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EXAMINING HEROIN AND OPIATE ABUSE IN SOUTHWESTERN PENNSYLVANIA

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH CARE

OF THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

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EXAMINING HEROIN AND OPIATE ABUSE IN SOUTHWESTERN PENNSYLVANIA

THURSDAY, OCTOBER 15, 2015

U.S. SENATE,
SUBCOMMITTEE ON HEALTH CARE,
COMMITTEE ON FINANCE,
Pittsburgh, PA.

The hearing was convened, pursuant to notice, at 2:13 p.m., in the McGovern Auditorium, Allegheny General Hospital, 320 East North Avenue, Pittsburgh, PA, Hon. Patrick J. Toomey (chairman of the subcommittee) presiding.

Also present: Senator Casey.

Dr. FARAH. Good afternoon. On behalf of Allegheny Health Network, I would like to welcome Senator Toomey, who sits on the Senate Finance Subcommittee on Health Care, and Senator Casey, who sits on the Senate Health, Education, Labor, and Pensions Committee. And a special welcome to our friends from CMS—Dr. Ling, thank you—Gateway Rehab, and Washington County, who have agreed to testify today. Nobody understands the complexity and severity of this issue more than our medical professionals and our law enforcement community. Thank you, Senator Toomey and Senator Casey, for your leadership on this issue.

Senator Toomey and others have introduced the Stopping Medication Abuse and Protecting Seniors Act. This is the act which is meant to prevent inappropriate access to opioids for Medicare patients, and the law would identify medical beneficiaries with a history of drug abuse and lock them into one prescriber and one pharmacy to reduce physician and pharmacy shopping.

Just a few days ago, Senator Casey visited an addiction treatment center in Norristown, PA. Senator Casey supports the Treatment and Recovery Investment Act, which would increase funding for prevention and treatment programs, including recovery programs for teenagers and pregnant women.

Both of these laws could help ease the drug abuse problem, and both our Senators understand the gravity of the opioid epidemic. The epidemic is growing in Appalachia, in Pennsylvania, and our own region. Pennsylvania now has the seventh-highest drug overdose death rate in the United States, West Virginia nearby has the highest overdose death rate, and Ohio has the eighth-highest rate. In our own State, we have more than 2,400 overdose deaths per year, and most of them are related to prescription painkillers. We now lose more people in Pennsylvania to overdose deaths than to car accidents.

This is a battle on multiple fronts. Painkiller abuse is linked to heroin abuse. A 2014 study found that 80 percent of the people who now use heroin were addicted to opioid painkillers first. The Attorney General's office says that Pennsylvania has about 40,000 heroin users, and that number is growing every year.

It is growing nationally too. Laws to restrict prescription shopping and to prevent painkiller abuse can work, but then some of those people who can no longer find painkillers are switching to heroin. You stop one, and the other then doubles.

We are trying to do our part here at Allegheny Health Network, and what we are doing is training our emergency room physicians, nurses, social workers, and dentists to spot the early signs of abuse and to know more about pain medications. And more than a year ago, we became one of the first health networks in the State to help equip law enforcement with Narcan, the generic then being naloxone. This is a life-saving heroin overdose drug. We have already seen the benefits of that.

Obviously these are serious problems that require serious leadership and a thoughtful response, not just from the medical and law enforcement communities, but from policymakers as well, which is why we are here today. I would like to thank Senator Toomey for convening this hearing and also thank Senator Casey for attending. And we thank you both for allowing Allegheny General Hospital and the Allegheny Health Network to be your host today.

OPENING STATEMENT OF HON. PATRICK J. TOOMEY, A U.S. SENATOR FROM PENNSYLVANIA, CHAIRMAN, SUBCOMMITTEE ON HEALTH CARE, COMMITTEE ON FINANCE

Senator TOOMEY. Thank you very much, Dr. Farah. I appreciate that. I appreciate you joining us today. I want to also thank John Paul and the Allegheny Health Network for making this terrific facility available to us. I also want to thank my fellow Finance Committee member, Senator Casey, for joining me today. I know that he and I both care very, very deeply about this very, very pressing problem that is occurring all across the Commonwealth and, in fact, across our country.

The fact is, as Dr. Farah mentioned, more Pennsylvanians will die this year from overdoses and misuse just of heroin and prescription painkillers than from influenza or homicide. And unlike past drug epidemics that tended to skew towards younger populations and were concentrated in specific locales, today heroin and prescription drug overdoses are spread across all races, regions, demographics, and ages.

As the Senate Finance Subcommittee on Health Care will hear today from our witnesses, sadly southwestern Pennsylvania has been hit particularly hard by this epidemic. It seems to me that stopping this epidemic and healing our communities will require at least a three-pronged approach, and I am trying to pursue that as chairman of the Senate Finance Subcommittee on Health Care. One element of this approach is to stop the illegal diversion of prescription painkillers, a second is reducing the overuse of opioids for treating long-term pain, and a third is to help those battling with addiction to receive the appropriate treatment.

Our witnesses today will discuss these issues and other issues that they will bring up, and I want to really thank all of our witnesses for taking the time to be with us today and for sharing their expertise and helping to shed light so that we can hopefully develop policies that will be helpful for our communities.

Our first panel will consist of Dr. Shari Ling. Dr. Ling is the Deputy Chief Medical Officer from the Centers for Medicare and Medicaid Services at the United States Department of Health and Human Services. After Dr. Ling testifies, Senator Casey and I will ask her some questions, and then we will proceed to a second panel.

And the second panel will consist of Dr. Neil Capretto—Dr. Capretto is the medical director of the Gateway Rehabilitation Center; Mr. Gene Vittone, who is the district attorney for Washington County; Dr. Jack Kabazie, who is the system director for the Division of Pain Medicine here at the Allegheny Health Network; and Ms. Ashley Potts, who is the team leader in the Crisis Stabilization and Diversion Unit for Southwestern Pennsylvania Human Services. I also want to point out that joining us this afternoon is U.S. Attorney David Hickton, who has provided outstanding leadership in this and many other areas. So, David, thank you for joining us.

I would like, just for a moment though, to consider how we arrived at this point. It seems to me the seeds of this crisis may well have been planted 2 decades ago with the advent of readily available painkillers like hydrocodone and oxycodone. And while these drugs no doubt produce immediate pain relief, they are easily abused. They are highly addictive, and they can be frequently diverted. The data that I have seen suggests that something on the order of 80 percent of heroin users previously abused prescription opioids.

And despite the crackdown on many of the so-called "pill mills" where unethical physicians intentionally prescribe very large amounts of powerful opioids in exchange for cash, the problem of diversion and over-prescribing still does exist. In fact, the nonpartisan Government Accountability Office has found that there are more than 170,000 Medicare enrollees who are actively engaged in doctor shopping—shopping for physicians who will unknowingly write redundant opioid prescriptions.

Now, when insurance plans, including Medicaid, spot this kind of fraud, the insurer will then limit or, as we say, lock in the individual to a single doctor or pharmacy in order to stop the pill diversion and help control access to the addictive medication. But unfortunately, Medicare does not have that tool, and that is why I have introduced bipartisan legislation, the Stopping Medication Abuse and Protecting Seniors Act. This legislation, which Senator Casey has co-sponsored—which I appreciate—will not only help individuals battling addiction to get treatment, but it will also save taxpayers something on the order of $79 million by stopping the illegal diversion of pain pills.

I think Medicare and other insurers also need to work with physicians to stop the medically unnecessary use of opioids to treat pain. This year about 260 million painkiller prescriptions will be filled—260 million. That is enough for every adult American to have their own bottle of pills, and, while opioids can certainly help

control intense pain immediately after surgery or a visit to the dentist or a traumatic event, the medical community has become concerned that long-term opioid use becomes less effective over time and is associated with higher rates of substance abuse, emergency room visits, accidental overdoses, and falls, especially in senior citizens.

Now, fortunately medical specialty societies have begun developing new guidelines that reduce both the dosage and the length of time that prescription opioids can be safely taken. For instance, the American Academy of Neurology now says that the risk of opioid abuse outweighs any benefits for treating headaches, lower back pain, and fibromyalgia. And when opioids are used in combination with other narcotics like Valium or Xanax, that combination can be deadly.

To help providers know the panoply of medications a patient is taking, I think there needs to be broader usage of robust prescription drug monitoring programs. Making them interoperable across State lines is particularly important for people who live near State lines. And it will help physicians as well as law enforcement to spot diversion and abuse, and that is why I have introduced with our colleague, the Democratic Senator from New Hampshire, Jeanne Shaheen, the reauthorization of the National All Schedules Prescription Electronic Reporting Act. NASPER is a Federal grant program that provides grants to States to develop interoperable prescription drug monitoring programs.

Finally, I think we need to explore ways to improve access to and the quality of care for people who are suffering from addiction. While addiction to an opioid, or alcohol for that matter, often has been viewed as a moral failing, in many ways it is a chronic disease like diabetes or heart disease. And while the medical profession continues to debate the optimal treatment approaches, I think everyone agrees that opioid addiction can be treated with professional help. So Congress and my subcommittee are closely examining a number of legislative ideas in this area.

Ending the epidemic of heroin addiction will require changes in the practice of medicine, government regulations, and societal views. There are steps we can and should take today that end diversion, reduce non-medical use of opioids, and approach this addiction like a treatable disease. So I want to thank everyone who is here today. This turnout, I think, shows the extent to which this tragedy affects so many people across southwestern Pennsylvania. I appreciate the passion with which you approach this issue to find solutions. By working together at the Federal, State, and local levels, with health care, law enforcement, and others coming together, I am confident that we can defeat this scourge.

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

Senator TOOMEY. I would now like to recognize Senator Casey for his opening remarks.

OPENING STATEMENT OF HON. ROBERT P. CASEY, JR., A U.S. SENATOR FROM PENNSYLVANIA

Senator CASEY. Senator Toomey, thank you very much, and I am honored to be here, and I am grateful that Senator Toomey called

this hearing. We are both members of the Finance Committee, but I am not a member of his subcommittee, so I am here by special permission or designation. So I am grateful to have that opportunity because, as he said, this is a problem and a challenge for our country that knows no geographic or political boundaries. This affects all of us, all of our communities, in one way or the other.

We are so grateful that Allegheny General Hospital has us here, and we are grateful for our witnesses, and we will be getting to our witnesses shortly. I will try to be as brief as I can. I want to thank David Hickton for being here, someone who has been in the trenches on this at the Federal level—and every level of government has to work on this problem.

We are here today because of a problem our country confronts, which might be described as the dark night of addiction and death that comes from the problems people have ultimately with painkillers, opioids, and often, unfortunately, the related abuse of heroin. And that dark night, I think, requires some light, and one of the reasons we gather and have a hearing like this is to hear from experts to consider different perspectives on how to confront this, and hope that together we can bring some of that light.

The numbers and the data points are almost endless. There are so many ways you could describe the problem. One has already been mentioned, the idea that in Pennsylvania today we can report sadly that the number of people who will die from overdose is higher than the number of people who would die from auto accidents. It is hard to comprehend that that is true, but that is what we are told.

Another way to look at it is, over 5 years, 3,000 people in this State have died either by way of opioid problems or heroin. If you look at it over a longer period of time, over 20 years, there has been a 470-percent increase in overdose deaths. Twenty years, Pennsylvania, 470-percent increase. The Coroners Association—maybe the most graphic number of all—tells us that just between 2009 and 2014, about 5 years, the number of overdose deaths went from 47—47—to 800. So no matter what number you use—we could go on and on with the numbers, and I will not—there is almost no way to adequately describe the horror that this has brought to our communities and to our families.

So what do we do about it? Well, if you are a legislator—and Senator Toomey outlined that we have a number of legislative proposals. The bill that he worked on and has sponsored with Senator Brown is one of those. I will just highlight very quickly a few others. Senate bill 1410 would increase the block grant funding, the so-called Substance Abuse Prevention and Treatment Block Grant. That particular block grant helps our States with planning, with implementing and evaluating efforts to prevent and treat substance abuse, and is funded now at about $1.45 million. I believe, and others believe, that number should go up.

Secondly, a piece of legislation that I have worked on deals with a segment of this problem as it relates to newborns. Senator McConnell, the majority leader, and I have a bill, Senate bill 799. The neonatal abstinence syndrome problem is the focus of this bill. That occurs when infants are born addicted to opioids, and what we would do with our bill is very simple. We direct the Department

of Health and Human Services to develop a strategy to fill in the gaps, whether they are research gaps or program gaps, and also at the same time require that HHS develop recommendations for preventing and treating this condition, so-called neonatal abstinence syndrome, among other things we can do.

