COMBATING THE OPIOID ABUSE EPIDEMIC: PROFESSIONAL AND ACADEMIC PERSPECTIVES

THURSDAY, APRIL 23, 2015

House of Representatives,
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
Washington, D.C.

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
Mr. {Murphy.} All right, good morning. We are here at
the Oversight and Investigation 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 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 be the point—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
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133 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.

139 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.

143 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.

151 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, and should--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 are--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:]

*************** COMMITTEE INSERT ***************
Mr. {Murphy.} I now recognize Ms. DeGette for 5 minutes.

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 student at--sixth-grader. 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 ineffective or dangerous? And finally, why not--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
dependency 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 wonder
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.

[The prepared statement of Ms. DeGette follows:]
Mr. {Murphy.} Thank you.

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

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, 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 if 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,
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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.

[The prepared statement of Mrs. Blackburn follows:]

*************** COMMITTEE INSERT ***************
Mr. {Murphy.} And nobody else on this side seeking final 2 minutes, then I will turn towards Ms. Schakowsky for 5 minutes.

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 allocations 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
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370 programs that patients rely on.
371 And I want to yield the balance of my time to
372 Representative Tonko.
373 [The prepared statement of Ms. Schakowsky follows:]

374 **************** COMMITTEE INSERT ****************
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
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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, 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, saving 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.

[The prepared statement of Mr. Tonko follows:]
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.} --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.

Dr. {DuPont.} Thank you.

Mr. {Murphy.} Make sure your microphone is on and as close to you as possible. Yeah, just pull it real close.

No, try again. Well--

Dr. {DuPont.} There we go.

Mr. {Murphy.} There you go.

Ms. {DeGette.} There

Mr. {Murphy.} Thank you. Okay.

Dr. {DuPont.} Thank you very much.

Mr. {Murphy.} Okay.
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 the--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 has--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, and I think that that--but I think that concept is very important, just like these people taking--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 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
stated 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, the—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 a--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
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535 because you think you are going to be fixed in treatment.
536 People are not fixed in treatment with opiate dependence.
537 Treatment can help them find their path to recovery, but
538 treatment is not recovery, and it is really important that
539 people are not fixed in any treatment, drug-free or
540 medication treatment. It is a lifetime struggle, and that is
541 a very important perspective on this.
542 Now, my concern is that treatment would--does not match
543 up with the disease. The treatment is always short-term.
544 Even medication-assisted treatment, which conceptually goes
545 on for a lifetime, has very high drop-out rates, very rapid--
546 patients drop out of the program for medication-assisted
547 treatment. And the other thing is a high percentage of
548 people in medication-assisted treatment continue to use
549 opiates and other drugs while they are in the program. That
550 is very important to notice that and pay attention to that.
551 But even more important, and the thrust of my testimony, all
552 of it is accountability for treatment. What are the results
553 during treatment? What percentage of the patients are
554 continuing to use drugs? How much retention is there? What
555 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.
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[The prepared statement of Dr. DuPont follows:]

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578  *************** INSERT A ***************
Mr. {Murphy.} Thank you. Thank you very much.

Dr. Seppala, you are recognized for 5 minutes.
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 prevent 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 euphoria, 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 are not--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 1/3 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 1/2 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
I would also like to emphasize the need to educate a wider culture about the dangers of opioid over-prescribing. The troubling trends began to emerge in the late '90s 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
It should be noted that doctors didn't start over-prescribing 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 over-prescribing 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.
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704  ***************** INSERT B *****************
Mr. {Murphy.} Thank you, Doctor.

Now, Dr. Westreich, you are recognized for 5 minutes.
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 assisted--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 use 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:]

*************** INSERT C ***************
Mr. {Murphy.} Thank you very much.

Dr. Lembke, you are recognized for 5 minutes.
^TESTIMONY 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 over-prescribing 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

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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 use—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 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
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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 over-prescribing, 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
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941 your leadership in addressing this public health epidemic.

942 [The prepared statement of Dr. Lembke follows:]

943 ****************** INSERT D ******************
Mr. {Murphy.} Thank you, Doctor.

Now, Dr. Bisaga, you are recognized for 5 minutes.
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 medications, 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 treatment--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. This--in addition, this approach can be very dangerous. Patients that do not receive medications are at--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 methadone 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
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628  effort of health professional, community advocates, and
629  policymakers is urgently needed to reverse this tragic trend.
630  Thank you for the opportunity to testify.
631  [The prepared statement of Dr. Bisaga follows:]

632  **************** INSERT E ****************
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.
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 pain 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:]
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. It is--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.} I ran back because I didn't want to waste--get caught up--I want to make sure we are back. Just give us one more minute for the members to return.
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.} 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.} Yeah, 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 in--this line is buprenorphine in--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, I--that is very important information, absolutely, and I think the--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, not—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 am—-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-mEDIATE. 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 trained--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?
Yeah, 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— the 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.} Yeah, 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 number of people that are treated with this medication. So it tells me—tell 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.

Ms. {Schakowsky.}

Dr. {Lembke.} Yeah, 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, okay.

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.} --pain.

Ms. {Schakowsky.} --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 120-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.} Yeah, 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.} Yeah. Yeah.

Ms. {Schakowsky.} Okay.

Dr. {Seppala.} So the--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.} Usually--I would say usually is a good description. Not always.

Ms. {Schakowsky.} Yeah. Okay.

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.} --get approved?

Dr. {Harris.} --get coverage for that, yes.

