we do here.

This is not quite the appropriate hearing, but this subcommittee does have jurisdiction over the Food and Drug Administration, and several times we have had the Food and Drug Administration in, I have asked the question why we cannot have the availability of naloxone or Narcan as an over-the-counter purchase. Why Federal law prohibits dispensing without a prescription, but why? No one is going to abuse Narcan. Narcan can be a lifesaving measure. Sure, I want first responders, police departments, EMTs, I want them to have it available in their armament when they arrive on the scene of a person who is unconscious. Are there—I don't think we will be inducing anyone to misbehave by having a rescue method at their disposal.

So, Mr. Chairman, I just wanted to get that out of the way. I do think the Food and Drug Administration needs to work on this. I think this is one of the things that—I mean you referenced in your opening statement the tragedies that occur happen in my suburban area as well. The tragedies that occur when we lose a young person through what presumably is an unintentional opiate overdose.

And then the other thing that I just feel obligated to talk about, I mean I was in practice for a number of years. Covered for other doctors, as we all do, and I know there were times that I was burned by a patient who was exhibiting drug-seeking behavior and I didn't immediately recognize it. I tried to guard against that. In fact, the latter years that I was in practice, I would not fill a prescription of a patient I did not know over the phone, I would go

to the office and look up their chart. If I couldn't find their chart, yes, that might be on us because we didn't have electronic records, we had paper charts, I would offer to meet that patient in the emergency room and evaluate their signs and symptoms, and if appropriate, prescribe a medication. Suffice it to say, most of the time that did not occur and the patient was not willing to come in and spend the time required.

But look, we have prescription drug monitoring programs. And I will tell you one time just sticks out in my mind how frustrated I was. Called in a prescription for a patient with a very plausible story, and the pharmacist said, you know, you are about the fifteenth doc that has called in medicine for that patient this month. And I said, what, that is crazy. Well, cancel the prescription. He said, you have already called it in, I will fill it for her when she shows up, but I just thought you ought to know. And I forget the number he gave me, but it was an astounding number of Tylenol III that this patient had received during the month. And forget the codeine part of the prescription; this was a multiple times lethal dose of acetaminophen that, if somebody had actually ingested it, their liver was long gone and someone would be paying for a liver transplant. We have prescription drug monitoring programs. We have one that was passed by this committee, called NASPER, and President Bush signed it into law in 2005. There is a competing program that was done by the appropriators. That is not your problem, that is our problem. But, Mr. Chairman, it just underscores how we need to fix that. And now, we ask the American people with the Stimulus Bill to fund this large electronic health records, and do we have the interoperability so a doc in practice would know what that patient is taking? We don't really have the availability of getting that because of HIPAA, there are some privacy concerns. Somehow we need to bridge that gap, and I really would welcome anyone's comments on the panel about the prescription drug monitoring aspect.

Dr. WESTREICH. I would like to comment——

Mr. BURGESS. Yes, Doctor.

Dr. WESTREICH [continuing]. On both. First, I agree 1,000 percent about Narcan, having that available not only to first responders but to families of people who have members who use opioids. I agree with you, and I don't see any reason why that can't happen.

Regarding the prescription monitoring programs, we have one in New York State where I practice, where I am obligated to look at it each time I prescribe an opioid medication. There is one in New Jersey which covers Connecticut and Delaware, but there is no national one. So someone can be getting an opioid medication in the State next door and I would have no idea from the pharmacy monitoring program. We need to have a fully national program, and it would be enormously helpful for treating our patients.

Mr. BURGESS. Our other problem is we have to—yes, Dr. Seppala? I am sorry.

Dr. SEPPALA. I would like to support both of your recommendations, Congressman. We should have over-the-counter naloxone. It is a very innocuous drug, you know that, and there are not many side effects or problems you could cause with it. It does one thing; it blocks opioid receptors in a very safe manner.

And as far as the prescription drug monitoring programs, when they are not mandatory, as was described earlier, only about 33 percent of the docs use it, so there is not adequate information on them. We need it to be mandatory and across State lines. So I agree with both.

Mr. BURGESS. Yes, Dr. Harris?

Dr. HARRIS. Yes, PDMPs are a valuable tool. They have valuable information, important information for doctors who are prescribing, however, they have to be easy to use, available at the point of care. Totally agree with interoperability.

I do want to say that we have some data, we look across the States, and where they are readily available at the point of care and have real-time information, doctors are using them, but where they are more burdensome and don't have real-time information, doctors are not using them as much. And so I think the AMA is actually—I chair a task force looking at this issue, and one of the things we might come up with is perhaps what should a model PDMP look like, to give guidance on that so that doctors increase their use of PDMPs.

Mr. BURGESS. Thank you.

Mr. Chairman, I will yield back.

Mr. MURPHY. Yes, just as a follow-up. So what you are describing here is just to even know when you are prescribing—you know if a patient has already been prescribed opioids by their physician, to be able to follow that up. And then in addition to that—but you are also treating someone with an addiction disorder. That is the 42 C.F.R. Part 2 issue.

Dr. Lembke, can you comment on that about how we need to make modifications to that? I am thinking that our former colleague, Patrick Kennedy, is always on me saying we have to fix this problem too, that someone has—getting addiction treatment, they are not even going doctor shopping, they are actually trying to get help, and they go see another doctor, the doctor doesn't know they are getting addiction treatment and he says, here, take this Percocet, take this. Can you comment on that, Dr. Lembke?

Dr. LEMBKE. Yes, so the phenomenon we essentially have today is that on one side of the aisle in a medical institution you have people prescribing Vicodin, on the other side of the aisle you have people trying to get them off of it, and each other doesn't know what the other is doing because, according to 42 C.F.R., we cannot—it is a higher burden of privacy than even HIPAA, if someone is getting substance use treatment, we cannot communicate without their expressed consent to another provider that they are getting that treatment.

This Code of Federal Regulations was implemented more than 2 decades ago with good reason. What was happening was that police were going into methadone maintenance clinics and essentially arresting people who were trying to get treatment for their addiction. And so it was a higher burden on privacy so that people wouldn't resist going into treatment because they were afraid of being exposed around their addiction. But in this day and age of electronic medical records, and this day and age of prescription drug misuse, most importantly, as well as just the fact that we are trying to advocate for addiction being a disease, and we can't advocate for ad-

diction being a disease if we treat it differently from other diseases. So I believe we have to amend 42 C.F.R. so that doctors can communicate openly about which patients are possibly misusing the drugs that they are prescribing to other providers caring for those patients.

Mr. MURPHY. Other people agree with that?

OK, Mr. Tonko, you are recognized for 5 minutes.

Mr. TONKO. Thank you, Mr. Chair.

All of us on this dais are seeing the toll that addiction can have on our communities. However, with that in mind, insufficient data are available in the field of opioid addiction treatment. I would like to better understand from our panelists just how we should move forward with investments in research. How should those efforts be utilized to improve recovery outcomes?

Dr. DuPont, you have been treating opioid addiction for a long time. How would you advise us in terms of research dollars—we obviously need to do more in research, I would hope that would be an agreement across the board here, but how should those dollars be invested, in what ways are they most beneficial?

Dr. DUPONT. Evaluations of outcomes over a longer period of time. But I want to bring up something that I don't think has been clear here, and that is no matter what happens with prescription drugs, there is a robust heroin market and it is getting bigger all the time, and I think it will be a huge mistake for us to think that the only problem we have is prescription drugs. That is contributing to it, that has kicked it off, but now it has taken off in an entirely different direction and it is huge, and I think we underestimate the power of heroin distribution in the country that produce high quality products at low cost, and that is just going to get worse. So I think that is something to keep in mind.

The other thing is——

Mr. TONKO. But that supply and demand equation is something we hear about all the time. I hear about it all the time in the district. People are very concerned.

Dr. DUPONT. Well, it is a very, very serious problem, and it drives me nuts that people who want to solve the drug problem by legalizing drugs. I say let's start with heroin. We are going to solve that problem by legalizing it? Give me a break. But it is a very serious problem for us to deal with.

But the other point is, most people who have this problem do not see that they have a problem. They do not want treatment. When they go to treatment, they drop out of treatment. To get good long-term outcomes the answer is not just in the treatment. You can improve treatment and improve treatment and improve treatment, and you are still going to have tremendous frustrations getting people in, and keeping them in and keeping them clean when they leave. And that is why I studied the physicians health programs, because what those programs do is monitor the people for 5 years. And the physicians don't have a choice of getting out once they are diagnosed, and it is interesting how positive they are about that. I think one of the things this committee could do is look at the environment in which the choice is made to use and not to use, and think about what can be done to change that equation.