Finally, as Senator Toomey mentioned, there have been legislative efforts. I do not think we are there in terms of progress yet when it comes to establishing requirements for DEA-registered prescribers and that interoperability that Senator Toomey mentioned. That is also part of the problem. Sometimes the first line of defense is a pharmacist, among the most trusted people in a community, and they can help us enormously in terms of pointing out problems.

I have been to a couple of places in this State over the last couple of months where we are seeing the manifestation of what a lot of advocates and a lot of experts in this room would tell us over and over again: good treatment works, but it has to be good treatment, and it has to be sustained, and we have to make sure we have the resources to sustain it.

So we are grateful that, on a day like today when we will focus on much of the horror, on much of the tragedy, much of that darkness, that so many people in this room, by way of your work, by way of your presence here, or by way of your testimony, starting with Dr. Ling, can bring some light to that darkness. And I want to thank Senator Toomey for gathering us today.

Senator TOOMEY. Thank you, Senator Casey. We will now hear from our first witness. Dr. Shari Ling is currently the Deputy Chief Medical Officer serving in the Center for Clinical Standards and Quality at the Centers for Medicare and Medicaid Services. Dr. Ling is a geriatrician and rheumatologist who received her medical training at Georgetown University School of Medicine, Georgetown University Medical Center, and Johns Hopkins University. She also is a researcher and staff clinician at the National Institutes of Health's National Institute on Aging, studying human aging and age-associated chronic diseases with attention to musculoskeletal conditions and mobility function.

Dr. Ling, thank you very much for joining us. Please present us a summary of your testimony.

STATEMENT OF SHARI M. LING, M.D., DEPUTY CHIEF MEDICAL OFFICER, CENTERS FOR MEDICARE AND MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES, BALTIMORE, MD

Dr. LING. Good afternoon, and, Chairman Toomey, Senator Casey, please accept my sincere thanks for the invitation to discuss the Centers for Medicare and Medicaid Services' work to ensure that all Medicare and Medicaid beneficiaries are receiving the medications that they need while also reducing and preventing prescription drug abuse.

As you have heard already, opioid addiction is taking a real toll on communities, families, and individuals, both here in Pennsylvania and across our Nation. And as a practicing rheumatologist and geriatrician, I understand the challenges of effectively managing frail, older adult patients with debilitating chronic pain. It begins with identifying the underlying source or cause of painful

symptoms, particularly in older adult patients where it can be challenging to decide which condition is the problem.

It then proceeds with understanding all of the medical, psychological, social, and other issues that must be addressed in every patient's plan of care. Intervention that addresses the underlying cause will improve symptoms; that is, it will alleviate pain if addressed effectively. However, when pain persists despite conservative management attempts and threatens the quality of life and function, chronic pain management should include non-pharmacologic as well as medicinal agents, but each time with clear and precise treatment goals. There will be patients for whom opioid medications are necessary, but oftentimes other pain management strategies can be as effective and more appropriate.

Combating non-medical prescription opioid use, overuse, dependence, and overdose is a priority for the Department of Health and Human Services, Secretary Burwell, and the administration at large. As part of that commitment, the Secretary has launched an evidence-based opioid initiative that focuses on three targeted areas: that is, informing opioid prescribing practices, increasing the use of naloxone as a second point, and the third being expanding the use of medication-assisted treatment to treat the opioid use disorder itself.

As part of our role in these efforts across HHS, CMS has released guidance to help States implement comprehensive evidence-based service delivery approaches to Substance Use Disorder treatment. Overall, CMS recognizes our responsibility to protect the health of Medicare and Medicaid beneficiaries here in Pennsylvania and across the Nation by putting appropriate safeguards into place that prevent non-medical use and abuse of opioids, while ensuring that beneficiaries access the needed medications that are appropriate for them.

Since its inception, the Medicare Part D prescription drug benefit program has made medications more available and more affordable for Medicare beneficiaries, leading to improvements in access to prescription drugs, better health outcomes in general, and greater beneficiary satisfaction with their Medicare coverage. But despite these successes, Medicare Part D is not immune from the nationwide epidemic of opioid abuse. The structure of the program, in which Part D plan sponsors do not have access to Part D prescriber and pharmacy data beyond the transactions that they manage for their own enrollees, makes it more difficult to identify prescribers or pharmacies that are outliers in their prescribing or dispensing patterns relative to the entire Part D program.

CMS has taken several steps to protect beneficiaries from the harm and damaging effects associated with non-medical prescription drug use, and to prevent and detect fraud related to prescription drugs. To prevent overutilization of opioid medications through strengthening CMS's monitoring of Part D plan sponsors, CMS has implemented the Medicare Part D Overutilization Monitoring System, or abbreviated as OMS. OMS requires Part D sponsors to implement effective safeguards to deter overutilization while maintaining a commitment to provide coverage for appropriate drug therapies that meet safety and efficacy standards. Through this system, CMS provides quarterly reports to sponsors' drug plans on

beneficiaries with potential opioid overutilization, and sponsors are expected to utilize various drug utilization monitoring tools if necessary to prevent overutilization.

We believe this Part D overutilization policy has played a key role in reducing opioid utilization in the program. That is, from 2011 through 2014, the number of potential overutilizers decreased by approximately 26 percent, or said another way, 7,500 beneficiaries over that 3-year period of time did not become overutilizers. So there was a significant reduction, but as we have heard from the numbers shared today, we have a long way to go.

CMS has also used and has available new tools to take action against problematic prescribers. CMS issued a regulation that both requires prescribers of Part D drugs to enroll in Medicare, and establishes a new revocation authority for abusive prescribing patterns. CMS is actively working to enroll over 400,000 prescribers in Part D by January of 2016. Requiring prescribers to enroll in Medicare will help CMS make sure that Part D drugs are prescribed by qualified individuals and will prevent prescriptions from excluded or already revoked prescribers from being filled.

Additionally, CMS has established its authority to remove prescribers from Medicare when they demonstrate irresponsible prescribing patterns, have their DEA certificate of regulation suspended or revoked, or if any State has suspended or revoked the physician's or eligible professional's ability to prescribe. These new revocation authorities provide CMS with the ability to remove problematic prescribers from the Medicare program and prevent them from treating people with Medicare.

In addition to these initiatives, the President's budget includes several proposals that would provide CMS with additional tools to prevent inappropriate use of opioids. One proposal to prevent prescription drug abuse in Medicare Part D would give CMS the authority to establish a program, commonly referred to as "lock-in," that would require high-risk beneficiaries to only utilize certain prescribers and/or pharmacies to obtain controlled substance prescriptions similar to the requirement in many States in Medicaid programs.

So in conclusion, CMS is dedicated to providing the best possible care to beneficiaries while also ensuring taxpayer dollars are spent on medically appropriate care. CMS has broadened its focus from ensuring beneficiaries have access to prescribed drugs to ensuring that Part D sponsors implement effective safeguards and provide coverage for drug therapies that meet the standards for safety and efficacy.

Although there is still a great deal of work that needs to be done, CMS is confident that our initiatives will help to reduce the rate of opioid addiction and overdoses in the Medicare population. Thank you.

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

Senator TOOMEY. Thank you very much, Dr. Ling. I am going to begin the questions, and I will try to keep to the 5-minute guidelines that we have established. Then I will yield the mic to Senator Casey.

I just want to confirm, though, and I think you stated it clearly, that it is both your view and the position of CMS that the lock-in

approach to a single provider and a single pharmacy for high-risk beneficiaries and beneficiaries who are abusing prescription opioids would likely reduce the diversion of pain pills. And so, you and CMS are supportive of that approach for Medicare, correct?

Dr. LING. So, if I may expand on it just a bit——

Senator TOOMEY. Sure.

Dr. LING. CMS is supportive of the principle of lock-in because what it does achieve is, it provides some guarantee of continuity of a source of that prescribing, and it is one measure that can complement the tools that are already in place. And we believe that that would result in better outcomes in general.

Senator TOOMEY. Okay, great. Thank you. Doctor, now you are a geriatrician. Maybe you could share with us just briefly some comments on vulnerabilities that might be greater among the older population, senior citizens, specifically with risk to either accidental misuse or other adverse effects from the use of opioids. Could you share with us your thoughts on that?

Dr. LING. Certainly, I would be delighted to. The older adult population not only has a higher prevalence of chronic conditions, including those chronic conditions that can cause painful symptoms—many of which can be managed without the use of opioid medications—but likely secondary problems.

We actually know from the Medicare data that among people, as an example, who have arthritis, which is a common reason that one would seek treatment from painful symptoms, the majority of those people also have competing other medical conditions, some of which may be related to the painful symptoms that they have; that is, they may have difficulty sleeping or sleep disturbance. They actually also may have kidney impairment, so their kidneys may not be functioning quite correctly.

And so, you can see how not only they may be at risk of a temptation to overuse prescription medications that could be potentially harmful, but taken together with the management of other competing conditions that may be associated, such as a sleep disorder, they may also be at increased risk of adverse events occurring. And those adverse events could include unintentional overdose from opioid medication. It could, as you alluded to earlier, Senator, increase the risk of falls, of confusion—and the cycle continues.

Senator TOOMEY. Thank you. I want to ask a question about the Overutilization Monitoring System, which sounds like it might indeed be helpful in spotting excessively high consumption of opioids. My understanding is that CMS tells plan sponsors when they identify a patient, a beneficiary, exceeding the equivalent of 90 milligrams of morphine per day. But I have seen some data suggesting that even at levels lower than that, maybe as low as 50 milligrams, there could be a significant risk of overdose, deaths, emergency room visits, accidental falls, and other unintended bad outcomes.

So my question is, is CMS able to track the outcomes for individuals who receive opioids at that lower threshold, and is it your view that we have to consider the consequences that are occurring at those lower thresholds, or do you think 90 milligrams is all we need to know?

Dr. LING. I will answer it in a couple of ways. Thank you for your question, first of all, because it actually gives me an opportunity

to talk about some of the balance in the system. We still want to maintain access for people who have painful symptoms, so it becomes an issue of threshold and what threshold to set in a monitoring program.

Indeed it is true that CMS provides plans with prescription drug event data. Some of the data can include dosing. Obviously, we have dosing as part of the data and a great deal of other data, but we provide that data on a quarterly basis. And then the plans are expected to review those data and to look at those data and to try to understand and work with prescribers as well as pharmacies looking for those overutilizers and, if necessary, put in place some case management efforts to try to curb that prescribing pattern.

Mind you, it is very safety-focused, so reaching a safety threshold, that is where we started. It is also a preventive action, so it is expected that the plans would put in place strategies to monitor and prevent future events from occurring. But it is a starting place, and the data do exist that would permit us to look further than what is currently utilized as a threshold.

Having said that, we believe that it is an effective method of monitoring, and in support of the Secretary's initiative in delivery system reform whereby information is used—that is, the Part D data being available to plans—it is an important step to achieving the reductions that we are hoping to achieve.

Senator TOOMEY. Okay. Thank you very much. Senator Casey?

Senator CASEY. Thanks very much, Doctor. Thanks for your testimony.

I want to ask you a question that relates to the position CMS is in as a payer, the Federal Government entity that oversees and has to operate both Medicare and Medicaid in addition to other programs, and this connection, which I think you began to focus on in your written testimony as well as the summary you provided. At the bottom on page 1 of your testimony, you said, "The monetary costs and associated collateral impact to society due to Substance Use Disorder," so-called SUD, "including opioid use disorder, are high." You go on to say, "In 2009, health insurance payers spent $24 billion treating Substance Use Disorder, of which Medicaid accounted for 21 percent. The Medicare program itself through Medicare Part D spent $2.7 billion on opioids in 2011."

What I am getting at is the connection between the two where you literally have a connection between two activities that relate to the Federal Government. What can you tell us, if anything, about whether or not CMS can use its leverage as a payer and encourage prescribers to scrutinize their activities or prescriptions more generally?

Dr. LING. Let me answer this in a couple of ways, and please let me know if I do not address your question fully.

Senator CASEY. Sure.

Dr. LING. So, as a payer, as you know, we are amidst delivery system reform, and part of that effort is to pay for high-value health care. That means quality health care or cost relative to quality. It is also a reform that requires that we practice differently, so how we actually deliver that care is more and more coordinated, it is better coordinated to be able to deliver the high value of care.

Now quality, as a focus, is an important factor because misuse of opioids, overuse of opioids, death from opioid use, are some of many undesirable events that we would think of as low-value health care. So, I think there is incredible opportunity to think about this problem in the context of delivery system reform and how we can go about placing the pieces that are necessary to improve the outcomes for medical care. Now, having said that, I do want to mention though, since you mentioned Medicare and also Medicaid, they are two distinct programs and authorities, but common to both is the need to improve how we deliver care.

I did want to mention that, within the Medicaid space, we have provided letters of guidance to State Medicaid Directors on the construct and the composition of comprehensive care services that are needed to address addiction and abuse. And there are also additional proposals in the President's 2016 budget that go further to expect or require States—many States monitor their prescription drug use patterns already, but it actually proposes to require States to do that, but also to use those data to adjust their planning and their strategies to meet the needs of the population.