Ms. {Schakowsky.} Thank you. Okay, I don't know, can Dr.--

Dr. {Bisaga.} Can I--yeah, 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 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—other treatment too, 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. What--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.} --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 believe 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 as--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.} --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.} Yeah, that those people are going to be--

Ms. {DeGette.} Yeah.
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Dr. {Lembke.} --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.} --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.} So everything—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 it is—what it is, it is kind of a
truncated treatment. It is like we are--

Ms. {Bisaga.} Again--

Ms. {DeGette.} --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.} Okay. 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.} -- and then they--

Ms. {Bisaga.} Detox them and sell them to 12-step groups.

Ms. {DeGette.} Okay.

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?

Okay.

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 a--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?
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1537 Dr. {Westreich.} Yes.
1538 Ms. {DeGette.} Yeah.
1539 Dr. {Lembke.} Can I just add one thing?
1540 Ms. {DeGette.} Please.
1541 Dr. {Lembke.} You know, MAT works for some people, it doesn't work for everybody--
1542 Ms. {DeGette.} Right.
1543 Dr. {Lembke.} --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--not--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.
1549 Ms. {DeGette.} Right, and if you can find a program to put them in.
1551 Dr. {Lembke.} Even to put them in the hospital--
1553 Ms. {DeGette.} Exactly.
1554 Dr. {Lembke.} --I mean even to put them in the hospital for 3 or 4 days is very hard.
1556 Ms. {DeGette.} And, you know, let me just say, Mr. Chairman, I really appreciate this hearing because this is
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1558 exactly what I have been trying to say is, it is not a one-
1559 size-fits-all solution for these patients, there are
1560 different types of solutions, but if you take out one of the
1561 programs that really works, like MAT, or the MAT plus the
1562 intensive long-term counseling, you are going to have--not
1563 only are you going to have a failure rate but you are also
1564 going to have deaths. So thank you.
1565 Mr. {Murphy.} And even that is difficult for them to
1566 get.
1567 Dr. Burgess, recognized for 5 minutes.
1568 Mr. {Burgess.} Thank you, Mr. Chairman. And I do have
1569 a number of questions for Dr. Harris. Thank you for being
1570 here today. I man end up submitting those to you in writing
1571 and ask for a written response because I do want to use part
1572 of the time that I have available to get on my soapbox. That
1573 is what we do here.
1574 This is not quite the appropriate hearing, but this
1575 subcommittee does have jurisdiction over the Food and Drug
1576 Administration, and for--several times, we have had the Food
1577 and Drug Administration in, I have asked the question why we
1578 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, yeah, 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
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1621 forget the codeine part of the prescription; this was a
1622 multiple times lethal dose of acetaminophen that, if somebody
1623 had actually ingested it, their liver was long gone and
1624 someone would be paying for a liver transplant. We have
1625 prescription drug monitoring programs. We have one that was
1626 passed by this committee, called NASPER, and President Bush
1627 signed it into law in 2005. There is a competing program
1628 that was done by the appropriators. That is not your
1629 problem, that is our problem. But, Mr. Chairman, it just
1630 underscores how we need to fix that. And now, we ask the
1631 American people with the Stimulus Bill to fund this large
1632 electronic health records, and do we have the
1633 interoperability so a doc in practice would know what that
1634 patient is taking? We don't really have the availability of
1635 getting that because of HIPAA, there are some privacy
1636 concerns. Somehow we need to bridge that gap, and I really
1637 would welcome anyone's comments on the panel about the
1638 prescription drug monitoring aspect.
1639     Dr. {Westreich.} I would like to comment--
1640     Mr. {Burgess.} Yes, Doctor.
1641     Dr. {Westreich.} --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 affirmatively—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 much 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 taskforce 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.} Yeah, 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.} Yeah, 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 addiction 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.} You--other people agree with that?

Okay, 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, and--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 agree 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.} It is a--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
100

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. Can't--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.} Our--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 Medicaid-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 Oxy days--Oxycontin days, but what do we need to do to better educate physicians and psychiatrists about how to treat addictions but I--we are not there, we are not even close to being there. And I applaud all of you for your work. And just--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 drug--medication-free treatment, not medication-assisted treatment. So we are
1894 working with the Bureau of Prisons, and hopefully you guys
1895 can help with that tool, to encourage them to use evidence-
1896 based treatment when they are making decisions about the
1897 medical treatments. It can be done in combination with the
1898 decision about the, you know, criminal justice with ability.
1899 So--
1900 Mrs. {Brooks.} Because, you are right, our prisons,
1901 which we also fund, obviously, as people are coming out of
1902 prison, probably one of the top reasons they recidivate and
1903 are back within a short period of time is they didn't have
1904 their addiction dealt with, and they are--anyone else like to
1905 comment--
1906 Dr. {Westreich.} Yeah, as--
1907 Mrs. {Brooks.} --or all of--
1908 Dr. {Westreich.} As to drug courts, I mean I would say
1909 on both of your questions, education is the key. I think
1910 drug courts are great. I think judges and lawmakers need to
1911 be educated about addiction itself and not practice medicine.
1912 In the same way, we clinicians need to be educated about law
1913 and about the necessity for a holding structure of people who
1914 are addicted. So I think drug courts work well when everyone
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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 psychiatry but primary care doctors and all physicians about prescribing practices, about—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 okay. 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 1/3 of the physicians in those programs are opiate addicts, about 1/2
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 that—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.--thank you, 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. I--
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. So--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 you people are addicted and that is fueling either because of over-prescription, 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 the--people will follow incentives, and is--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 ask--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 resources 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 over-prescribed, and I want to get to the why if that is the case?

Dr. {Seppala.} Yes, they are being over-prescribed, 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 the--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.} --they still have to kind of catch up, so we do need to educate our physician population.

Ms. {Clarke.} So the--Dr. Lembke, I would like to get your thoughts on that as well.

Dr. {Lembke.} Well, there is a long story to why we over-prescribe 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.} Yeah, 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 behavioral 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
2209 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 1-1/2 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 is--committee is adjourned.

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