One area of tremendous potential is the criminal justice system, where there is the kind of leverage that you have. You have 5 million people on probation and parole in this country, many of whom are opiate dependent, but I think also for families to understand that they have to be concerned about somebody who has an opiate problem, and not—and essentially manage that environment for that person, because that person's judgment is changed by the addiction and they are helpless on their own without somebody intervening. So I would suggest 2 things. One is look long-term, and the other is think about the environment in which that is going on, and think about ways of using the environment to promote recovery.

Mr. TONKO. And to our other panelists, are there ways that research can be connected into positive treatment outcomes?

Dr. SEPPALA. Absolutely. It should be one of the focuses of most research to look at positive treatment outcomes, and actually negative treatment outcomes, to define both for the rest of the field so we know what we are doing, and we can individualize care in a much better way. Right now, there is no research that shows who should be on buprenorphine versus who should be on Vivitrol. It has not been defined. Our field is limited in regard to the type of research to make those decisions. We need a great deal more research in this field.

Mr. TONKO. Is there anything that has been planted as a seed that needs to be grown to a bigger program of research, or is it just being avoided in general?

Dr. SEPPALA. I think research dollars are so limited across medicine right now that it is really hard to get——

Mr. TONKO. Well, there is a theme around here at times to cut research, which I oppose. I think it is the wrong path, but——

Dr. SEPPALA. We have a huge system, we are in 16 States, and we don't even have the infrastructure to gain grants from NIH. We can't do that, we have to partner with people to get research dollars. The research we are doing on this program I described is self-funded. We can't get the money we need to do the research in our setting.

Mr. TONKO. Anyone else on the panel? Yes, Doctor.

Dr. BISAGA. Well, I mean, you know, the most of the rest of the medicine is moving towards personalized medicine or precision medicine, but we are trying to find out which treatments work best for which patients so we can avoid wasting time giving ineffective treatments. And this is very relevant to this hearing because we have four methods of treatment; three medication and maybe some people will even respond to no-medication treatment. And we have a lot of people affected by the illness. So investing in pursuing, again, research, which patients should be treated with which medications, which can be done probably, would be the very smart way to use the research dollars to address this, you know, huge problem.

Mr. TONKO. I, with that, yield back.

Mr. MURPHY. Thank you. Excellent questions.

Ms. Brooks, 5 minutes.

Mrs. BROOKS. Thank you, Mr. Chairman, and thank you so much for holding this critical hearing.

Last year in Indianapolis, an area that I represent, and to the north, we saw massive spikes, and I heard from our public safety officials, and I a former United States Attorney, about the increased use of heroin in our communities. I met with law enforcement officials first before meeting with treatment providers to see what they were seeing, and one of the greatest frustrations some of the law enforcement officials in Indianapolis had, who have now been trained in the use of Narcan, it is a pilot project being used in the city, they would save someone, and about 2 weeks later save them again. Same person who they have saved their life, they are now getting saved once again by even the same officer. And what they were so frustrated about is, where are the treatment providers. You know, we are saving them, you know, they are taken to the hospital, where is the system, what are we doing.

Then when I met with treatment providers, obviously, as we have learned, I mean it is very, very difficult, A, to get people to stay in treatment, to realize they need the treatment. Drug courts sometimes work, and not enough communities have drug courts, although I have recently heard that drug courts—some drug courts are not allowing medication-assisted treatment. I am curious what your thoughts are about that, because we fund drug courts. Much of their funding comes from Federal grants. And so I think that is something that we ought to realize that when these patients are going in to the drug courts, which can save their lives, there is no question about it, would like your comments on that. And then finally, I just would ask all of you, because physicians, whether they are in the ER, whether they are part of treatment providers, or whether they are treating them for something else, what more should we be doing to educate our physicians, because I have also prosecuted physicians who became pill mills for communities, this was back in the Oxycontin days, but what do we need to do to better educate physicians and psychiatrists about how to treat addictions, because we are not there, we are not even close to being there. And I applaud all of you for your work. And I guess I would start with the drug treatment courts that we actually may have some leverage over. I don't know who would like to comment about drug treatment courts.

Dr. BISAGA. If I may. You know, I have a lot to say on the issue of these topics, but this is very important topic because a lot of people who are under criminal justice system custody really are there because they have a disease that affects their functioning and may cause them to do criminal things, and the way to help them get out of the custody is to treat their medical illness, which is an addiction. However, the drug courts and the judges still, I think, tend to think in the old days, thinking that the way to treat them is to send them to the medication-free treatment, not medication-assisted treatment. So we are working with the Bureau of Prisons, and hopefully you guys can help with that tool, to encourage them to use evidence-based treatment when they are making decisions about the medical treatments. It can be done in combination with the decision about the, you know, criminal justice with ability. So——

Mrs. BROOKS. Because, you are right, our prisons, which we also fund, obviously, as people are coming out of prison, probably one

of the top reasons they recidivate and are back within a short period of time is they didn't have their addiction dealt with, and they are—anyone else like to comment——

Dr. WESTREICH. Yes, as——

Mrs. BROOKS [continuing]. Or all of——

Dr. WESTREICH. As to drug courts, I mean I would say on both of your questions, education is the key. I think drug courts are great. I think judges and lawmakers need to be educated about addiction itself and not practice medicine. In the same way, we clinicians need to be educated about law and about the necessity for a holding structure of people who are addicted. So I think drug courts work well when everyone is educated about what they are doing, about therapeutic jurisprudence, which is what that is.

Secondly, as far as educating doctors, I agree 100 percent. I think we need to have much better efforts both through the auspices of groups like mine, and organized medicine in general, to educate not only psychiatrists but primary care doctors and all physicians about prescribing practices, and then about recognizing and treating addiction in an evidence-based manner. So education in both spheres, I think.

Dr. LEMBKE. We give a lot of lip service to addiction being a chronic medical illness, but we don't actually treat it like one, either in the medical system or in the criminal justice system. I cannot imagine a judge working with someone in the criminal justice system saying you have to go off your diabetes or your hypertension meds, otherwise you can't be in this court system. We wouldn't accept that, and yet we accept them saying to these individuals you can't be on Suboxone.

So obviously, we don't regard it as an illness. Even within the medical system, doctors do not treat it like a medical illness. So we need a huge frame shift. And I think education is really important, but unless, again, you incentivize doctors and judges, and whoever it is, to really treat it like an illness and create the infrastructure to treat it like an illness, you are not going to make any headway.

Mrs. BROOKS. And while my time is up, Mr. Chairman, I believe Dr. Seppala would like to address that question as well, if that is oK. Thank you.

Dr. SEPPALA. I would. We have had a couple of leaders of the drug court system come and look at our program, and they have held a fairly conservative stance in regard to the use of Suboxone and other maintenance medications for opioid dependence over time, but I think they are shifting. So I believe that you could play a huge role in pushing them along in this direction. They need to go there.

Mrs. BROOKS. And their education.

Dr. DUPONT. Could I just make one quick comment about this? In the physicians health programs, about ⅓ of the physicians in those programs are opiate addicts, about ½ are alcoholics, and the rest are other drugs. We looked at what happened to the opiate addicts' physicians, none of them were given Suboxone or methadone, and they did as well as the alcoholics in their long-term outcomes. They did very, very well without medication. Now, that is a specialized population, I don't want to generalize it, but I just want to get that clear.

I would suggest in the drug courts that the committee encourage the drug courts to actually look at the question, like they are doing in Hazelden, and see for themselves, do they get better results when they offer that as an option. I think that is a researchable question. I think it could go either way. I don't know what would happen, but I think that would be the way to talk about it with them, and I think they would be receptive to that.

Mrs. BROOKS. I want to thank you, Mr. Chairman, for that. And I think with respect to educating judges and lawyers, while you are focused on physician addicts, there are plenty of judges and lawyers who also could share their knowledge and experience, and maybe help better educate our judges and lawyers.

I yield back.

Mr. MURPHY. Thank you.

I now recognize Mr. Kennedy for 5 minutes.

Mr. KENNEDY. Thank you, Mr. Chairman. I want to thank the chairman and the ranking member. I want to also thank an extraordinary group of panelists for your dedication to this issue, which is really—it is a preeminent group that we have here. So thank you for your testimony today. It has been a big help, I think, as we try to think through these issues.

And, Chairman, I also want to thank your kind comments about my cousin, Patrick, as well. This has obviously been an issue that has been very close to his professional life's work, and I appreciate your recognition of those efforts.

A number of you have talked about incentives over the course of the testimony today. And, Dr. DuPont, you also mentioned the impact of heroin and the heroin trade. I, like my colleague, Ms. Brooks, was a prosecutor—I was a State prosecutor. I ended up prosecuting an awful lot of property crimes; breaking and entering cases, that were more—it was kids, 18, 20, 22 years old, that were breaking into 15 cars in a night to try to feed an Oxycontin addiction. Massachusetts has been struggling with this for years now. I met recently with the DEA and, you know, rough numbers, but they describe the drug trade with Mexico alone to be in the order of $30 billion a year. And a big percentage of that is heroin. So until we kind of wrap our minds around the fact that, as the street market for Oxycontin is 80—or essentially, a buck a milligram, so $80 a pill, but you can get heroin for $3 or $4 a bag, there is a very strong economic incentive to push you into heroin. And I think I have said this before at these hearings, meeting with local law enforcement, meeting with Federal law enforcement back home, a widespread recognition, we will not arrest our way out of this problem. So the question becomes, if it is a demand-based epidemic, because people are addicted and that is fueling either because of overprescription, because of easy access, and then a migration towards heroin, how do we make sure that we don't even get there in the first place?