Now, they can choose to focus on prescription drugs or opioids, they can choose something else, but the opportunity exists. And I will conclude by also saying that there are two new programs—that is, the section 1115 waiver through the 1115 waiver authority, as well as a Medicaid innovation accelerator program—that will support new care and payment models for States in this space with addiction and opioid overuse as a focal point. So there are new demonstration authorities that can support us in figuring out how we provide better care and deliver that care that meets the needs of the population and contributes a solution to this problem.

Senator CASEY. And I appreciate what you are trying to get to in that answer, but I just hope you use that leverage as a payer. And I know that is a startling number, Medicare through Part D spending $2.7 billion on opioids in 1 year, but that is a lot of leverage.

My last question—I know I am probably over my time. I will just be really brief. Naloxone is a remarkable advancement. Here you can literally, at the scene of an overdose, be able to reverse that horrific consequence. It is a lifesaver. It is a wonderful innovation. The problem we are having is—one problem among several, I guess, is kind of a patchwork where some States are using it, some communities are using it, others not as much.

There are no Federal standards. I am not sure there need to be. But what can you tell us about what HHS, CMS, can do to advance the use of naloxone, or what they are doing currently?

Dr. LING. Yes. So, as you know, increasing the availability and access to naloxone is the second prong in the Secretary's proposal to address this problem, the first being, of course, providing the education and information to providers so that they are aware of their prescribing practices and how to improve on them.

If I can go into a little detail, naloxone is available, and it is covered in specific instances. So, as part of the Part B service or benefit, it is coverable if it is incident to a physician's care services under Part B of Medicare. Now, that is important because physician services are also what are needed for comprehensive addiction

management, so it is not just a prescription, but it is actually much more than that.

So the medication is available. There are other medications that are also available through Part D, pretty much medications such as methadone for pain. And buprenorphine and naloxone for any medically accepted indication are also available through Part D. So those are available.

Senator CASEY. I hope we can work on that so we make it more readily available. Thank you.

Dr. LING. Yes.

Senator TOOMEY. I have just one quick follow-up for a second round, Dr. Ling, if I could, and that is, it is my understanding that there is a widespread view in the medical community that opioids may not be a suitable treatment for long-term chronic pain management, episodes lasting 60 and 90 days and longer. And in light of that, my understanding is that in Massachusetts, Massachusetts Blue Cross and Blue Shield has adopted a policy of requiring prior authorization for any prescription that exceeds 30 days for opioids.

And I am just wondering whether you think that is an approach that has some merit or not. My understanding is it has reduced the frequency of these longer-term prescriptions. What are your thoughts on that, Dr. Ling?

Dr. LING. So my thoughts are, there are many approaches that need to be taken. It is also a proposal to require additional clinical information on prescriptions so that there is a means of identifying and knowing about off-label uses beyond what would be medically indicated perhaps. Prior authorization is one such mechanism.

I will also remind you that, as part of the Overutilization Monitoring System, the authority that we have is to encourage certain desirable plan behaviors. And so, plans have the ability in their toolbox to implement formulary edits, such as a maximum number that can be dispensed at a given time, and other safety edits. Those can all be put in place and should be used by plans when appropriate.

So there are many different mechanisms that can achieve the same outcome, but really the outcome that we want and that we remain focused on is, how do we actually improve the outcomes, reduce these events of harm, improve safety, and still make available the treatment and services that the populations need to improve their own health?

Senator TOOMEY. Senator Casey, anything else?

Senator CASEY. No. Thank you very much.

Dr. LING. Thank you.

Senator TOOMEY. All right. Dr. Ling, thank you very much.

Our second panel can now take their seats. Let me start with the introductions of the people on our second panel here, and then I will recognize them individually to give their testimony.

First, Dr. Neil Capretto is the medical director of Gateway Rehabilitation Center in Beaver County. He is certified by the American Board of Psychiatry and Neurology with qualifications in addiction psychiatry, and is a medical review officer and fellow of the American Society of Addiction Medicine. He is frequently consulted in both local and national press on addiction and treatment, and has

served on the U.S. Attorney's Working Group on Drug Overdose and Addiction.

Mr. Gene Vittone is the District Attorney for Washington County. Prior to being elected, Mr. Vittone served as prosecutor for more than a decade and supervised the Elder Abuse Prosecution Unit. He has prosecuted numerous crimes, including violent felonies, sex crimes, child abuse, drug trafficking, and financial crimes. He is active in his local community as a volunteer firefighter and EMT.

Dr. Jack Kabazie is the system director, Division of Pain Medicine, for the Allegheny Health Network. Overseeing the operations of all Allegheny Health Network pain physicians, Dr. Kabazie is often called on to provide expert commentary in the media on addiction and opioid abuse. He is a member of the American Society of Addiction Medicine and received his medical doctorate from the Medical College of Pennsylvania. Dr. Kabazie also served in the military for the U.S. Special Forces as a Green Beret from 1972 to 1975.

And finally, Ms. Ashley Potts is a team leader for the Crisis Stabilization and Diversion Unit of Southwestern Pennsylvania Human Services in Washington County. Ashley started using OxyContin when she was 13 years old, then became addicted to heroin by 17. She was lucky to finally get help and has been clean since September 11, 2006. She is a graduate of California University of Pennsylvania, is currently pursuing a masters degree, and had previously worked at the Washington, PA Drug and Alcohol Commission in Prevention Services.

Dr. Capretto, you may begin with your testimony.

STATEMENT OF NEIL A. CAPRETTO, D.O., F.A.S.A.M., MEDICAL DIRECTOR, GATEWAY REHAB, ALIQUIPPA, PA

Dr. CAPRETTO. Thank you. Thank you very much, Senators Toomey and Casey, for inviting me here to speak with you today about the opioid epidemic in southwestern Pennsylvania.

I have now been at Gateway full-time practicing addiction medicine for 26 years. And during that time, I have been directly involved in treating well over 15,000 individuals in our community struggling with prescription, opioid, and heroin addiction. I have really personally witnessed the evolution of this epidemic on a day-by-day basis starting in the mid- to late-90s, and it has devastated the lives of thousands of individuals and families in our community.

The sad news is, as of today, there are more people in our region addicted to prescription opioids and heroin than at any time in our lives. And most signs indicate that if this problem is not addressed adequately, it is likely to continue to grow. It has also led to record numbers of overdose deaths.

When I finished my residency at St. Francis in Pittsburgh in 1985, there were 22 drug overdose deaths in Allegheny County, and there was outrage about that, and it was considered an inappropriate, tragic loss of life that must be corrected. But as this new opioid epidemic started coming in in the 90s, in 1998 Allegheny County reached over 100 with 104. We thought, would we ever see that again? Well, it stayed over 100. In 2002, it went over 200. It

has been over 200 a year every year since then. Last year we set a record with 307, going from 22 to 307.

The other news is, surrounding counties are now actually seeing higher rates based on their populations. You know, the Centers for Disease Control last year described this as the worst drug overdose epidemic in U.S. history. Well, how did we get there? I talk about the perfect storm, and I often give lectures for many hours, but you have summarized it.

In a nutshell, it has been this dramatic rise of prescription medicine starting in the 1990s. We absolutely have to treat pain, but how to do that properly is open for debate. There was heavy marketing by pharmaceutical companies. There was a dramatic rise in prescriptions of opioids. Western Pennsylvania was hit particularly hard because of our demographics. There was over a 500-percent increase in oxycodone.

Thousands of people in our area became addicted. It spilled onto the streets, and at the same time this was occurring, the new heroin was coming in. Old heroin from Asia was about 10-percent pure. New heroin coming from Colombia and Mexico was well over 50-percent pure. You could now snort that, avoid using a needle. And by the thousands, people who got addicted to prescription opioids who could no longer afford them switched over to heroin, and it spread through every community. It is everywhere, in every town, rural and suburban. You cannot get away from it at this point. In the last probably 5 to 10 years, the last several thousand new heroin users I have talked to in our area, probably easily 90 to 95 percent of them all started with prescription medicines.

So what should we do about it? I mean, obviously we have to focus on safe and proper use of opioid pain medications. Dr. Ling gave some suggestions. I mean, we definitely have to educate our medical community, and we are starting to do that. I mean, there are efforts going on. The medical community is making progress. The Pennsylvania Medical Society has some good guidelines. But, goodness, we have a long, long way to go. I mean, these prescription drugs in our community did not come from Afghanistan or Colombia. They came from our medical system, and we have to come out of denial that that is the reality.

We need things like Prescription Drug Monitoring Programs. The good news is, our legislature in Pennsylvania passed one last fall. The bad news is, it is not funded yet. We are desperately waiting for that to become available. Such programs work, and as you said, Senator Toomey, we really need this to be regional and national to make it very effective.

The Stop Medication Abuse and Protecting Seniors Act to me is a very good thing. You identify people who are already drug diverters and drug seekers, and you direct them to particularly a healthcare professional, to one pharmacy. And what you end up doing is, you are going to provide medical care to that person. You are going to protect them from devolving into their addiction. You are going to reduce drug diversion on the street. You are going to protect the community, and you are going to save money. That seems like a pretty common-sense no-brainer to me, you know.

And obviously we have to provide treatment. As we restrict prescription medicines, we have to be careful about people converting

over to heroin, which is happening. We have to make sure that it is adequate, available, and of enough duration of time. The National Institute of Drug Abuse suggests a minimum of 90 days of treatment for people with addition. That is the minimum. Few people really get that over time. We also have to have adequate availability of naloxone to save lives. That is evolving, and I want to see that continue to expand.

And finally, when we look at all these numbers and data of thousands of thousands, it is important that we just not get numb to those numbers. And it is important that we never, ever forget that behind every number is a real life, a real family struggling, like 16-year-old Billy, whom I met back in 2001. Great kid. Great sense of humor. Good student. I had a son about the same age. He had an infectious laugh. He won an award for drafting and talked about his dreams to be an architect one day.

Like many kids, he was at a party and somebody offered him this new drug called OxyContin. He liked it, quickly became addicted to it, escalated his use, could not afford it, switched over to heroin use, and Billy died of a heroin overdose 2 days before his 17th birthday. And I talked to his mother on what would have been his birthday, and I will never forget her words. She said, "Today I just bought the last birthday present I will ever buy for my son, and it was a casket." Those words continue to haunt me.

But since Billy died in 2001, there have been nearly 5,000 other people in western Pennsylvania who have died from this condition. It is really a major epidemic, and I thank you, Senators, for addressing it and for inviting me today to speak on the issue. Thank you.

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

Senator TOOMEY. Thank you, Dr. Capretto. I appreciate that.

Mr. Vittone?

STATEMENT OF EUGENE A. VITTONE II, DISTRICT ATTORNEY, WASHINGTON COUNTY, PA

Mr. VITTONE. Thank you, Senator. Good afternoon. Thank you, Senator Toomey and Senator Casey, for the honor and opportunity to provide testimony to this committee. I met Senator Toomey last year when he convened a working panel in Washington County, and I appreciate your efforts to fight the increasing problem with addiction in our country.

I would also like to thank our local United States Attorney, David Hickton, for his leadership and help on this immense national problem of opioid abuse. Mr. Hickton is a champion and a great partner for law enforcement as we fight this epidemic.

It is no secret that our Nation is in the midst of an epidemic of drug-related deaths caused by prescription drug abuse. This is a public health and a public safety crisis. Nationally, tens of thousands have died due to overdoses caused by opioid drugs. We in Washington County are not immune. Since 2011, we have had more than 230 Washington County residents lose their lives due to accidental poisoning caused by opioid drugs. In August of this year, we had a string of overdoses caused by fentanyl-laced heroin, which

claimed several lives and placed Washington County in the national news.

This epidemic, however, goes beyond the overdoses. It significantly impacts the area where I work, which is the criminal justice system. I reviewed our criminal case filings for 2014 and found that at least 30 percent of our criminal cases were directly linked to opioid abuse coming from both pills and heroin. This is roughly equivalent to the exact number that we are running into with alcohol. Based upon my 17 years of working in the Washington County District Attorney's Office, I can assure you this is a new phenomenon. Not too long ago, it was rare to see a heroin case in our court. Now it is rare not to have a case involving heroin or prescription medication.

Our coroner in Washington County, Tim Worco, does a very good job of documenting the deaths, and his data reveals that this is not just a problem for young people. This data reads that 41 percent of our deaths since 2011 were people over the age of 40, and 46 percent were a combination of two or more drugs, and 57 percent were from prescription medications.

Now, the connection between opioid medication abuse and heroin is well established. As local law enforcement officials, we have had to respond to this, and we have developed an evolving plan to deal with it. We conduct local drug educational seminars at local schools to warn children of the dangers of the abuse of pharmaceuticals. We have drop boxes in our police stations for unwanted medications. We have embedded a Federal prosecutor in my office to aggressively go after the dealers who are distributing these drugs, and we have heightened and promoted, in connection with our local SCA, treatment for nonviolent criminal offenders.

What we are trying to do is work on both the supply side and demand side of the problem. While I am proud of what we have done thus far, I feel that these measures will not be sufficient alone to eliminate the problem. Dr. Capretto talked about the Prescription Medication Monitoring Program. I second what he said. We did get that established last October. However, the funding did not come through. I have learned from our State representative, Brandon Neuman, that some funding has come through from the Federal side, but we really do need to get that program in place. And, Senator Toomey, your bill on NASPER is certainly going to be helpful in helping us with interstate medication diversion.

Now, Washington County geographically is close to Maryland, Ohio, and West Virginia. Due to our location, we are an easy drive for those looking to acquire medications, either using forged prescriptions or through doctor shopping. An example of this is, in 2013, we arrested 12 individuals who were operating as far to the east as Chambersburg and as far north as Warren County.

What is interesting is that they were not going into other States to get the medications. They were staying in Pennsylvania because they could get the diversion. They obtained Opana, OxyContin, and other opioids from various pharmacies. They would not have been able to do this had there been a lock-in provision with our health insurance plans. We have also seen Suboxone starting to be diverted. We have had increased criminal activity near Suboxone

clinics, and we have made arrests of people selling Suboxone on the street.

In 2012, the United States Attorney's Office arrested Dr. Oliver Herndon, who was dispensing powerful oxycodone and oxymorphone in the area. He was one of the largest suppliers of diverted medications on the eastern seaboard. His parking lot frequently had cars from out of State in his lot. During one visit by an undercover officer, he actually told the undercover officer that you need to get these prescriptions filled as far away from here as you can because the pharmacies were on to him. He was also medical director for a hospice organization and two nursing homes. He was successfully prosecuted in Federal court for Drug Act violations.

So as I said, over 50 percent of the people who die from accidental overdoses are over the age of 40. These facts emphasize the need for the legislation Senator Toomey is requesting on a lock-in for medication, and I would like to second that also.

In closing, I am thankful for the opportunity to address the committee today. In the 4 years I have been District Attorney, I have had to learn a great deal about this, both on the medical end and on the law enforcement end. We need to help at all levels of government to make this happen. I am just one District Attorney in one county in Pennsylvania, but there are many more facing the same crisis, and we would like to continue to serve, and do our job, and do the best we can to fight this epidemic.

Thank you.

[The prepared statement of Mr. Vittone appears in the appendix.]

Senator TOOMEY. Thank you very much, Mr. Vittone.

Dr. Kabazie?

STATEMENT OF A. JACK KABAZIE, M.D., SYSTEM DIRECTOR, DIVISION OF PAIN MEDICINE, ALLEGHENY HEALTH NETWORK, PITTSBURGH, PA

Dr. KABAZIE. Senator Toomey, Senator Casey, thank you for shining a spotlight on this devastating epidemic that we have in our region and across the country.

In the 1980s and 1990s, multiple factors contributed to a change in opioid prescribing for chronic non-malignant pain. Based on scant and faulty medical data, the risk of addiction was touted as rare, end organ toxicity non-existent, and incidence of tolerance extremely low. Armed with this information, physicians became less reluctant to prescribe opioids. Patient advocacy groups demanded better treatment for chronic pain, and pharmaceutical companies began reformulating opioids into extended-release preparations. This brought about a dramatic increase in analgesic prescribing for chronic non-malignant pain that coincided with the rise in opioid-related morbidity and mortality.

Currently, we in this Nation consume more opioids than the rest of the world combined. Primary care physicians and internal medicine physicians prescribe the majority of opioid preparations in this country, but most were not trained in addiction or pain management. While most doctors prescribe opioids with good intent, once they move down that path, it is an extremely difficult path to reverse. This can lead to disgruntled patients. It can lead to frustrated physicians. In addition, physicians who have compensation

or employment tied to patient satisfaction scores may feel pressure, if you will, to prescribe opioids in response to patient pain complaints.

Nationally, there are major disparities in prescribing opioids for chronic pain. In some regions, including southwestern Pennsylvania, this has resulted in "pill mills" for profit. There are also physicians who tacitly prescribe opioids to continue patients on a long path of procedures that financially benefit the physician with little long-term benefit to the patient. In some circles, these are known as "pills for pokes" practices. This is a very small—very, very small—but difficult practice pattern to detect without close oversight.

While much attention has been focused on opioid abuse, addiction, and mortality, there is also the issue of unintentional overdose from misuse and subsequent adverse events. This is an issue especially in the elderly population, who are at extreme risk for falls and fractures, cognitive impairment, and unintentional overdosing. Many of these seniors forget that they took one dose, and they take another dose, and this places them in significant danger. These adverse events result in increased emergency room visits, hospital admissions, and length of stay, adding strain to the healthcare costs in the United States.

To curb the prescription opioid epidemic, State medical boards have published guidelines on the use of opioids to treat chronic, non-malignant pain. However, studies show that many providers do not follow these guidelines even with high-risk patients. Prescription drug monitoring programs are useful. However, they are significantly underutilized when they are not mandatory.

To further address inappropriate opioid prescribing, Physicians for Responsible Opioid Prescribing, or PROP for short, has petitioned for a mandatory limit on the amount and duration of opioids that can be prescribed to a patient with chronic non-malignant pain. This has resulted in condemnation from patient advocacy groups who fear absolute rules will leave many chronic pain patients without help.

We cannot address the opioid epidemic by painting this with a broad brush of absolutes, mandating dosing and time limits. There is, in fact, a small subset of patients who will require large doses of opioids for extended periods of time, and with monitoring they do very well. They should not be denied this therapeutic option. However, this should be a treatment of last resort. When all other attempts to control their pain have failed, they can be, in fact, candidates—if they have a well-defined pain generator—for opioids on an ongoing basis. However, most patients with chronic pain can be treated with satisfactory results using a multidisciplinary approach without the use of long-term opioid therapy.

We need more than published guidelines that are either ignored or underutilized. It has already been shown that if there are guidelines, they do not necessarily have to be followed. One group of physicians that I asked about the published guidelines stated to me, "They are only guidelines."

The Risk Evaluation and Mitigation Strategy, or REMS for short, is a voluntary program using extended-release and long-acting opioids. Rather than a voluntary program, why not develop a man-

datory REMS coupled with obtaining a DEA number to prescribe opioids for chronic pain for longer than 3 months? This might be one strategy. You should also include short-acting opioids, as they are widely associated with abuse. Pill mill laws should be enacted in every single State in this Nation and adhered to, and offenders should be prosecuted.

A prescription monitoring program, easily accessible and user-friendly, should be mandatory across the Nation, but it should be mandatory every time a prescription is written and every time a prescription is filled in a pharmacy. Referral to a multidisciplinary pain program should be made in a timely fashion for evaluation and treatment, and, to curtail this prescription opioid epidemic, all stakeholders need to come together to solve this problem.

Senators, thank you very much.

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

Senator TOOMEY. Thank you, Dr. Kabazie.

Ms. Potts?

STATEMENT OF ASHLEY POTTS, TEAM LEADER, CRISIS STABILIZATION AND DIVERSION UNIT, SOUTHWESTERN PENNSYLVANIA HUMAN SERVICES, INC., CHARLEROI, PA

Ms. POTTS. Yes. First, I want to thank Senator Toomey and Senator Casey for giving me the opportunity to testify before you today. It is an honor to be able to be here before you.

My name is Ashley Potts, and I currently work for Southwestern Pennsylvania Human Services. I am the team leader for the Crisis Diversion Unit. Before working there, I worked for 3 years at the Washington County Drug and Alcohol Commission on their Drug Court program. However, it is important to understand that 9 years ago, I found myself homeless, facing a State prison sentence, and addicted to heroin.

A few things about my story that I think are prevalent to understand are the impact of stigma, the importance of treatment, and that recovery is possible. I took my first drink of alcohol when I was 9 years old. My mother has addiction issues, so culturally I did not really understand the fact that it was wrong and it was not something that I should be doing. As Senator Toomey said, I took my first OxyContin when I was 13 years old, and despite the fact that it physically made me ill, I had fallen in love with that feeling. I started having behavioral issues in school, I started acting out, and my addiction just continued to progress.

It is also important to understand that I always said, "I am never going to be a heroin addict." That was something that I was never going to do. But just because these prescription pain pills are approved by the FDA, that does not make them safe.

I kept having behavioral issues. When I was 15, I was expelled from school. I started using crack cocaine at the age of 16, and I started running away. I ran away multiple times. I got arrested several times. And when I was 17 years old, again, despite the fact that I said I was never going to be a heroin addict, I found myself an IV drug user.

When I was 18, it was the first time I decided that I was going to try to stop using drugs, and I remember I had not talked to my

father for quite some period of time because I was a runaway. And I called him, and I begged him. I said, "Dad, if you do not come get me, I am going to kill myself." I was only 18. He came, he got me, I moved back into his house, and I went through the physical withdrawals of heroin. And despite the fact that with every agonizing breath I said, "I am never going to use again," I still did not go to treatment. I still did not have any supports. I still did not participate in a 12-step fellowship.

After moving in with my father, I found out that I was 4 months pregnant. I was able to remain abstinent for the remainder of my pregnancy. I gave birth to a child on May 20, 2005. Her name is Riley. Shortly after having Riley, I thought that I could just drink alcohol. Me thinking I could just drink alcohol led me to just snorting bags of heroin, which ultimately led to me being in the same position that I was when I started: back to being an IV drug user.

I moved out of my father's home. I moved into a house, and my addiction just continued to escalate. My father had knocked on the door one day, and he begged me to give him temporary custody of my daughter and for me to go to rehab, which I did. I spent 20-some days in rehab, and despite the fact that my family had begged them to keep me, I refused a halfway house, and I returned home to my father's house.

I got out of rehab on May 13th, and Riley would have been one on May 20th. And despite the fact that I was determined to be the best mom that I could be, on May 17th I was using, and I missed her first birthday. I was kicked out of my father's home, told if I ever stepped foot on his property again that I would be arrested. I was homeless. I was living in my car. I lost the ability to function as a normal human being. I did not shower. I did not brush my teeth. I was living on the street.

I moved back in with my mother for a period of time, after which ultimately I was walked out of her home in handcuffs. I wrote fraudulent checks. I robbed an innocent person's house. I did things that I said that I would never do because I was a slave to a needle. And again, I always said that this was something I was never going to do, and I woke up one day and realized that that is exactly what I had become.

I was 20 years old, and I remember I never thought that I would live to see my 21st birthday. The time came down where I decided that my daughter deserved another chance, and I was either going to get clean and really try this thing, or I was going to commit suicide. So I decided to go to treatment, and this time I did long-term treatment. And I truly believe in long-term treatment wholeheartedly.

I spent 216 days in treatment. I did 7 days of detox, 29 days in inpatient, and then 6 months in a halfway house. When they offered me a halfway house this time, I jumped on the opportunity. While I was in the halfway house, I was testing at a 6th grade education level. I turned myself in because I had multiple warrants out for my arrest, and I just continued to do what they do. For the first time in my life, I was willing to try something different because I did not want to live that way anymore, because I knew if I went back out there, I would become another statistic of what we are talking about today.

In April of 2007, as I was supposed to go to State prison, my life truly changed forever, when the judge granted me 216 days time served and immediate parole. But something also happened on that day. I became a convicted felon. I have two felony convictions on my record, and this is where stigma really comes into play.

So at 13, when I took my first OxyContin, I did not understand the gravity of how being a convicted felon would impact the rest of my life, because I did not even think I would live to see the rest of my life. So it is important to understand that recovery is possible, because 9 years ago I was homeless. I was on my way to State prison. Today I am on a management team with Southwestern Pennsylvania Human Services. We are an organization that provides treatment to individuals all the way from adolescence, all the way up to the Area Agency on Aging, and everybody in between.

I am in graduate school. I went from testing at a 6th-grade level to being in graduate school. I went through some of the programs in the halfway house; I now sit on the board of directors.

You know, my felonies have affected my life in many ways. I have been kicked out of college and laughed at by landlords when applying for housing. I have been hired and fired in the same day, and it has impacted every decision that I have ever made with my life. But it is important to understand that, despite the fact that society tried to bring me down, I never gave up, you know. I just continued to do everything that I could to stand up for a purpose and let everybody know that recovery is possible.

And despite all this stuff I have on my record, today I am relatively successful, and today I do everything that I can in order to try to give back and let everybody know that recovery is possible and that treatment works. Thank you. [Applause.]