So, one, I wanted to get some thoughts from you, Dr. DuPont and Dr. Lembke, as to what we can be doing to make sure that your efforts here hopefully one day aren't necessary, but then two, we have touched on this a little bit, in my study of this—people will follow incentives, and the Federal Government has systematically underinvested in substance abuse treatment and in mental health

now for decades. I hear from our hospitals, our doctors, our patient groups, everybody, our judges, our court system, there are not beds for people to get treatment. So if we start reimbursing for—if you start to put the economic incentives in for doctors to get compensated adequately for their time for there to be actually treatment facilities, you will see more beds, you will see more treatment facilities, you will see more wraparound services. So I was hoping to get both of you to comment on that as well, and what—I guess bifurcated question to start, what should we be doing to—hopefully to make sure we actually one day don't need all of these services you are talking about, and in the meantime, what incentives—where should we be really focused on these incentives to build up and flush out so that people can get the continuum of care that they need?

Dr. DUPONT. Well, I think one thing to focus on is the drug problem is not just about heroin or opiates; we have a very serious drug problem across a very broad spectrum to deal with. But I also want to just say it has been my privilege to work with Patrick often, and he is a genuine hero of our field and a hero to me. An extraordinary guy who is making a tremendous contribution.

And I want to go back to those young men you were arresting and prosecuting. One of my preoccupations is the use of the criminal justice system in what was described as therapeutic jurisprudence. When that person is arrested, there is an opportunity to change his life direction in a very positive way. And one of the most striking programs about this is called Hope Probation from Hawaii, which uses the leverage of the criminal justice system to promote recovery. I visited out there, and let me tell you something, the treatment programs love the people that they get from Hope probation because they do stay, they do pay attention, they do get better, because they are required to be drug-tested for their probation. And so it makes treatment work like that. And I think that there is a real opportunity to use that as an engine for recovery that should not be overlooked when a person is out of control. But I don't think we are going to treat our way out of this either. We have to deal in an integrated way with a very complex problem, and the problem is the drugs really work. People do not understand the potential. They think somehow there is—some small percentage of the population is vulnerable to drug addiction. That is not correct. It is a human phenomenon, it is a mammalian phenomenon. And when there is access to these drugs, an awful lot of people are going to use them, and a lot of the people who use them are going to be stuck with that problem for the rest of their lives. This is a very big problem, of which this is a very important part.

Mr. KENNEDY. I am already over time, but if I could ask you to just answer as briefly as you can.

Dr. LEMBKE. Just briefly. I really appreciate your emphasis on incentives, particularly in changing doctors' behavior and creating the infrastructure to treat the illness. Even if you don't believe addiction is a chronic illness, we need to pretend like it is because, from a practical perspective, if we don't, we will just make people sicker, we won't make them well.

And then what is really driving the recent heroin increase is young people, so I absolutely agree that we need to put our re-

sources toward youth, and not just for the short term, but they need to learn how to live differently in the world and whatever that takes, changing the structure of their lives and their friendship groups, giving them jobs, socializing them in a better way to adapt to contemporary culture is, I think, you know, where it is, not just short-term and long-term.

Mr. KENNEDY. Thank you.

Thank you, Mr. Chairman.

Mr. MURPHY. And, Ms. Clarke, you are recognized for 5 minutes.

Ms. CLARKE. Thank you, Mr. Chairman. And I want to thank all of our witnesses for giving this committee the benefit of your expertise and experience today.

I would like to focus my questions on the prevention side of the equation. I know we have discussed the array of access points to heroin and opiates, and I would like to focus us back to the universe of prescribed opiates.

According to the National Institutes on Drug Abuse, the number of prescriptions for opiates in the United States escalated from 76 million in 1991, to about 207 million in 2013. Between 2000 and 2010, there was a fourfold increase in the use of prescription opiates for the treatment of pain. The uptake in prescriptions for opiates has been accompanied by a corresponding increase in the number of opiate-related overdose deaths.

So let me start with Dr. Seppala. My question to you is, are opiates being overprescribed, and I want to get to the why if that is the case?

Dr. SEPPALA. Yes, they are being overprescribed, and they are being used for purposes that they are not necessarily proven to be effective for, and particularly when it comes to chronic pain.

Opioids are the best, most powerful painkillers on the planet. They are necessary for the practice of medicine and for relief of suffering, but primarily, in an acute pain situation. Chronic pain studies are not long-term and don't show over the long-term the effective relief of chronic pain. Opioids just don't work that well, and yet they are being prescribed readily for that, so people are taking them for months and years.

Ms. CLARKE. So is there a standard of care as to when it is appropriate to prescribe opiates for the management of pain?

Dr. SEPPALA. Yes, there are standards of care defined for the prescription of opioids for pain, for acute pain and for chronic pain, and there has been a shift in how that is viewed, and the standards have shifted over the last 10 years, first to increase the prescribing of opioids for chronic pain, and now to decrease and go back to a more conservative approach. So it is being understood in medicine but, you know, I am reading the literature right out of the pain folks who understand this, and the primary care docs don't necessarily follow suit for years——

Ms. CLARKE. Um-hum.

Dr. SEPPALA [continuing]. They still have to kind of catch up, so we do need to educate our physician population.

Ms. CLARKE. Dr. Lembke, I would like to get your thoughts on that as well.

Dr. LEMBKE. Well, there is a long story to why we overprescribe prescription opioids, which we do, and basically, it started in the

1980s when there was this recognition that we were not doing enough to treat pain. It also coincided with the hospice movement. And there was a big push to use opioids more liberally for the treatment of pain, so doctors did that. What happened was that the evidence that showed the use of opioids was indicated for people who were dying was then turned over to the use of opioids in those who have chronic pain conditions. And Purdue Pharma and others aggressively marketed to doctors to use opioids for chronic pain, although there is no evidence to show that they are effective for chronic pain. And now reports are coming out that the risks far exceed any benefits that you might have for an individual patient. So now there has been a big seat change in that regard. Nonetheless, it is hard to get doctors to catch up with that seat change.

Ms. CLARKE. So are physicians not getting the appropriate level of training and education in pain management, and how to identify patients who may be at risk for addiction? And I don't know what that universe looks like. It sounds to me, just in hearing the dialogue, that just about everyone can be a candidate for addiction under that construct.

Dr. LEMBKE. They are now getting that education, and there are standards. The problem is that a doctor gets paid twice as much for a 5-minute medication management visit as they do for 1 hour talking to patients, so there is, again, no infrastructure to incentivize doctors to not prescribe pills. There is a lot of incentive for them to prescribe.

Ms. CLARKE. Dr. Harris, would the AMA support mandatory CME or responsible opioid prescribing practices in addiction tied to the DEA registration of controlled substances?

Dr. HARRIS. So I think the mandatory is the issue, and I think the AMA would like to offer an alternative approach because mandatory CME just feels like sort of a one-size-fits-all. You have many psychiatrists here on the panel, and the education that we may need might be different than the education of our primary care colleagues, and so certainly more education is the key. We are right now cataloging best practices. Each of the specialties are looking at how should they educate their own colleagues. And so really it is about the right education at the right level, for the right specialty. So education is key, but certainly not mandatory. Feels like that is a one-size-fits-all——

Ms. CLARKE. I am over time but, Dr. Lembke, do you agree, should we be mandating or do you think that it should be left to the field to make——

Dr. LEMBKE. Yes, so I respectfully disagree with Dr. Harris. I think that when doctors get their DEA license to prescribe controlled and potentially addictive medications, they should mandatory be taught how to use a prescription drug monitoring system, that that just simply should be the standard of care, independent of their subspecialty.

Ms. CLARKE. Mr. Chairman, I thank you for your indulgence. I yield back.

Mr. MURPHY. Thank you. This has been quite an enlightening panel. I have been writing down some of your recommendations. I have a number of things here. Change the 42 C.F.R. program to bring us up to 2015 standards of integrating physical and behav-

ioral medicine so that we can know who is getting addiction treatments, and help the practices. Improve the intra and interstate communication between pharmacies and physicians so they can distinguish between patients who truly need a medication, versus those who are involved with addiction shopping. Better define recovery. Dr. DuPont, you had said not in terms of just today if they are off medication, but recovery as a longer term. And many of you have used the word chronic. And we need to be paying attention to longer-term data. We need more education to monitor physicians, and more education of monitoring for physicians so they understand prescription drug use here, and what treatment from pain is. We also have to make sure we do have insurance parity to truly deal with this treatment, something we have been dealing with on this committee for 6 or 7 years now. We need more providers who are trained and experienced with mental illness, severe mental illness, and addiction. More inpatient beds for treatment for detox, for in-depth treatments that meets the needs of the patients. And understanding that medication-assisted therapy and psychosocial therapy are not enough; we have to make sure that we have this spectrum, the pallet of treatments available to people to meet their needs.