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

Senator TOOMEY. Ms. Potts, thank you so much for having the courage to share your testimony with us, and for being the inspiration that you are to so many people, and for your leadership. We are very, very grateful.

I will begin the questions now of our second panel witnesses. Thank you all for your testimony. I would like to start with Dr. Capretto. You have been in the trenches of fighting addiction for a long time.

Dr. CAPRETTO. Yes.

Senator TOOMEY. Could you just briefly summarize for us the demographic changes you have seen from the time you first got into addiction medicine to what you are contending with today?

Dr. CAPRETTO. In terms of opioid addiction, when I started at Gateway full time in 1989, we averaged four people in detox. Three were alcohol and one was maybe opioid. And usually almost all those came from the city, usually the inner city, the poor, impoverished areas. As this has spread, right now we have 28 detox beds. We still have three alcohol, and the rest are opioids with usually a dozen people waiting to come in every day.

The demographics—it is everyone. It is every community, and it is actually mainly disproportionately Caucasians, middle and upper middle class right now, in terms of the pills and the heroin. And it is all age groups. We certainly see the young age group, but I

am starting to see newer people over 40, over 50, even over 60 using heroin for the first time, and usually because they got on pain medicine and were given a lot.

The community is different. You know, 20 years ago, if you got on these medicines, you took them for a few days; your doctor gave you a limited supply. Now you are likely to get a larger supply, but then your neighbors or co-workers are going to say, what did you get, we will give you some money for that, you know, stay on it, that is some good stuff. So the culture—it is definitely everybody and all age groups. In fact, one of the leading groups of overdose deaths is the over-50 group right now.

Senator TOOMEY. Thank you. My understanding is, the FDA recently approved an indication for the use of OxyContin to treat severe pain in patients age 11 to 16 who may suffer from cancer or other very serious and painful conditions. What are your thoughts on the suitability of providing a drug like that to people of that age?

Dr. CAPRETTO. Well, for the poor kids who have cancer and are terminal, which is a small number, we absolutely have to help them. Okay. My concern is that the headlines are, OxyContin for kids, so if it is safe for kids, then people think well, it is approved, it is safe, so kids are more likely to take it. Adults are more likely to take it because it is safe for kids, though it is intended to be for pain specialists giving it to terminal kids.

My concern will be—what we saw with regular OxyContin is—maybe it is going to be given for kids with a sprained ankle from soccer or an infected tooth. And again, we have seen this with adults. So I do have concerns about that. We certainly need to educate the medical profession and the public about this.

Senator TOOMEY. Yes, that seems very, very important. Thank you. Mr. Vittone, you talked about, and we have heard a lot about, pill mills that have been closed down and where bad physicians have been successfully prosecuted.

Mr. VITTONE. Yes, sir.

Senator TOOMEY. Is it your view, though, that prescription painkiller diversion is still a serious problem despite this?

Mr. VITTONE. Very much so. As I indicated, just from Coroner Worco's data, 57 percent of the deaths we have had have been due to prescription drugs. So we are still seeing the diversion. I checked with the head of my drug task force the other day to see what the effect is, and he confirmed for me that diversion is still a big problem in Washington County.

Senator TOOMEY. Yes, hence the need for the legislation that might——

Mr. VITTONE. Exactly.

Senator TOOMEY [continuing]. Help to impede this. Thank you very much. Dr. Kabazie, in your testimony you mentioned something that you called "pills for pokes." Could you explain exactly what that is, and why is it worrisome?

Dr. KABAZIE. It is an underground term that patients use as they discuss with each other diversion and abuse in obtaining pills. What it refers to—and again, it is a very small problem in regards to the numbers of physicians who do this, but it is still a real prob-

lem. Physicians may, in fact, see an opportunity to do a procedure on a patient in exchange for giving the patient opioids.

In other words, the patient will come into the office and have a complaint of low back pain, and the physician may say, well, I think we need to do a procedure that may help you with your low back pain. I am not sure it will, but it might. And in turn the patient says, yes, but I was thinking more along the lines of some pain pills. Could you give me some pain pills?

And the doctor will think about that for a second and say, sure, I will give you some pain pills, but I still think I need to do that procedure. And if I give you the pain pills, we should do this procedure, and then it seems to roll on and on and on.

And I have seen this at least in the southwestern Pennsylvania area, and in some cases in other States, and what this rolls into is an ongoing cycle of bringing the patient back, doing a procedure that may give the patient some temporary relief, if that, followed by another procedure in exchange for medications that continue to escalate in quantity and dose.

Now, it is a very hard thing to track because most of the physicians—and again, the small amount of physicians—who do this, they document as best they can to cover their tracks in that regard.

Senator TOOMEY. And you pointed out, I am sure correctly, that this is a tiny percentage of physicians who are doing this. What is their motivation?

Dr. KABAZIE. It is purely—well, the motivation is this. With physicians, it is the state of affairs. Physicians get paid to do procedures. That is what we get paid to do at present. We get paid to do procedures. We typically do not get paid as much money if we sit and talk to a patient or handle routine problems. So doing a procedure in exchange for medications generates money for the physician.

Senator TOOMEY. Yet another reason why it would be good to get away from the fee-for-service payment model that we generally have, but that is another topic. [Laughter.]

Ms. Potts, I wonder if you could—and I am going over slightly, Bob. Thank you. Do you have some advice for people who might be currently struggling with addiction and looking for a way out?

Ms. POTTS. Absolutely. My advice would be that there is help, that even if people say that you are not worth it or you are not going to make it, I am living proof of that, because I was told I was never going to make it. But long-term treatment does work, individualized treatment works, and we need to just wrap them around with supports and let them know there are peer-to-peer supports. We have been there before. We can jump in there and help pull you out of that hole.

Senator TOOMEY. Thank you very much. Senator Casey?

Senator CASEY. Thanks very much. Ms. Potts, I will start with you and pick up where Senator Toomey left off. You said in your testimony—you said 216 days of treatment?

Ms. POTTS. Yes.

Senator CASEY. Tell us about it, because we often will say good treatment works, but you have to sustain it. We all say that, but I am not sure those of us who are not professionals or have experience with it fully understand what we are saying or the meaning

of it. And I guess I would ask you to look at the treatment question in two ways, and I am assuming in my question that both were essential for you, both duration and quality.

But tell me if you can, and I know this is difficult because cases vary. But you were in a severe circumstance, as difficult as it gets, I guess, based upon your testimony. Walk us through those 216 days. What was it about the quality or the nature of the treatment that was effective in your case other than the necessary duration of it?

Ms. POTTS. Okay. Other than the length of being there——

Senator CASEY. Right.

Ms. POTTS [continuing]. I think it is important to understand that when I first walked in the doors, I had nothing but the clothes that I had on, just dirty clothes. I was not living as a normal person would. I had no idea how to write a job resume. I had no idea how to interact with people in the community. I had no idea how to speak to people. In my case, I was literally that stereotypical street junkie, so that was the level that I was at.

So the importance of that is, when I went to my first court hearing, I had on a hoodie and ripped-up jeans and all that, and by the time I went to sentencing court, I was dressed like a professional, and I had letters that I had been volunteering, and that I had a job, and that I was employable. So I went from not understanding the importance of having a job or being employed to being able to have that.

You know, statistics say the longer that we are in treatment, the better success that we have, so it takes time for our brains to start going back to normal. And Dr. Capretto could probably speak more on the brain and the brain functioning on drugs. It takes at least 90 days just for that normal chemistry to come back in the brain. And I just think that the longer—you know, you learn life skills. You learn all of these things that in my case I missed growing up along the way.

Senator CASEY. What would you recommend in terms of the structures we have in place now for the kind of quality treatment that you are talking about? I hope that your case was not unique in the sense that you had the benefit of programs that others often do not.

Ms. POTTS. No, there are plenty of me's out there.

Senator CASEY. In other words, if you were designing the ideal treatment course, what would be the elements of it?

Ms. POTTS. The ideal treatment course to me would be opioids detox, long-term treatment, halfway house, partial hospitalization, intensive inpatient treatment, and then outpatient, and you are in that continuum for up to 2 years. I did outpatient after I was in the halfway house, so I stayed connected to those services. I stayed in therapy, and I stayed doing the things that were suggested to me because I was not going to fix 20 years of trauma in 6 months, if that makes sense.

Senator CASEY. Yes, that is very helpful. [Applause.]

It is important for us to hear the nature of it, but also the duration of it, and we have to figure out ways to support that. Dr. Capretto, in your testimony in the recommendations, you quoted a study—this is on page 4 of your testimony, and I am quoting from

the summary of the study and your testimony. You say, "Physicians who check the PDMP," the management program for prescriptions, "change their original decisions about the prescribed medication more than 40 percent of the time." Tell us about that.

Dr. CAPRETTO. Right. There was a study of physicians who use it, and Dr. Kabazie said it is important that they use it. It found that they actually changed their original decision about 41 percent of the time. About 70 percent was to prescribe less because they found out information, but about 30 percent of it was to prescribe more because somebody that they were worried about, they saw that they were not involved with diversion, so they could build trust with the legitimate patient. And we need to do this.

I have a colleague in another State who has a big pain practice, and he was only using it for the patients who really looked suspicious, and somebody challenged him to do everybody in his practice. And he said if he were to pick the least likely five in his practice—and the number-one least likely guy, he was a CPA, banker, always came in with a suit, never missed an appointment in a year. He checked the database, and that person was going to five different physicians for opioids. So you cannot judge a book by its cover. So it is a useful tool, and it gives us information. It is one piece of the whole puzzle, as many of these pieces are.

Senator CASEY. Just one question for the panel. I know we may go to a second round, which is helpful, I think. But just one question about this, the price dynamic of this. I heard testimony recently just in the last 2 weeks from someone who had been addicted and had a real problem for years. He was saying that the price of heroin——

Two things on heroin. Number one, the strength of it, the—what is a better word?

Dr. CAPRETTO. The potency.

Dr. VITTONE. The potency.

Senator CASEY. Potency. "Potency" is a better word. The potency of it is much greater.

Dr. CAPRETTO. Absolutely.

Senator CASEY. And the price, according to this individual—and now he was talking about the market that he was living in then—but the price is literally the same price as the early 1970s, at least according to his testimony. Even if he is off by a little bit——

Dr. CAPRETTO. It is actually less than that.

Senator CASEY. Yes. And so, that is the heroin problem. So how do you deal with that price dynamic where, if you are aggressive on opioids and the price goes up, they will turn to heroin and start there as opposed to starting with opioids? And I know it is both a medical and a healthcare issue, but also a long-term issue.

Dr. CAPRETTO. Well, two ways. Number one, you want to limit or minimize new people getting addicted to opioids with all the things we have talked about it, but, number two, you want to have adequate treatment safety nets. You want to have adequate naloxone to keep people from dying. You want to have adequate access and availability of treatment. They say with this disease, only around 10 percent of people who have the problem ever get any type of legitimate treatment for it.

So we need to reach out to them because, if we do not, it costs us. Even if you do not care about these people, and look at the wonderful turnaround with Ashley, it is a good investment in reducing crime, improving jobs, taxes, everything. It is a good human investment, and signs indicate that the purity is going to continue as cartels are getting more aggressive, and the price may come down. So we absolutely have to hit this head-on.

Mr. VITTONE. Senator, if I can follow up on that, we have always had heroin in Washington County, though not to the extent we have it now. So the difference has been the prescription pills that came out in the 1990s that really added fuel to that fire. So it is cross-cultural, and now it is all over the area because of that. So I do not know that you are going to ever eliminate completely that heroin baseline, but it certainly was not at this level. Do you agree, Doctor?

Dr. CAPRETTO. Oh, absolutely, nowhere near it.

Mr. VITTONE. You know, this is several years ago, so——

Senator CASEY. Thank you.

Senator TOOMEY. Dr. Capretto, so we have discussed how, I think you indicated, a vast majority of heroin addicts actually were initially addicted to prescription opioids.

Dr. CAPRETTO. Yes.

Senator TOOMEY. Could you share with us a little bit, how does that initial addiction occur? Is it people who had surgery and then get hooked on the medicine that was prescribed post-surgery? Is it kids that raid the medicine cabinet? Is it both? Is it others? How does it happen?

Dr. CAPRETTO. It is all of the above. You know, back in the 1990s when this was being marketed, they were trying to tell doctors this will never occur if you give it to your pain patients, less than 1 percent. We now know that is not true.

I would say of the people whom I see, probably about 30 percent of them, it started with going to a physician who kept them on it too long, and it evolved into an addiction. Another group gets it recreationally. It is diverted. And then there is the in-between. They might have had a pain problem, and I hear this, and they were on it for a while. They kind of liked it, and they got away from it, but now they go to their local bar or sporting event, and there are people using it. These are very much part of our culture and available, so they get back on it. But it all comes back to their original source, which is our medical community.

Senator TOOMEY. Yes. Dr. Kabazie, this might be difficult to generalize, but I am wondering if you can give us any sense of how long a period of time it is safe for most people to be consuming a prescription opioid. Is it possible to generalize? Is there a point beyond which the risk of addiction becomes much greater than a shorter duration, or is it too specific to the individual?

Dr. KABAZIE. It is. It is very specific to the individual. We know addiction is a biopsychosocial disease, and Dr. Capretto knows this quite well. If you are genetically predisposed to addiction, to a substance, and you are never exposed to that substance, you have absolutely zero chance of becoming addicted to it. But if you are genetically predisposed and you are exposed to even a small amount, then you are off to the races.

So keeping in mind that this is a disease, there is a bio, a psycho, and a social component. And so, it is people, places, and things. It would be too generalized to say that there is a discrete time period at which the incidence or risk of addiction goes up. We just cannot say that. We do know that we continue to monitor for that. We also know that the higher the dose, the more likely addiction will occur.

People who have an addiction issue many times, and I am sure Dr. Capretto has seen this, do not take the medication, the opioid, the heroin, to get high anymore. They are so far along that they are taking it just to function. On the street it is called "dope sick." They are deathly afraid of getting dope sick, and they will do anything they possibly can to keep from getting dope sick.

Without their medication, without their prescription drugs, without their heroin, they will get violently ill. They cannot function. Once they get it, they can function as normal human beings, and you would never know that they have a problem because they need that just to function. It is a scary proposition to anyone who has an addiction issue.

Alcoholics can be the same way. You can have a functioning alcoholic and never know it. As long as they are drinking, they are completely straight and they are functioning, and without, they do not do a very good job.

We know that the longer you are on an opioid, the more likely you are to become tolerant. You are certainly going to be dependent, and then the long-term effect can be endocrine dysfunction. We certainly know that now. We probably knew it back in the 80s and 90s, and we just sort of ignored it. And we know that opioids over time can actually cause pain, and that is called opioid-induced hyperalgesia, which causes a significant problem if a patient goes to surgery and the pain is extremely difficult to control because they are on high-dose opioids.

We have a patient who is on an opioid—and I think my orthopedic colleagues have seen this. If they are on opioids and going in, for instance, for a joint replacement, it could be extremely difficult to control their pain and get them through the rehab that they need. So our job is to try to get them off the opioids if we can so that they do not suffer in that regard.

Senator TOOMEY. Thank you very much, Doctor. My last question is for Ms. Potts. Dr. Kabazie described this addiction as a biopsychosocial issue or problem. Could you give us a sense—I think we intuitively understand that there is a chemical problem here. There is a biological problem that has to be solved. But what about the social problems? What about the behavioral issues? How important are they for someone recovering from an addiction like this?

Ms. POTTS. Absolutely. He mentioned people, places, and things, and individually, for me, I had to make a geographical change. I live 75 miles now from where I used to live because I know that going back to the same people, to the same problems, to the same situations, and not knowing anything different, I would ultimately end up with the same issues. So for me, I had to move away and start a whole new life.

Senator TOOMEY. Thank you very much. My understanding is, that is a really important part of the curing process. Senator Casey, did you have any other questions?

Senator CASEY. I did, but just maybe I will do it by way of a lightening round because I took more than my time last time. Maybe starting with Dr. Capretto and going down the panel, if you had to, in a little more than a sound bite, kind of itemize steps you hope we would take on a whole range of issues, whether it is healthcare legislation, or legislation in Washington, local law enforcement, more resources, more treatment options, what would be your top three?

Dr. CAPRETTO. We need to really make sure there are adequate treatment options that are available to people in a timely fashion and in a long enough period of time that is overseen by people who really understand how to treat addiction, not just manage funds. And we also need greater emphasis on education of our medical community, starting in medical school residencies, to treat this. This condition is so prevalent, yet the medical community gets minimal, and sometimes very little to no, education on this issue. And we have to worry about our kids.

I mean, one of the things I did not mention with OxyContin is the developing brain. We know that the younger kids start using it—I mean, nobody questions the logic of a pregnant female abstaining from use of alcohol or drugs because of the developing brain. At birth, is the brain done developing? Absolutely not. It continues to develop until the mid-20s. The earlier you expose that brain to drugs of abuse, whether it be opioids, alcohol, marijuana, the greater likelihood addiction will develop, and it will derail their life in so many ways. So, a comprehensive approach.

Senator CASEY. Thanks.

Mr. VITTONE. A prescription medication database is a huge asset. We need to know who is getting what. Also, law enforcement needs access to that, where prescribing patterns become criminal. The second thing I would advocate, as Dr. Capretto indicated, is education for the medical professionals, law enforcement, and the community as to the dangers.

And lastly, treatment. In speaking with Secretary Gary Tennis of the Pennsylvania Department of Drug and Alcohol Programs—I have asked him, "Why are people dying in Washington County?" He said it is because they are being under-treated. They are not getting enough treatment. They need to get, as Ashley said, that full panoply of treatment, and that needs to be available. Thank you.

Senator CASEY. Thank you. Doctor?

Dr. KABAZIE. I will leave the treatment and the law enforcement to my two colleagues to the left here. I think we need mandatory, mandatory, mandatory prescription monitoring. We need to monitor the drugs in the United States, and it has to be mandatory. In other words, we need a Prescription Drug Monitoring Program that is nationwide, or at least one in which the States will exchange information. And that needs to be mandatory, so we need physicians to use it every time they write a prescription, and we need pharmacists to use it every time they fill a prescription.

We already know that voluntary guidelines do not work. They do not work. We have plenty of guidelines out there that nobody follows, so we need to make those things mandatory. I know I will get pushback from some of the people in the medical community,

but without making these mandatory, they will not work. We need to have a mandatory REMS project, a Risk, Evaluation, and Mitigation Strategy, that is mandatory for physicians to take if they want to prescibe opioids across the class, not only for extended-release medications, but for short-acting medications. I think those two things will go a long way to cutting down at least on the prescription drug problems that we have right now and the epidemic that we have right now with physicians writing inappropriate prescriptions.

Senator CASEY. And, Ms. Potts, I know—now that we know something about you, we are calling you "Ashley." Is that all right?

Ms. POTTS. Absolutely. Absolutely. [Laughter.]

I agree with what everybody said. You know, I think that we should not put a limit on treatment. If we take, for example, two 20-year-olds both addicted to heroin, one has been using 3 months, one has been using since the age of 10, one is going to need a little bit longer treatment than the other one. So I think it is important to have an individualized treatment approach with a comprehensive support team—and what everybody else said, of course.

Senator CASEY. Thank you very much.

Senator TOOMEY. Thank you. At this time, I would like to ask our panelists to stay here if they would, and I would like to use this opportunity to give the audience a chance to ask questions or make some comments. They can direct it at any of our witnesses, or myself, or Senator Casey as they see fit, but we only have a few minutes.

I want to ask anybody who would like to ask a question or make a comment to approach the mics on either side of the room. Please state your name and any affiliation that you have that would be relevant, and then please try to ask your question as succinctly as you can so that we can get to multiple questions. And we will start with the gentleman on the left.

Dr. WONG. Hi. My name is Kevin Wong. I have been a family physician in Westmoreland County for over 33 years, and I appreciate the Senators' efforts to help as well as our panelists'.

We have heard over the years how people like Dr. Kabazie help family physicians try to prescribe appropriately. We do need the PDMPs in this State. As you know, that is locked up, and that is why the Federal Government needs to get after every State that does not have one. And it needs to be interoperable immediately, because otherwise, as you just said, we are a terrible State. We have West Virginia next to us, and Ohio is just as bad, and drug abusers can all go back and forth over the waters as they see fit.

The PDMPs also need the pharmacists, who are our line of defense when somebody is prescribing, to not have fear of a HIPAA violation, to call a physician and say, you just prescribed somebody a prescription and another physician had just prescribed recently. The pharmacists are very afraid or do not want to get involved.

As Dr. Kabazie said, the pills for pokes are something we see as family physicians. I have had many patients go to some of these places, be there a year, 15 months, finally get kicked out for breaking the pain contract. They come back to me with two to three times the amount of pain meds we sent them to the clinic with in the first place. We need legitimate pain clinics that are treating

people. As we said, we need to think and not poke. Thank you very much.

Senator TOOMEY. Thank you very much. Unless there is a response to that——

Dr. CAPRETTO. We agree.

Senator TOOMEY. I think that was more a recommendation, which I think the panel is probably sympathetic to. The gentleman on the right.

Dr. FULLER. Hi. I am Dr. Mark Fuller. I am the CEO of Value Behavioral Health. We are a Medicaid managed care program. We help administer the Pennsylvania Health Choices Program in western Pennsylvania. So the first thing I want to say is, thank you to both Senators for your advocacy, for dragging this problem out in the light of day where we can have this kind of discussion.

The second thing I want to say is, as a payer, we are fully committed to doing whatever we need to do to crush this epidemic. We are all in, so anything we can do, we are there for. Thank you.

Senator TOOMEY. Thank you.

Senator CASEY. Thank you.

Senator TOOMEY. Yes, ma'am?

Ms. BESICK. My name is Pat Besick. I am the manager of the Behavioral Health Unit at Saint Clair Hospital. And I really appreciate everyone's expertise today, but there was something that nobody really talked about, which is really a barrier. Drug treatment is voluntary unless you are in drug court. So we get families involuntarily committing people to our psych unit just to get them in treatment, thinking they are going to take care of their drug problem. And once we have done the evaluation and have them a few days, maybe the doctor started an antidepressant for the depression/anxiety, which, of course, you would have when you are abusing drugs or alcohol. We get to a point where, if a patient does not want to go for treatment, it stops there.

So it is voluntary. You can have all the treatment centers, but how do you get to the next level where people will go into treatment? At some point, Ms. Potts, you had the insight to put things together, but it took a while to say, "My life is not going too well, I need to change something."

But this is a huge barrier with most people. They will not take that step, and families can be upset. Smart families will say, "Well, you cannot come back home," and they kind of force the issue, but that is pretty much what we have to do with people to get them into treatment. So what are we doing to address the issue of people who just will not go into treatment?

Senator TOOMEY. Anybody?

Dr. CAPRETTO. That is clearly an obstacle. You cannot, in mental health, commit somebody to addiction treatment. There can be leverage in the legal system. Drug court is a wonderful thing. Families can put pressure, and sometimes families themselves, I recommend they reach out to a therapist, maybe an interventionalist, to try to help raise the bar.

Those who are working with them in hospital, I encourage you to get trained in motivational interviewing to kind of help move them along. I would welcome any leverage or help from legislature in getting people in. But it is an obstacle, absolutely.

Ms. POTTS. I also think it is important to understand that addiction is a family disease, so families are struggling along with that individual. And just because they are showing up again, and again, and again, at least they are showing up, and at least we still have the opportunity to try to save that person's life.

Senator TOOMEY. Mr. Vittone, did you have something you wanted to add?

Mr. VITTONE. Yes. The drug courts do work. We have had one since 2005 in Washington County. You use the leverage of the criminal justice system to get these people to reform, but it is a very intense process. It is very time-consuming. It is well worth it, and we have been able to get people to reform and get into recovery, so it does work.

Senator TOOMEY. Great points. Thank you. The gentleman on the right.

Dr. PIERCE. Thank you. It has been a very informative day, and I would like to thank the Senator for all your efforts as far as helping with this problem. I would like to thank the expert panel witnesses for your testimony. I learned a lot personally. My name is Dr. Pierce. I am the regional medical director in Pennsylvania overseeing four methadone clinics. I also do buprenorphine therapy in my office. This is a passion and a calling for me.

I would just like to say, without taking up too much time, one of the things that I noticed—and I do the initial evaluation of a lot of patients, in fact, most of the patients at the methadone clinics. And a lot of times what you see is that really people are predisposed to getting this disease process. It is a chronic relapsing disease of the brain. And really there is not much we can do to stop them from getting this disease once they become exposed to the drug itself.

I mean, when you look at people who have—when they are younger, we call them adverse childhood events, which means traumatic events that children are exposed to during the developmental years: the physical abuse, the sexual abuse, the verbal abuse, parents that divorce, and abandonment issues. These are one part of the environmental insults that contribute to a person getting or being predisposed to this disease.

Also, you have the adolescent exposure to substances of abuse, but then you look at tobacco, and alcohol, and marijuana, which will probably be legalized in this State, and those three major substances in themselves, when used during the adolescent years, actually contribute to predisposing a person to entering this process. Now, you add to that the undiagnosed and untreated mental health disorders, which can be as little as social anxiety or mild depression—it does not have to be a full-blown bipolar disorder.