I think now as we look at that sobering number of 43,000 overdose deaths, and 1 ½ million on some of these medications as treatments, we have our marching orders. This is not something that is simple, but it is something that I think is doable. And the good news is this is the committee that can do it, so we will get our work together.

Again, I want to thank this very distinguished panel. Remind members that they have a few days to get to us their—what is it?

VOICE. Ten business days.

Mr. MURPHY. Ten business days to submit questions for the record. And ask all the witnesses if you would respond promptly to this. Again, thank you so very much. We have our work cut out for us.

This committee is adjourned.

[Whereupon, at 1:03 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

April 21, 2015

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing on "Combatting the Opioid Abuse Epidemic: Professional and Academic Perspectives."

On Thursday, April 23, 2015, at 10:15 a.m. in 2322 Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing entitled, "Combatting the Opioid Abuse Epidemic: Professional and Academic Perspectives." The purpose of this hearing is to solicit insights and findings, drawn from clinical practice and research—as well as constructive policy recommendations—from some of the nation's foremost professional and academic experts on opioid abuse. Subcommittee members will hear testimony on treatment options currently available as well as new and emerging evidence-based practices supporting individuals living with opioid abuse and addiction.

WITNESSES

- Robert L. DuPont MD, President, Institute For Behavior and Health;
- Marvin D. Seppala, MD, Chief Medical Officer, Hazelden Betty Ford Foundation;
- Laurence M. Westreich, MD, President, American Academy of Addiction Psychiatry;
- Anna Lembke, MD, Assistant Professor of Psychiatry and Behavioral Sciences, Stanford University Medical Center, Psychiatry Department;
- Adam Bisaga, MD, Columbia University Medical Center, NYS Psychiatric Institute; and
- Patrice Harris, MD, American Medical Association

BACKGROUND

This hearing follows up on the March 26, 2015 Subcommittee hearing on "Examining the Growing Problems of Prescription Drug and Heroin Abuse: State and Local Perspectives." At that hearing, the Subcommittee heard from a panel of witnesses offering a "boots on the ground"

perspective addressing the opioid abuse epidemic at the state and local levels, aiming to inform and improve the effectiveness of the federal public health response to this nationwide problem. Last year, on April 29, 2014, the Subcommittee held a hearing on "Examining the Growing Problems of Prescription Drug and Heroin Abuse." At that hearing, the Subcommittee heard from a federal panel of witnesses from the Office of National Drug Control Policy (ONDCP), the National Center for Injury Prevention and Control (CDC), the Office of Diversion Control (DEA), the National Institute on Drug Abuse (NIDA), and the Center for Substance Abuse Treatment at the Substance Abuse and Mental Health Services Administration (SAMHSA).

Origins and breadth of the problem

From 1999 to 2013, the rate for drug poisoning deaths involving opioid analgesics, or pain medications, nearly quadrupled.[1] Deaths related to heroin, an illicit opioid, have also increased sharply since 2010, including a 39 percent increase between 2012 and 2013.[2] Mortality data show that there was a 6 percent increase in overall drug overdose deaths between 2012 and 2013 and approximately 37 percent of those deaths involved prescription opioids.[3] The mortality rate from heroin overdose increased each year from 2010 to 2013.[4] Deaths due to heroin overdoses increased by 39 percent from 2012 to 2013 alone and constituted as much as 19 percent of all drug overdose deaths in 2013.[5] Heroin and prescription opioid abuse can also result in other health consequences such as neonatal abstinence syndrome, increased risk of transmission of HIV and Hepatitis C, and bone fractures in older adults due to falls.[6] On average, heroin addicts lose about 18 years of life expectancy, and the mortality rate for injection users is roughly 2 percent per year.[7]

Although heroin use in the general population is low, the number of people beginning to use heroin has been steadily rising since 2007. According to NIDA, this may be due in part to a

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[1] Centers for Disease Control and Prevention. QuickStats: Rates of Deaths from Drug Poisoning and Drug Poisoning Involving Opioid Analgesics – United States, 1999-2013. MMWR Weekly. Retrieved from: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6401a10.htm.

[2] Hedegaard H, Chen LH, Warner M.; National Center for Health Statistics (NCHS). Drug-poisoning deaths involving heroin: States, 2000-2013. NCHS data brief, no190. Retrieved from: http://www.cdc.gov/nchs/data/databriefs/db190.pdf.

[3] Centers for Disease Control and Prevention. Wide Ranging Online Data for Epidemiologic Research (CDC WONDER). Available at: http://wonder.cdc.gov/.

[4] *Id.*

[5] *Id.*

[6] Creanga AA, SabelJC, Ko JY, Wasserman CR, Shapiro-Medoza CK, Taylor P, Barfield W, et al. Maternal drug use and its effect on neonates: a population-based study in Washington State. Obstet Gynecol. 2012; 199(5):924-933.; Zibell JE, Hart-Mallory R, Barry J, Fan L, Flanigan C. Risk Factors for HCV infection among young adults in rural New York who inject prescription opioid analgesics. Am J Public Health. 2014 Nov;104(11):2226-32. Doi: 10.2105/AJPH.2014.302142. Epub 2014 Sep 11.; Mateu-Gelabert P1, Guarino H2, Jessel L2, Teper A2. Injection and sexual HIV/HCV risk behaviors associated with nonmedical use of prescription opioids among young adults in New York City. J Subst Abuse Treat. 2015 Jan;48(1):13-20. Doi: 10.1015/j.jsat.2014.07.002. Epub 2014 Jul 11.; Rolita L, Spegman A, Tang X, Cronstein BN. Greater number of narcotic analgesic prescriptions for osteoarthritis is associated with falls and fractures in elderly adults. J Am Geriatr Soc. 2013;61(3):335-340.; Miller M, Sturmer T, Azrael D, Levin R, Solomon DH. Opioid analgesics and the risk of fractures in older adults with arthritis. J Am Geriatr Soc. 2011;59(3):430-438.

[7] B. Smyth, et al., Years of potential life lost among heroin addicts 33 years after treatment, 44 Preventive Medicine 369 (2007).

shift from the abuse of prescription pain relievers to heroin as a more potent, readily available, and cheaper alternative to prescription opioids.[8] In fact, nearly half of young people who inject heroin surveyed in three recent studies reported abusing prescription opioids before starting to use heroin.[9] Among those who began abusing opioids in the 2000s, 75 percent of individuals indicated they initiated their abuse with prescription opioids.[10] Although the available literature indicates that abuse of prescription opioids is a risk factor for future heroin use, only a small fraction, roughly 4 percent of opioid abusers, transition to heroin use within five years of initiating opioid abuse.[11]

Overprescribing of painkillers has been a significant driver of our present opioid and heroin epidemic. Since 1997, the number of Americans seeking treatment for addiction to painkillers has increased by 900 percent.[12] The prevalence of opioid addiction started rising as long-term prescribing of opioids for chronic pain, a practice encouraged by opioid manufacturers, became more common.[13] As a result, many states started to make extensive use of their prescription drug monitoring programs as a tool to monitor prescription sales of controlled substances.[14]

President Obama's FY 2016 Budget includes an increase of $99 million over FY 2015 levels for targeted efforts to reduce opioid-related morbidity and mortality and the prevalence and impact of opioid use disorders. In response to the opioid abuse epidemic, in the FY 2016 budget, CDC requested an increase of $54 million to fund prescription drug overdose and heroin prevention efforts.

Paths to recovery

There is a wide consensus among experts that medical best practice demands a full menu of behavioral, pharmacological and psychosocial treatments be made available to individuals with opioid addiction. This is especially critical, as the Center for Addiction and Substance Abuse at Columbia University, in a five-year study, found that only 1 in 10 people with alcohol or drug addiction other than nicotine receive any form of treatment, and of those only 10 percent

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[8] Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. The changing face of heroin use in the United States: a retrospective analysis of the past 50 years. JAMA Psychiatry 2014;71:821-6.

[9] NIDA Report Series, "Heroin," NIH publication number 15-0165, 3 (November 2014, rev.). Some data have higher estimates. Data from SAMHSA shows that 81 percent of people who started using heroin from 2008 to 2010 had previously abused prescription drugs. Amy Pavuk, Rx for Danger: Oxycodone crackdown drives addicts to other drugs, Orlando Sentinel, July 28, 2012, http://articles.orlandosentinel.com/2012-07-28/health/os-oxycodone-drug-shift-dilaudid-20120728_1_oxycodone-prescription-drugs-dilaudid-pills.