But these are the three conditions that predispose people to getting this disease process, so by the time they take the opioid pill, they are set up to get it. And it really does not matter if you give them 30 milligrams, 60, or 100, they are probably going to get the disease process. So I think what we have to really focus on is the treatment component of it.

And what I am seeing now is that we have the buprenorphine, different companies are making it now. But the problem is that when you get this disease process, about one out of 10 can go to

detox, can go to rehab, and be successful. But there are another 90 out of 100 people who, no matter how long you keep them in rehab, they are not going to be able to stop the cycle of this disease.

Part of this disease process is that the part of the brain responsible for controlling behavior is now compromised. It is not functioning. So therefore, the simple act of choosing to do something or not to do it has been taken away. It is robbed from the patient. Their brain has essentially been hijacked. So what we have to do is have a medication that can help them to be in the state of mind where they can actually now get the therapy that they need.

And these different medications—one of them is methadone, which is used very successfully. Another one is the buprenorphine. And basically what these medications are is, they are relapse prevention medication. It stops the patient from relapsing so they can get the therapy that they need in order to make the cognitive and behavioral changes that will allow them to be successful as far as getting off the medication once and for all.

So my point is that we have this limit on physicians as far as, they can only treat 100 buprenorphine patients at one time, and that is limiting our ability to help patients who have this disease process. Granted, only 20 percent of the people who have this disease process are actually in medical treatment, but if you do not have the physicians available outside of a methadone clinic—not everyone wants to go to a methadone clinic. Not everybody needs to go to a methadone clinic.

We have to have individualized treatment for these different patients. I mean, not everybody needs to go to detox and rehab. That is like taking every depressed patient and telling them you are going to put them into a confined setting and give them a rehab and not give them any medication. It just does not work.

So I think we need to eliminate that limit of 100 patients and allow some physicians, maybe the ones who are board certified in addiction medicine, to be able to increase the number of people they could treat. I think that would go a long way to helping this situation.

Senator TOOMEY. Well, thank you very much for that thought. Senator Casey, you had a comment?

Senator CASEY. I know we have to move on, but there is a new bill that speaks to this, Doctor. I hope you can take a look at it, Senate bill 1455, which would lift that cap. But 1455 is the bill.

Dr. PIERCE. Thank you.

Senator TOOMEY. Could I ask the panelists, does everyone on the panel agree that that cap should be lifted?

Dr. CAPRETTO. I agree, but you have to be careful about how you do it. I would recommend a first step, making it for addiction specialists, those who could provide kind of wraparound services and not just open it up to everybody. We certainly do not want to create pill mills in that direction.

Dr. PIERCE. I agree, and certainly only those board certified by the American Board of Addiction Medicine. That would be the criterion to do that.

Senator TOOMEY. Dr. Kabazie, did you want to respond?

Dr. KABAZIE. Well, I think we need to be very, very careful. I think everyone who prescribes Suboxone has seen Suboxone pre-

scribers who are not doing it appropriately. And, if we open up that cap, that will open up the floodgates. And again, I am going to harp on physician reimbursement here. It is very easy to see a Suboxone patient in very quick fashion, sign your name to that prescription, and send them out the door. And just as I have seen very, very bad pain physicians, I have seen very, very bad Suboxone providers. And that Suboxone either ends up on the street or in the hands of someone who should not have it. And we need to look at that very, very carefully.

You know, I may speak out of turn here, but I do not understand an obstetrician, an OBGYN, prescribing more than a hundred Suboxone prescriptions or patients, a pediatrician, orthopedic surgeon, prescribing Suboxone to more than a hundred patients or even a hundred patients, simply because they sat through a course for 8 hours. That is a problem.

So in the right hands, it would be an appropriate thing to do, but only in the right hands, and I think we need to look at that more closely.

Senator TOOMEY. Thank you very much. We only have time for two more questions, so I want to let the gentleman who has been waiting patiently over here and then the lady at the other mic ask their questions. And then I am going to see if Dr. Farah wants to wrap things up here.

Mr. BACHARACH. I will be relatively short. My name is Paul Bacharach. I am the CEO at Gateway Rehab. I work with Dr. Capretto every day. In western Pennsylvania, we have an elderly population, and one of the impediments to—and this may be more directed to Dr. Ling. One of the impediments to treatment is the fact that Medicare does not cover non-hospital residential treatment for addiction, so there are very limited resources when it comes to hospitals providing short-term rehab and detox. We are unable to provide services to Medicare patients because it is not currently a covered service—that is the short-term detox, and 28-day.

So I think one of the things that needs to be looked at to provide access to that elderly population that obviously is vulnerable also is to at least open up coverage for that group.

Senator TOOMEY. Great. Thank you very much. The lady on the right.

Ms. BELL. Hi. Thank you. My name is Alice Bell, and I am the overdose prevention project coordinator for Prevention Point Pittsburgh, which provides harm reduction-based services in southwestern Pennsylvania. A large part of my job is making sure that naloxone is available to people who might be at risk of an overdose or who might witness an overdose. And I appreciate Senator Casey's support of those efforts and his comments regarding that.

The one thing that I feel is missing in the conversation today is the dramatic increase that we have seen in heroin use. And I would agree that doing a better job of more careful opioid prescribing is part of that, that if we do not have young people starting to get involved with prescription opioid misuse and abuse, then we are going to see less heroin use.

I do have a real fear that at this point we are seeing such a high level of heroin use that we are going to have young people starting

on heroin because they have friends who are already doing heroin, and that we have to look at that as a problem in its own right. And a big issue that we are seeing is a dramatic increase in injection-related blood-borne diseases, like hepatitis-C and HIV.

And so I feel like, to address that problem, we really need to look at the need for access to sterile injection equipment for people who are already injecting. That is a small piece of the large problem that is being discussed here, but it is an important piece. When we look at lives and we look at costs as well, the cost to treat hepatitis-C, to treat HIV, that could easily be prevented if people have greater access to sterile injection equipment. Thank you.

Senator TOOMEY. Does anybody want to react to that?

Dr. CAPRETTO. I totally agree, and I also share Alice's concern that now that there is so much heroin out there, even though historically it has been prescription medicines leading to heroin, as it is out there and available, that is definitely something that we may see that may also harm reductions.

I really want to personally thank—Alice has done more to champion the cause of overdose prevention and harm reduction in our area than anybody, so thank you very much, Alice. [Applause.]

Senator TOOMEY. And on that note, I want to thank everybody who came out today, and thank the audience members who made comments or asked questions. I thought that was a very thoughtful contribution to this process. I really want to thank the witnesses for all of your time, including Dr. Ling, and your very helpful testimony. [Applause.]

And, Dr. Farah, as our host this afternoon, do you want to wrap things up?

Dr. FARAH. Sure. Senator Toomey, thank you very much for chairing this session. I think everyone in this audience would more than agree that this has been invaluable, not only in accomplishing the goals that you have set out to achieve, but also to educate us. I think a big part of what we heard today, from the panelists especially, is the educational piece that we can all use whether we are medical professionals or not.

I also want to thank Senator Casey. Thank you for participating here at Allegheny General Hospital. All the panelists, Dr. Ling, U.S. Attorney David Hickton, thank you for attending this.

I think we would all agree that this has been a remarkable show of bipartisan leadership here in western Pennsylvania on an issue that is impacting not only friends and families, but our patients as well. And on behalf of Allegheny Health Network, I would like to thank both of the Senators. We are very proud to have you represent us here in Pennsylvania and the United States. Thanks again. [Applause.]

Senator TOOMEY. Thank you very much, Dr. Farah. The hearing is adjourned.

[Whereupon, at 4:10 p.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF NEIL A. CAPRETTO, D.O., F.A.S.A.M., MEDICAL DIRECTOR, GATEWAY REHAB

INTRODUCTION

Mr. Chairman and members of the committee, thank you very much for inviting me to speak with you today about the epidemic of opioid abuse in southwestern Pennsylvania, which has devastated the lives of thousands of individuals and families, and has led to record numbers of overdose deaths in our region.

I am an addiction psychiatrist and the medical director at Gateway Rehab, which is our region's largest nonprofit addiction treatment provider. Our mission is to help all affected by addictive diseases to become healthy in body, mind and spirit. With 20 locations throughout western Pennsylvania and eastern Ohio, Gateway Rehab treats more than 1,500 patients daily.

I have worked full time at Gateway since 1989 but started in the field of addiction in 1981 at St. Francis Hospital in Pittsburgh. I am board certified in general psychiatry, addiction psychiatry, and addiction medicine, and I am a fellow of the American Society of Addiction Medicine.

I served as a co-chair of the Western Pennsylvania U.S. Attorney's Working Group on Drug Overdose and Addiction, and currently serve on the board of directors of the Pennsylvania Society of Addiction Medicine, the Allegheny County Overdose Prevention Coalition, and the Beaver County Prescription Drug Abuse Coalition. I also consult with many professional and grassroots groups focused on addressing the addiction problem in our community.

During my career at Gateway Rehab, I have directly been involved in treating more than 15,000 individuals in our region with prescription opioid and heroin addiction. I have personally witnessed, on a day-by-day basis, the evolution of our current opioid epidemic, which began in the late 1990s. The sad reality is that, today there are more people in our community with addiction from opioid pain pills and heroin than at any other time in our history and, if this problem is not addressed adequately, it will continue to worsen.

OUR REGION'S OPIOID EPIDEMIC

When I finished my residency in psychiatry in 1985, there were 22 accidental drug overdose deaths in Allegheny County, which, at that time, appropriately was viewed as an unacceptable tragic loss of lives that must be corrected.

With a rising opioid problem beginning in the late 1990s, Allegheny County saw triple-digit overdose deaths for the first time in 1998 with 104. This number remained over 100 for the next 3 years and then reached more than 200 in 2002, remaining such every year since. However, in 2014, Allegheny County set a new record with 307 accidental drug overdose deaths (OverdoseFreePA 2015).

Moreover, based on population, most surrounding counties are now seeing higher overdose death rates than Allegheny County. Drug overdose deaths are now the leading cause of accidental death in our region, far exceeding traffic fatalities.

CAUSES

Several factors have contributed to our current opioid epidemic; however, by far, the primary factor in our region leading new individuals into opioid addiction is prescription opioid pain pills.

In the mid to late 1990s, the medical profession came under increasing criticism for not adequately treating pain, and there was a greater national emphasis to treat non-cancer pain with opioids. However, much of this emphasis was coming from pharmaceutical companies who sold opioid pain medications. Also, many physicians declared that abuse and addiction of opioid medications was essentially a non-issue (Van Zee 2009). Then, in 2000, the Joint Commission declared pain as "The Fifth Vital Sign." These circumstances resulted in a very quick and dramatic rise in the medical community prescribing opioids for pain.

From 1999 to 2011, consumption of hydrocodone more than doubled and consumption of oxycodone increased by nearly 500 percent (Jones 2013). Unfortunately, during that same time, we saw the rate nationally of unintentional death from prescription opioids nearly quadruple (Chen, Hedegaard, Warner 2014), and the Centers for Disease Control and Prevention in 2014 described this as the "worse drug overdose epidemic in U.S. history" (Paulozzi 2010).

Historically, most drug trends would start in other parts of our country and then reach southwestern Pennsylvania several years later. However, with the prescription opioid abuse problem, southwestern Pennsylvania was one of the first and hardest hit areas of our country. This was largely due to the demographics of our region, which included an older population and a large blue collar, working population that both have higher rates of medical problems resulting in pain. This led to heavy marketing of physicians in our area by pharmaceuticals to prescribe more opioids.

In March of 1999, I saw my first patient come to Gateway with OxyContin addiction. By July 2000, I had seen more than 300. By the end of 2005, I had seen more than 2,000 people in our region with OxyContin addiction. OxyContin significantly accelerated and expanded the opioid addiction problem in our regional at a level never seen before.

By the end of 2001, we were seeing large numbers of people, of all ages and from all social economic levels, coming into treatment with opioid addiction from virtually every community in our region. As many of these people continued to use more opioid pain pills, over time they developed tolerance, which resulted in them needing larger daily amounts to keep from going into opioid withdrawal and getting sick. The average person we were seeing was using more than 150 mg of Oxycodone per day, and some more than double that amount.

The price of Oxycodone on the street at that time was approximately 70 cents to a dollar per milligram. It was costing most people hundreds of dollars a day to support their opioid pill addiction. We then started to see a growing number of people who could no longer afford their opioid pills switch to a "new" heroin that would give them a similar and often stronger effect than opioid pills for about a quarter of the daily cost. This trend continues today and has created thousands of new people in our region addicted to heroin.

Of the several thousand heroin users that I have interviewed since 2000, well over 90 percent have told me they started with opioid pain pills. This is the primary reason why, 20 years ago in 1995, heroin use was essentially unheard of in the vast majority of communities in our region, especially the suburbs and the rural communities. Now, today, fueled by opioid pill addiction, heroin addiction has spread like an infectious disease into every community in our region.