[10] Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. The changing face of heroin use in the United States: a retrospective analysis of the past 50 years. JAMA Psychiatry 2014;71:821-6.

[11] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States. August 2013. Retrieved from: http://www.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf.

[12] Science Daily, "Opioid and heroin crisis triggered by doctors overprescribing painkillers," Brandeis University, February 4, 2015. http://www.sciencedaily.com/releases/2015/02/150204125945.htm .

[13] *Id.*

[14] Ileana Arias, et al., Prescription Drug Overdose: State Health Agencies Respond, Association of State and Territorial Health Officials, 2008, http://www.astho.org/Programs/Prevention/Injury-and-Violence-Prevention/_Materials/Prescription-Drug-Overdose/.

receive evidence-based treatment.[15] Nearly 80 percent of opioid-addicted persons do not receive treatment for their addiction because of limited treatment capacity, financial obstacles, social stigma, and other barriers to care.[16]

In particular, the data suggests that medication-assisted treatment (MAT) is effective in treating opioid addiction and reducing overdose deaths. As drug abuse changes the way the brain works, resulting in compulsive behavior focused on drug seeking and use, medications can be helpful in treating the symptoms of withdrawal during detoxification – which often prompt relapse – as well as become part of an ongoing treatment plan.[17] Scientific research has established that MAT increases patient retention and decreases drug use, infectious disease transmission, and criminal activity.[18]

At present, the Food and Drug Administration (FDA) has approved only three medications for the treatment of opioid dependence. Methadone, a Schedule II controlled substance used as maintenance treatment for documented opioid addiction for over 40 years, may only be dispensed by clinics, certified by SAMHSA, and subject to both federal and state regulation.[19] Buprenorphine, a Schedule III controlled substance – which may be offered, under certain circumstances, by methadone treatment clinics – is a more recently introduced synthetic opioid treatment medication approved as an outpatient physician-prescribed treatment for opioid addiction.[20] Naltrexone is a physician-prescribed clinician-administered injectable medication for the prevention of relapse of opioid dependence after detoxification, commonly known by the brand name Vivitrol.[21]

Notably, the Department of Health and Human Services includes expansion of MAT to reduce opioid use disorders and overdose among Secretary Burwell's top three priority areas to combat opioid abuse, announced on March 26, 2015.[22] While MAT is a critical component of opioid addiction treatment, concerns have been raised that substance use disorders, as chronic conditions like diabetes or heart disease, demand a treatment model where long-term, sustained recovery – including extended engagement following formal periods of treatment – takes the place of what is too often the episodic, largely unsupervised prescription of medication followed by relapse to old habits.[23]

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[15] http://www.casacolumbia.org/addiction-research/reports/addiction-medicine
[16] C.L. Arfken, et al, Expanding treatment capacity for opioid dependence with buprenorphine: National surveys of physicians, 39 Journal of Substance Abuse Treatment 96 (2010).
[17] NIDA Topics in Brief. Medication-Assisted Treatment for Opioid Addiction. April 2012. https://www.drugabuse.gov/sites/default/files/tib_mat_opioid.pdf
[18] *Id.*
[19] The American Society of Addiction Medicine. Advancing Access to Addiction Medications: Implications for Opioid Addiction Treatment. http://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addiction-treatment_final
[20] *Id.*
[21] *Id.*
[22] HHS Office of Assistant Secretary for Planning and Evaluation. Issue Brief, Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths. March 26, 2015. http://aspe.hhs.gov/sp/reports/2015/OpioidInitiative/ib_OpioidInitiative.pdf
[23] McGovern, John P. Insitute for Behavior and Health, Inc. The New Paradigm for Recovery: Making Recovery – and not Relapse – the Expected Outcome of Addiction Treatment. March 2014. http://ibhinc.org/pdfs/NewParadigmforRecoveryReportMarch2014.pdf

With the aim of recovery in mind, long-term monitoring, both during and after episodes of MAT, is necessary to screen for the concurrent use of alcohol, illicit drugs, or the non-medical use of other prescription opioids that readily interfere with evidence-based treatments.[24] Dr. Robert DuPont, the first Director of NIDA, President of the Institute for Behavioral Health, and a witness at this hearing has argued that widespread acceptance of "harm reduction" as the ultimate goal of MAT, has often undermined efforts to frame recovery, as opposed to relapse — or simply maintenance — as the expected outcome of addiction treatment.[25]

At the March 26, 2015 hearing, the Subcommittee received testimony on the need for greater oversight of MAT and the need for standards on how these programs should be run. Professor Sarah Melton of East Tennessee University testified that "in Tennessee and southwest Virginia some buprenorphine programs have become pill mills where the physicians charge them high prices, they come in and get their medication, and they leave." She also confirmed the "devastating" trend of medication-assisted programs providing methadone or buprenorphine in cash transactions and being incentivized to become pill mills. She also testified that there is a "dearth of access to good treatment, and by 'good treatment,' I mean patients being seen frequently, getting urine drug screens at nearly every visit, if not every visit, requiring 12-step programs, group counseling, and not co-prescribing with other drugs of addiction such as benzodiazepines."

Other issues

Use of methadone for pain. In addition to the overprescribing of prescription painkillers, public health risks have worsened by the increased prescribing of methadone for pain (as opposed to use in addiction treatment). The use of methadone as a treatment for pain has expanded in recent years. Although methadone can effectively treat pain, it carries outsized risks due to its unique pharmacologic properties, such as a long half-life, short analgesic window relative to respiratory-depressant effect, and potential for drug-drug interactions.[26] While methadone from methadone clinics is in liquid form which addicts drink on-site, methadone prescribed for pain is in pill form, making it easier to divert and misuse. In contrast to the regulation of methadone clinics, no special licensing or monitoring is required to prescribe methadone in pill form. Methadone accounts for two percent of opioid prescriptions for pain control, but is responsible for one-third of overdose deaths, according to a 2012 CDC Vital Signs report.[27] Most state Medicaid programs encourage the prescribing of methadone as a first line treatment for pain, often due to its low cost, even though safer therapies are available.[28] Moreover, the FDA, the CDC, the American Academy of Pain Medicine, and the American

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[24] *Id.*
[25] L. Merlo, M. Campbell, G. Skipper, C. Shea, and R. DuPont, "Recovery from Opioid Dependence: Lessons from the Treatment of Opioid-Dependent Physicians," (Study supported by the Robert Wood Johnson Foundation, submitted for publication and currently under review) (2015).
[26] The Pew Charitable Trust, "Prescription Drug Abuse Epidemic: Spotlight on Methadone," August 2014.
[27] http://www.cdc.gov/vitalsigns/MethadoneOverdoses/
[28] The Pew Charitable Trusts' Prescription Drug Abuse Project, Undated handout (provided to committee staff, March 20, 2015).

Society of Interventional Pain Physicians have recommended that methadone not be used as a first-line therapy for chronic pain.[29]

Prescription Drug Monitoring Programs. Prescription drug monitoring programs (PDMPs) are state-run electronic databases of prescriptions for controlled substances. PDMPs can provide a prescriber or pharmacist with information regarding a patient's prescription history, allowing prescribers to identify patients who are potentially abusing medications. Currently, 49 states, the District of Columbia, and Guam have legislation authorizing the creation and operation of a PDMP and all but the DC program are operational.[30] While there is evidence indicating the potential of PDMPs to identify high-risk patients and impact prescribing behaviors, the effectiveness of PDMPs is constrained by the lack of timely data in some states and limited interoperability with other PDMPs. Witnesses at the March 26, 2015 Subcommittee hearing also testified about their concerns over methadone clinics not being required to report methadone dispensing to PDMPs. One witness said it was "a very serious situation" because if these patients do not disclose their methadone treatment to their primary care providers and the providers do not know about it from accessing the PDMP, other opioids or benzodiazepines could be prescribed leading to death.[31] Another concern related to neonatal doctors not being able to know about methadone treatment for pregnant women who are drug-addicted, which poses potential problems for the mother and the life of the fetus if the methadone is being increased during the same time the mother and baby are receiving opioid medication to treat the addiction.[32]

ISSUES

The following issues may be examined at the hearing:

- What evidence-based treatments are currently available to treat individuals suffering from opioid addiction?
- What is medication-assisted treatment, and what are its strengths and limitations?
- What can be done to increase levels of individual compliance with opioid addiction treatments and boost the chances of long-term recovery?
- How can federal policy better support efforts to develop new and promising treatments?

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[29] American Society of Interventional Pain Physicians, Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 2 – Guidance, 15 Pain Physician Journal S67 (2012), http://www.painphysicianjournal.com/2012/july/2012;%2015;S67-116.pdf

[30] PDMP Training and Technical Assistance center, PDMP Frequently Asked Questions. http://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq

[31] Testimony of Fred Wells Brason II, Executive Director, Project Lazarus, Moravian Falls, North Carolina. (Unofficial hearing transcript, 40).

[32] *See* testimony of Stefan R. Maxwell, MD, Chair, West Virginia Perinatal Partnership, MEDNAX Medical Group, Director NICU, Charleston Area Medical Center, Charleston, West Virginia. (Unofficial hearing transcript, 90).

- What are the best practices for treating opioid addiction, and how can federal policy better incentivize these practices?

STAFF CONTACTS

If you have any questions regarding this hearing, please contact Alan Slobodin, Sam Spector, or Brittany Havens of the Committee staff at (202) 225-2927.

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225-2927
Minority (202) 225-3641

May 14, 2015

Dr. Robert L. DuPont
President
Institute for Behavior and Health
6191 Executive Boulevard
Rockville, MD 20852

Dear Dr. DuPont:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Thursday, April 23, 2015, to testify at the hearing entitled "Combatting the Opioid Abuse Epidemic: Professional and Academic Perspectives."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Thursday, May 28, 2015. Your responses should be mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to brittany.havens@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Tim Murphy

Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment

May 15, 2015

Robert L. DuPont, MD

Answer to Question Below

Many opioid-dependent patients enter substance abue tretment programs that do not iinclude buprenorphine, methadone or naltrexone in their programs. Some of these patients do well and others do not. Two distinguished abstinence-oriented treatment programs with which I am familiar now include medications as an option: Hazelden in Center City Minnesota and Kolmac in the Washington DC area. Hazelden offers both buprnorophine and naltrexone while Komlmac offers only buprenorpine. Both rograms have found that some opioid patients chose medication while other do not and both have found that offering medication is useful in increasing retention intreatment of opioid dependent patients.

There is much to be said for encouraging both medication-assisted treatnemt and drug-free treatments to publicly report their retention rates and their rates fo of continued alcohol and drug use during treatment. And for both types of treatment to identify their rates of achieving 5-year recovery of patients entering their treatments. Pending these neessary assessements it would be unreasonable to insist that all drug-free treatments offer medications to their opioid patients. Beyond this I note that few MAT programs offer their patients the full range of medication options: buprenorphine, methadone and naltrexone. Treatment diversity is important. What is needed now is more data on the effectivenss of alternative treatments for opioid dependence, esecially in terms of their achieving 5-Year Recoery. Even without additional data it is clear that patient dropout, drug use during treatment and relapse on discharge from treatment are major problems with all current opioid treatments, whether they offer mediations or do not offer them.

The Honorable Larry Bucshon

1. What are the implications of most opioid-dependent patients not getting medication in their treatment programs?

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States
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May 14, 2015

Dr. Marvin D. Seppala
Chief Medical Officer
Hazelden Betty Ford Foundation
P.O. Box 11
Center City, MN 55012

Dear Dr. Seppala:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Thursday, April 23, 2015, to testify at the hearing entitled "Combatting the Opioid Abuse Epidemic: Professional and Academic Perspectives."

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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Tim Murphy

Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment

hazeldenbettyford.org

Hazelden Betty Ford Foundation
P.O Box 11
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mseppala@hazeldenbettyford.org

May 26, 2015

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Chairman Murphy:

Thank you very much for the opportunity to testify before your Subcommittee. I am honored to respond to the additional questions that were submitted. Here are my responses to the questions from the following Members:

The Honorable Larry Bucshon

Will you expand on your experience specifically with naltrexone, and how greater access could be helpful across the nation?

We have found naltrexone, particularly the injectable extended-release form known as Vivitrol, to be a potent resource in our treatment approach. We started using it with our opioid-dependent patients in 2012, and consistent with the medical research, have found that it reduces opioid craving and supports abstinence from opioids. If it were more affordable and widely available, that would certainly aid in the nationwide fight against opioid addiction.

Naltrexone reduces cravings and blocks the effect of any opioids. It is available in two forms: a pill that is taken daily, and the extended-release injection (Vivitrol) that is provided once a month. The daily pill option has limitations due to the lack of adherence. If it is provided in a monitored manner to ensure daily use, it is effective; otherwise it is not because people may refuse to take it every day. We seldom use the pill form, but provide the injections regularly. The great benefit of Vivitrol is that the patient only has to make a once-a-month decision to continue therapy, rather than a daily decision.

Patients who take Vivitrol are more likely to remain opioid-free and adhere to other aspects of ongoing treatment like group therapy, individual therapy and Twelve Step meeting attendance. The medication also has little in the way of side effects.

Because people can't get intoxicated while on Vivitrol, it eases concerns of family members, and less monitoring is required. Also, because the injection lasts a month, patients who get sudden urges to use again are compelled to learn other coping skills, which help them get beyond the craving, avoid relapse and establish lifelong recovery practices.

Another advantage of Vivitrol is that it's easy to discontinue once it is no longer necessary. Unlike some other medications, it is not an opioid so there is no withdrawal syndrome.

We have found that if patients suddenly want to stop their Vivitrol injections, especially in early recovery, they are invariably planning a relapse to opioids. That is a strong cue for us to engage their family and all other resources in an attempt to persuade them to remain on the medication and involved in other means of treatment.

In summary, we have found Vivitrol to be a very effective and essential option for treating opioid use disorders. A downside to its use is that it is expensive, and unfortunately not all insurance companies cover it. Patients must also be abstinent from opioids for 10 to 14 days before Vivitrol can be safely initiated, and this can be difficult to carry out in an outpatient setting. Greater access would certainly result in more people staying abstinent from opioids, thus reducing overdose deaths.

The Honorable Markwayne Mullin

> **Dr. Seppala, can you speak to the challenges you've seen in treating someone who is addicted to opioids versus other substances, like alcohol, for instance. What are the challenges specifically related to what those people may need once they have left an inpatient program?**

Opioid addiction is an especially difficult addiction to treat, when compared with addictions to other substances like alcohol. Individuals dependent on prescription pain medications and/or heroin face unique challenges that can undermine their ability to stay in treatment and achieve long-term abstinence.

They are hypersensitive to pain and more vulnerable to stress. Their anxiety, depression and intense craving for these drugs can continue for months, even years, after getting free of opioid use. They experience a strong desire to feel "normal" again – to escape what seems like a permanent state of dysphoria, which puts them at high risk of relapse. They are also at higher risk of accidental overdose during relapse because they no longer have the tolerance to handle the same doses they were taking prior to treatment. In other words, with opioids – unlike other drugs – relapse often means death.

People with opioid dependence tend to leave treatment early, especially when feeling a bit better right after detoxification. This is a chronic illness and they require long-term care. Unfortunately, insurance often does not allow for the extended period of care needed by these individuals.

Many of these patients are compelled to enter treatment by family and friends through an "intervention," and have little initial interest in treatment. They have great difficulty recognizing the consequences and problems associated with opioid use, which undermines their ability to begin to engage in treatment. Our challenge is to engage them and help them see this illness for what it is, improving the likelihood they will successfully adhere to treatment recommendations and seek abstinence.

Patients with opioid use disorders can be impulsive, angry and treatment-resistant, which can be a challenge in a group treatment setting. This can undermine the formation of positive relationships, which are so important to recovery. Also, the craving these patients experience is severe and long lasting. They also tend to enter treatment in late stages of addiction, and as with any disease, the late stages are harder to treat. For these reasons, patients need longer periods of treatment and abstinence before they are stable in recovery and able to effectively monitor and structure themselves.

In addition, the stigma of opioids, especially injectable heroin, is worse than other drugs, which can prevent people from seeking treatment and undermine recovery efforts. For example, many sober homes will not accept residents who are taking opioid addiction medications like Suboxone. Some recovery support groups are resistant to accepting these individuals as well.

Another challenge is that opioid-dependent patients have frequently burned bridges with family and friends to such a degree that they have lost the support that is so essential to recovery. They may have gained money for drugs by engaging in behaviors they are ashamed of and reticent to discuss. This burden of shame can undermine treatment, and the behaviors may have placed them at high risk for serious infections like HIV, hepatitis and staph.

Thank you very much for your leadership on these important issues. Please let me know if you need additional information on these specific questions, or if I can ever be helpful to you.

Sincerely,

Marvin D. Seppala, M.D.
Chief Medical Officer, Hazelden Betty Ford Foundation

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225-2927
Minority (202) 225-3641

May 14, 2015

Dr. Anna Lembke
Assistant Professor of Psychiatry and Behavioral Sciences
Psychiatry Department
Stanford University Medical Center
401 Quarry Rd MC 5723
Stanford, CA 94305

Dear Dr. Lembke:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Thursday, April 23, 2015, to testify at the hearing entitled "Combatting the Opioid Abuse Epidemic: Professional and Academic Perspectives."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Thursday, May 28, 2015. Your responses should be mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to brittany.havens@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

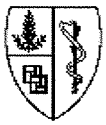
Sincerely,

Tim Murphy

Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment



Anna Lembke, M.D.
Chief, Addiction Medicine Dual Diagnosis Clinic
Director, Stanford Addiction Medicine Program
Assistant Professor, Psychiatry & Behavioral Sciences
Stanford University School of Medicine
Stanford, California 94305-5723
[redacted]

May 18, 2015

Attn: Subcommittee on Oversight and Investigations, Committee on Energy and Commerce

Re: Questions regarding the hearings on "Combatting the Opioid Abuse Epidemic"

Dear Members of the Committee,

Thank-you for giving me the opportunity to respond to these questions. My answers follow below in the format requested.

The Honorable Tim Murphy:

The Committee has received a variety of reports on the impact of 42 CFR Part 2 both on the fight against the new epidemic of opioid abuse in the United States as well as efforts to integrate mental health and addiction services into the larger health care system.

Specifically we've heard reports that the stringent consent requirements associated with Part 2 aid and abet illicit doctor shopping for prescription opioid medications. Further, we understand that this federal regulation – based upon law passed in the early 1970's – interferes with the ability to coordinate care for people with major substance use disorders. For example, most Health Information Exchanges refuse to accept addiction medical records and CMS must redact all data containing addiction medical information before sharing it with Medicare ACOs, State Medicaid agencies and Medicaid Health Homes.

1. **Can you give us your assessment of the interaction between Part 2 and efforts to reduce prescription drug abuse through efforts like Prescription Drug Monitoring Porgrams (PDMPs)?**
2. **Do you think the time has arrived for new statutory exceptions to Part 2? For example, would it be appropriate to create new exceptions for PDMPs, Health Information Exchanges, Medicare Accountable Care Organizations, Medicaid Health Homes and other programs designed to**

coordinate care for people with serious behavioral health conditions and comorbid medical/surgical chronic diseases?

I wholeheartedly believe that 42 CFR Part 2 needs to be amended for the following two reasons: 1.) Patient privacy is adequately protected by HIPAA, the federal Health Insurance Portability and Accountability Act of 1996; 2.) 42 CFR Part 2 interferes with doctors' ability to provide safe and effective treatment to patients with substance use disorders, and therefore represents a form of discrimination against this sub-population of patients within the health care system.

a. A basic quality measure of good health care is "medication reconciliation", which means assessing and documenting all the medications a patient is taking, to make sure drug-drug interactions are avoided, and the best treatment is achieved. As a result of 42 CFR Part 2, a doctor's ability to complete medication reconciliation is compromised. For example, a patient who is getting methadone from a methadone maintenance clinic, who fails to inform the doctor of this medication, is at increased risk for iatrogenic (doctor caused) harm if the doctor prescribes opioid pain relievers (e.c. Oxycontin) and/or benzodiazepines (e.g. Valium) on top of the methadone, thus increasing the chances of death due to accidental overdose, cardiac arrhythmia, etc. Attempts to reconcile medications using the Prescription Drug Monitoring Databases (PDMDs) will be of no help, because many states' PDMDs exclude methadone, as required by 42 CFR Part 2.

b. 42 CFR Part 2 limits what medical records can be exchanged between health care organization, and even between certain departments within health care organizations. Although these records can in theory be acquired at the time of a medical emergency, in reality, 42 CFR Part 2 limits urgent access to a vital part of the patient's medical history, thus limiting the doctor's ability to provide the best care. For example, a patient who presents to the emergency department in life-threatening alcohol withdrawal, unable to verbally communicate, no longer with a detectable alcohol level in his or her blood (hence no data to suggest an alcohol use disorder), and no records of alcohol addiction in the electronic medical record database, is at increased risk of complication and even death as the doctors attempt to figure out what has rendered the patient delirious.

c. Integrating substance use disorder treatment with other health care should be a national priority, yet 42 CFR Part 2 greatly hinders integration and coordination of care, for the very reasons you cite above, namely that Health Information Exchanges refuse to accept addiction medical records and CMS must redact all data containing addiction medical information before sharing it with Medicare ACOs, State Medicaid agencies and Medicaid Health Homes. Also Qualified Service Organization Agreements (QSOAs) cannot be signed between two treatment providers covered by 42 CFR Part 2, which prevents the use of QSOAs between an alcohol and drug program and a community mental health center, hospital or clinic that also provides covered alcohol and drug services.

Finally, on a more philosophical note, we cannot expect true parity reform for the treatment of substance use disorders, until we treat addiction as a disease, which means integrating it within mainstream health care and subjecting it to the same rules and regulations as other diseases.

The Honorable Markwayne Mullin

Dr. Lembke, Olklahoma has one of the nation's biggest problems when it comes to prescription drug abuse. Just yesterday, it was reported that last month there were more Oklahomans enrolled in Medicaid than there have ever been. We have over 830,000 people enrolled in SoonerCare. It is my understanding that most state Medicaid programs encourage doctors to prescribe methadone for pain, because it is cheap, even though the Food and Drug Administration (FDA), the CDC, and two pain medicine doctor groups recommend that methadone not be used as a first-line therapy for chronic pain. Do you think this is appropriate given the issues we've seen with Methadone being responsible for more than 30 percent of overdose deaths while accounting for just 2 percent of opioid prescriptions for pain?

I agree that methadone should not be used as first line treatment for pain, given the high risk of accidental overdose death associated with the unique pharmacology of this drug. However, I would emphasize that opioid analgesics should not be first line treatment for any chronic pain condition, as data show they are not an effective treatment long-term for pain. Furthermore, although methadone in pill form for the treatment of pain accounts for a large share of accidental overdose deaths in this country, the same cannot be said for methadone in liquid form prescription for the treatment of opioid addiction. The latter has proven, over decades of accumulated data, to be one of the most safe and effective treatments for opioid addiction, and is not associated with high rates of accidental overdose.

Sincerely,

Anna Lembke, MD

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS

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Minority (202) 225-3641

May 14, 2015

Dr. Patrice Harris
American Medical Association
25 Massachusetts Avenue, N.W.
Washington, D.C. 20001

Dear Dr. Harris:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Thursday, April 23, 2015, to testify at the hearing entitled "Combatting the Opioid Abuse Epidemic: Professional and Academic Perspectives."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Tim Murphy

Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment

PATRICE A. HARRIS, MD, MA
SECRETARY
[redacted]

ama-assn.org
[redacted]

May 28, 2015

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Chairman Murphy:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to respond to the additional questions submitted by Representative Michael Burgess, MD as part of the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce's hearing entitled, "Combatting the Opioid Abuse Epidemic: Professional and Academic Perspectives."

Questions Posed by the Honorable Michael C. Burgess, MD

1. **The current standard of care for treating pregnant women with opioid dependence, according to the American College of Obstetricians and Gynecologists, is medication assisted therapy, such as buprenorphine or methadone. Medically supervised tapered doses of opioids or abrupt discontinuation are contrary to the current standard of care and are only appropriate in a highly controlled research setting. Dr. Harris, can you tell us more about the standard of care for treating these patients?**

In addition to the increasing numbers of Americans misusing and abusing prescription drugs and dying from unintentional overdose, there are increasing data on the rise of neonatal abstinence syndrome (NAS).[1] As a starting point, it should be noted that substance abuse and addiction is a disease and should be treated as such. This applies to all patients, including women who are pregnant.

Preventing inappropriate opioid use among pregnant women and women of child-bearing age is crucial. For pregnant women who misuse and abuse drugs and alcohol, including prescription opioids, our shared goal must be a healthy outcome for both mother and baby. The AMA recommends that policymakers support the extensive work done on this issue by the nation's leading national medical specialty societies,

[1] Neonatal abstinence syndrome (NAS) is a condition affecting newborns whose mothers used opiates during pregnancy. As detailed in the April 30, 2012 issue of the *Journal of the American Medical Association*, NAS not only can have severe health consequences on fetuses and newborn babies, but NAS raises issues concerning appropriate treatment of pregnant women, Medicaid, and the financial costs to the health care system.

[redacted]

including the American Academy of Pediatrics (AAP), the American Congress of Obstetricians and Gynecologists (ACOG), and the American Society of Addiction Medicine (ASAM). The information from these and other medical societies can help legislators and public health officials design policies that put the interests of the pregnant woman and her baby first and foremost. There are excellent evidence-based practice guidelines (ACOG, AAP, ASAM) that are used today to effectively treat mother and baby. Physicians know how to treat this and are currently doing so across the nation.

However, medically-appropriate opioid use in pregnancy is not uncommon. Opioids are often the safest and most appropriate treatment for a variety of medical conditions and severe pain during pregnancy. The current standard of care for pregnant women with opioid dependence is referral for opioid-assisted therapy with methadone or buprenorphine. Safe prescribing during pregnancy includes opioid-assisted therapy. Medically supervised tapered doses of opioids during pregnancy often result in relapse to former use. Moreover, abrupt discontinuation of opioids in an opioid-dependent pregnant woman can result in preterm labor, fetal distress, or fetal demise. Like diabetes or hypertension, a substance use disorder (such as opioid dependence) is a disease requiring a public health, rather than a punitive response. The same holds true for pregnant women with opioid dependence, who should not be criminalized or face immediate revocation of child custody.

Among its resources, the AAP published "Neonatal Drug Withdrawal,"[2] a clinical report that contains important background on opioids; the clinical presentation of opioid withdrawal; differential diagnosis; assessment and nonpharmacologic treatment; and the rationale and comparative evidence for pharmacologic treatment. There also is information on managing patients, key clinical considerations and an extensive list of references. In short, the AAP report, while not a standard of care, does provide evidence-based information from which medical decisions are made.

Two resources from ACOG's Toolkit on State Legislation[3] may also be of interest. One document highlights the key terms and issues surrounding NAS, including that the "shared goal must be a healthy outcome for both mother and baby" rather than "punitive drug enforcement policies."

ASAM is developing resources as part of the Providers' Clinical Support System for Medication-Assisted Treatment (PCSS-MAT). One part of the PCSS-MAT program is designed to encourage physicians trained in addiction medicine to serve as mentors to other physicians, such as primary care physicians, pediatricians and obstetrician/gynecologists, who may deal with women's issues in addiction, according to ASAM officials.[4]

Finally, the Association of State and Territorial Health Officials (ASTHO), has a comprehensive report on this issue entitled, "Neonatal Abstinence Syndrome: How States Can Help Advance the Knowledge Base

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[2] Clinical Report: Neonatal Drug Withdrawal. Hudak, Mark L., Tan, Rosemarie C. The Committee on Drugs and The Committee on Fetus and Newborn. Pediatrics 2012; 129; e540. Jan. 30, 2012. Available at http://pediatrics.aappublications.org/content/129/2/e540.full.pdf+html

[3] The two documents are "Pregnant Women & Prescription Drug Abuse, Dependence and Addiction" and another document focused on suggested legislation. Both are available from the ACOG Government Affairs division.

[4] Med-Sci: ASAM Steps Up Efforts to Reduce Incidence of NAS. American Society of Addiction Medicine. April 17, 2014. Available at http://www.asam.org/magazine/read/article/2014/04/17/med-sci-asam-steps-up-efforts-to-reduce- incidence-of-nas

for Primary Prevention and Best Practices of Care," which includes information on primary prevention, prenatal care, care of the neonate, and management of NAS.[5]

2. In your testimony, you write that the "American Medical Association (AMA) strongly opposes stigmatizing patients who require opioid therapy." How does this stigma manifest itself and what can be done about it?

As we stated in our written testimony, patients in pain and/or with a substance use disorder deserve compassionate care just like any other patients physicians treat. Language matters, and when we take steps to see those in pain or with a substance use disorder as patients rather than as "junkies," "malingerers," or "drug seekers," we will have taken a great step forward in overcoming the damaging psychological stigma associated with these terms.

Unfortunately, stigma manifests itself in various ways. First, many patients are reluctant to accept that they have a chronic illness and do not seek treatment. Verbal stigma is compounded by social stigma that tends to view someone with a substance use disorder as "weak" or someone who fails to exhibit self-control. Moreover, patients who do seek treatment are often unable to find a provider who offers comprehensive, medical treatment options. SAMHSA estimates that 23 million Americans have a substance use disorder but only 11 percent actually receive treatment. Part of this is likely due to the fact that there are too few providers available to treat this patient population. Yet another component is that some treatment centers do not believe that medication assisted treatment (MAT) should be offered due to the false belief that MAT "trades one addiction for another." The bottom line is that medical science teaches us that MAT, in conjunction with nonpharmacologic treatment, offers patients evidence-based treatment that allows them to lead healthy, productive, fully functioning lives. Finally, patients who are in treatment may find that the prescribed course of treatment may be limited by the type or duration of treatment covered by insurers. For example, many insurers require fail first or step therapy protocols for patients to be approved for either pharmacologic or non-pharmacologic therapies. These administrative barriers serve to effectively deny and delay timely care for patients.

What can be done about the stigma problem? First, the national dialogue should emphasize that patients with a substance use disorder should be treated as any other patient with a chronic disease. The nation experienced a similar stigmatizing debate with HIV/AIDS, and much could be learned from how the country eventually focused on treatment rather than making HIV/AIDS patients feel stigmatized about their medical condition. Second, the AMA will continue to support ONDCP's and SAMHSA's efforts to encourage the use of MAT where appropriate, including in Medicaid and drug courts. The AMA strongly believes that the Administration should continue to assess state Medicaid agencies' efforts to eliminate barriers to accessing MAT and removing prior authorization and other barriers. There also need to be state-by-state efforts to eliminate these barriers in the private and group markets. Finally, the AMA strongly urges increased efforts to encourage physicians and other providers to treat patients with substance use disorders by increasing reimbursement levels for such treatment.

3. In your testimony, you discuss the need for physicians to balance their ethical obligation to treat legitimate patient pain management needs with a responsibility to spot potential misuse or abuse of prescription drugs. I am also a big believer that we MUST not be over reactionary

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[5] Neonatal Abstinence Syndrome: How States Can Help Advance the Knowledge Base for Primary Prevention and Best Practices of Care, 2014. Available at: http://www.astho.org/Prevention/NAS-Neonatal-Abstinence-Report/

and deny patient's relief from sometimes unimaginable pain – going backwards and not alleviating human suffering is the last thing we should do.

I believe we need to give doctors the tools they need to stop addiction before it starts. E&C has led this charge and have passed bills that have become law to secure the supply chain and crackdown on rogue Internet pharmacies.

Many times I have spoken about the common sense items Congress could do right now:

- **Help support State PDMPs – fund NASPER and make these systems more interactive, timely, physician friendly, interoperable and real time;**
- **Focus law enforcement efforts not on doctor's who specialize in treating pain or treating painful conditions;**
- **Further crackdown down on rogue distributers and Internet pharmacies; and**
- **Allow coverage of drug monitoring tools to ensure patients are taking their medications (and are processing those medications) as intended.**

Can you share AMA's position on these potential solutions?

The AMA agrees with you that there are several opportunities to take advantage of existing technologies and give physicians, other prescribers, and pharmacists the tools they need to ensure patients are receiving the care they need while working to prevent abuse, misuse, and illegal behavior.

The AMA strongly supports reauthorizing and fully funding NASPER to help states make their PDMPs fully modernized and optimized, with a continued strong public health focus. We are concerned, however, that as introduced, the current NASPER reauthorization bill would allow law enforcement and Justice Department access and engagement with state PDMPs that we cannot support. We do not support law enforcement access to patients' protected health information in a PDMP without a court order.

PDMPs can be helpful clinical tools. But, in order to be most useful, PDMPs need to be able to ensure that the data is available "real-time" at the point of care, that the data is accurate and easy to use, and that it contains all relevant information, including data updated in a timely manner by pharmacists who dispense medications, and potential prescriptions that were dispensed from other states. When PDMPs contain these important elements, we believe that physicians will use them as an important clinical tool to make treatment decisions based on patient-specific needs.

To date, PDMPs mostly have been used to identify so-called "doctor shoppers," but it is unclear whether those efforts are targeting individuals who seek drugs for illegal activities as opposed to patients with a substance use disorder and who need treatment. Although many PDMPs have been used in states for years, there is little data on how to best use these databases to help increase access to treatment. Using these tools as a means to monitor adherence, as you suggest, is one such promising idea. The current focus, however, must be on ensuring that PDMPs are fully funded and modernized so that they can be used in ways that enhance patient care.

The AMA agrees with you that law enforcement efforts should be focused on securing the supply chain and stopping illegal pill mills and rogue, online pharmacies. The AMA has no tolerance for any prescriber or dispenser who engages in illegal activities. There is a difference, however, in appropriate oversight and intrusive investigations not based on probable cause. This is a challenging balance, but the AMA is committed to working with and supporting efforts to help law enforcement get this right. We

also believe that law enforcement, along with first responders and others, should carry Naloxone with them to prevent overdose fatalities. Finally, law enforcement has an important role to play in helping to ensure that suspects and offenders with substance use problems have access to treatment.

Thank you again for the opportunity to testify and to provide these responses for the record. Please do not hesitate to contact me if I can be of further assistance to the Subcommittee. The AMA applauds your leadership in tackling the opioid epidemic and looks forward to working with you and your colleagues to advance public health-focused solutions to prevent and reduce opioid misuse, abuse, overdose, and deaths.

Sincerely,

Patrice A. Harris, MD, MA
Secretary, Board of Trustees

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations
The Honorable Michael C. Burgess, MD
James L. Madara, MD