We first started seeing this "new" heroin in the mid-1990s. Most heroin in our region prior to that point, I am told, averaged about 10 percent purity. That was still strong enough to cause severe addiction and death from an overdose, but the only way to get an appreciable effect from 10 percent heroin was to inject it intravenously. However, fears over contracting HIV in the late 1980s led to an increased reluctance by many to use a drug intravenously. In the mid-late 1990s, we starting seeing people come into treatment reporting they were using this "new" type of heroin, which would give a very strong effect by simply snorting intranasally.

This "new" heroin was much stronger, usually greater than 40 percent purity, and often, in our area, reached levels of 70–90 percent purity. Besides just giving a much more powerful opioid effect, this stronger heroin allowed people to get an appreciable effect from snorting intranasally, without injecting intravenously. How-

ever, almost all new heroin users that I have seen in the past 20 years that started out by snorting heroin, well over 80 percent switched over to intravenous use within 6–12 months because, as they developed tolerance to heroin, they learned that using heroin intravenously gives a quicker and stronger effect. As large numbers of individuals addicted to heroin switched from snorting it to injecting it, several thousand new people in our community developed Hepatitis C.

Two other destructive trends we are seeing, which have magnified the opioid problem in our region, include adding fentanyl to heroin and opioid enhancement with sedatives.

Although heroin is very potent and results in high rates of addiction, and it alone is very capable of causing an overdose death, in what is believed to be an effort to create greater demand for their product, some drug traffickers are adding fentanyl to heroin. Fentanyl is about 70–100 times stronger than morphine per milligram and is much stronger than heroin alone. Due to its high opioid potency, fentanyl-laced heroin generally leads to a greater street demand and, unfortunately, spikes in overdose deaths because it is more lethal. I have talked to people who were using more than 20 bags of heroin per day who went unconscious with the needle still in their arm after only using one or two bags of fentanyl-laced heroin. We have seen several spikes in overdose deaths in our community in the last several years due to fentanyl-laced heroin.

Another growing trend, which I believe is largely unrecognized and/or neglected by much of the medical community, is the growing number of people with opioid addiction to pain pills or heroin who also take large amounts of sedatives to boost the effects of their opioids. The majority of these sedatives are benzodiazepines, drugs such as Xanax, Ativan and Klonopin. Adding these sedatives to opioids will definitely boost the effect, but it also increases the danger of an overdose death.

A significant proportion of overdose deaths we are now seeing in our area are showing a combination of opioids and sedatives. Over the past 2 years, approximately 50 percent of the individuals coming to Gateway to seek treatment for abusing opioids also are addicted to sedatives and, if not detoxed properly, sedative withdrawal can result in seizures and possible death.

Some have referred to our current opioid epidemic crisis as a "perfect storm" that resulted from the dramatic rise in opioid pain pills at the same time the "new" and stronger heroin was introduced. These factors, along with the enhancing effects of fentanyl and sedatives, have continued to fuel this storm of opioid addiction in our community to now the highest level ever seen.

RECOMMENDATIONS

Unfortunately, there is not one easy, clear solution to this problem. It is clear that properly addressing this problem will require a large, multidimensional collaborative effort from many parts of our community. The Western Pennsylvania U.S. Attorney's Working Group on Drug Overdose and Addiction, under U.S. Attorney David Hickton, which I co-chaired along with Dr. Michael Flaherty, released a comprehensive 51-page report in September 2014, which discussed this issue in detail and offered many recommendations (U.S. Attorney's Working Group on Drug Overdose and Addiction 2014).

One other obvious and important area of focus is the proper and safe use of opioid pain pills. There is consensus within the medical community that it is important to treat pain properly, and that no individual with legitimate pain should be neglected. The challenge, though, is to treat pain adequately while minimizing the potential for addiction, not only in the patient but also in the community. This will require several measures, including better education of the medical community and the public, along with better management and monitoring of opioid pain medications. This would include not only an assessable State prescription drug-monitoring program (PDMP) for health professionals, which we hope to soon have in Pennsylvania, but, also, a national monitoring program for all scheduled prescriptions to minimize interstate drug diversion, which is a significant problem in our tri-state region.

Use of PDMPs by a health professional is an integral part of practicing responsible medicine. A responsible physician would not order antihypertensive medication for a patient without first checking their blood pressure or order insulin without first checking blood glucose. Therefore, in light of our current opioid epidemic, a responsible physician should not order powerful opioids without first checking a prescription database.

One study (Baehren 2010) showed that physicians who check a PDMP changed their original decision about the prescribed medication more than 40 percent of the time. The majority of these changes were to prescribe less medications, but in some cases more because it helped build trust with legitimate patients. Another study (Feldman, Williams, Coates 2012) found that use of a PDMP increased physician confidence that the medications they prescribed were medically warranted.

In light of the significant problem we have with prescription medicine abuse in our community, I believe the actions called for in Stopping Medication Abuse and Protecting Seniors Act [S. 1913] or lock-in bill are very much needed. The patient would continue to have adequate access to necessary medical care and medications in a manner that would likely improve the quality of their medical treatment, and reduce the likelihood of them progressing into addiction. It would also help to protect the public safety by minimizing the possibility of drug diversion in the community. In addition, it would likely result in saving taxpayer dollars.

For those individuals currently struggling with addiction, it is very important to offer them evidenced-based, comprehensive treatment of adequate intensity, and for a significant period. For those seeking help, comprehensive treatment should be readily available and not difficult to access. This would include reducing or removing the barriers that restrict Medicare patients from non-hospital, addiction treatment programs, which would not only improve their access to treatment but would also save taxpayer dollars

It also will be very important to increase professional and public overdose prevention training, and increase the availability and use of naloxone to help decrease the tragic number of overdose deaths.

I believe that over time such efforts can not only improve our ability to better treat patients with legitimate pain but, also, help reduce the problem with opioid addiction in our community.

Thank you, again, for your time and for inviting me to discuss this important topic.

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PREPARED STATEMENT OF A. JACK KABAZIE, M.D., SYSTEM DIRECTOR, DIVISION OF PAIN MEDICINE, ALLEGHENY HEALTH NETWORK, AND PROGRAM DIRECTOR, PAIN MEDICINE FELLOWSHIP

INTRODUCTION

Mr. Chairman and committee members, thank you for the invitation and opportunity to address you on this important issue that has contributed to the staggering increase in abuse, diversion, addiction and overdose deaths in our region and the country.

I am the Medical Director for the Allegheny Health Network Division of Pain Medicine, board certified in anesthesiology and pain medicine by the American Board of Anesthesiology and American Board of Medical Specialties. My responsibilities include oversite of both employed and independent pain medicine physicians in the Allegheny Health Network, developing policy and procedures and direct patient care. During my career I have been invited to lecture on pain medicine at national, regional and local meetings.

In addition to my role as medical director, I am also the Program Director for the Multidisciplinary Pain Medicine Fellowship, Allegheny General Hospital/Western Pennsylvania Hospital Medical Education Consortium. The fellowship involves multiple medical disciplines, including psychiatry, neurology, physical medicine and rehabilitation and anesthesiology. Since starting the fellowship in 2000, I have trained 51 fellows and countless residents.

My medical career began at the Western Pennsylvania Hospital. After completing my fellowship, I started a pain medicine program to serve patients in the community, and assist my medical colleagues with their chronic pain patients. Around that time Purdue launched Oxycontin and a small but nationally influential group of physicians in positions of prominence were extolling the virtues and safety of opioids for chronic nonmalignant pain. Since that time I have observed a dramatic increase in opioid prescribing in southwestern Pennsylvania by physicians, many of which were ill equipped and under trained to deal appropriately with chronic pain patients.

THE PRESCRIPTION OPIOID EPIDEMIC

One of the major contributors to the current opioid epidemic in the United States is the over prescribing of opioids for chronic pain. As a Nation, we consume approximately 99 percent of the hydrocodone, 80 percent of the oxycodone and 58 percent of the methadone produced in the world (Institute of Addiction Medicine). This has contributed to a dramatic increase in opioid abuse, addiction and deaths due to overdose. In addition to the tragic personal toll, the direct and indirect economic cost associated with opioids places a significant burden on health care dollars (Birnbaum HG).

MULTIPLE DRIVERS OF THE EPIDEMIC

In the 1980s and 1990s, multiple factors contributed to a change in opioid prescribing for chronic nonmalignant pain. Based on scant and faulty medical data, the risk of addiction was touted as rare, end organ toxicity nonexistent and the incidence of tolerance low (Portenoy RK). Armed with this information, physicians became less reluctant to prescribe opioids, patient advocacy groups demanded better treatment for chronic pain, and pharmaceutical companies began reformulating opioids into extended release preparations (1996 Purdue launches Oxycontin). This brought about in a dramatic increase in analgesic prescribing for chronic nonmalignant pain that coincided with the rise in opioid related morbidity and mortality (Braden JB). Little has been done to effectively address and curtail the over prescribing of opioids.

Primary care physicians and internal medicine physicians prescribe the majority of opioid medications in the United States, and most were not trained in addiction or pain management (Volkow ND). While most doctors prescribe opioids with good intent and to treat their patients' pain with compassion, once that treatment path is started, it is often times very difficult to reverse. This can lead to disgruntled patients and frustrated physicians. Physicians who have compensation or employment

tied to patient satisfaction scores may feel pressure to prescribe opioids in response to patient pain complaints.

Nationally, there are major disparities in prescribing opioids for chronic pain (Paulozzi LJ). In some regions, including southwestern Pennsylvania, this has resulted in "pill mills" for profit. They prey on those with the disease of addiction out of greed. This has been addressed by legislation and law enforcement. Ten States have enacted a pill mill law as of May 2013. There are also physicians who tacitly prescribe opioids to continue patients on a long path of procedures that financially benefit the physician with little long term benefit to the patient, in some circles known as "pills for pokes." This is a very small but difficult practice pattern to detect without close oversite.

While much attention has been focused on opioid abuse, addiction, and mortality, there is also the issue of unintentional opioid misuse and subsequent adverse events. This is an issue especially in the elderly population who are at increased risk of falls and fractures (Miller M), cognitive impairment and unintentional overdosing. These adverse events result in increased emergency room visits, hospital admissions and length of stay adding strain to the health care costs in the United States (Birnbaum HG).

To curb the prescription opioid epidemic, State medical boards and physician groups have developed and published guidelines on the use of opioids to treat chronic nonmalignant pain (Hughes MA). The Center for Disease Control and Prevention is currently drafting guidelines as well. Where treatment strategies do exist to aid providers, studies show that some providers do not follow them, even for high risk patients (Gupta A). When queried about inappropriate opioid prescribing in light of published guidelines, one group of physicians responded, "they are only guidelines." While opioid prescribing has slowed, it still remains at problematic levels. The CDC found that in 2012, United States physicians wrote 82.5 prescriptions for opioids for every 100 people.

A promising tool to combat prescription drug abuse are State Prescription Drug Monitoring Programs (PDMPs). As of July 2013 there are 47 States with operational PDMPs, however they are significantly underutilized when not mandatory. To further address inappropriate opioid prescribing, Physicians for Responsible Opioid Prescribing (PROP) has petitioned for a mandatory limit on the amount and duration of opioids that can be prescribed to a patient with chronic nonmalignant pain. This has resulted in condemnation from patient advocacy groups, fearing absolute rules will leave many chronic pain patients without help.

RECOMMENDATIONS FOR CONSIDERATION

We cannot address the opioid epidemic by painting with a broad brush of absolutes, mandating dosing and time limits. There is a small subset of patients who will require large doses of opioids for extended periods of time and do well (Kalso E). They should not be denied this therapeutic option. However, this should be a treatment of last resort, when all other attempts to control chronic pain have failed. Most patients with chronic pain can be treated with satisfactory results using a multidisciplinary approach without the use of long term opioid therapy (Flor H).

To engage physicians in this endeavor we will require more than published guidelines that are either ignored or underutilized. Many physicians have opted out of the Risk Evaluation and Mitigation Strategy (REMS) for extended release and long acting (ER/LA) opioids as it is voluntary. Mandatory REMS coupled with obtaining a DEA number to prescribe opioids for chronic pain of longer than 3 months might be one strategy. This should include short-acting opioids as well as they are widely associated with abuse (MMWR). The REMS would require physicians to discuss with and educate the patient about potential risks, possible benefits, outline goals, and develop an exit strategy. This would not interfere with a physicians' ability to treat acute pain with opioids for a short period of time when appropriate.

Enacting pill mill laws in all States may be a promising modality to help curb abuse, diversion and overdose.

There needs to be in place in every State, and on the Federal level, a prescription drug monitoring program, easily accessible and user friendly that is available to physicians and pharmacies. The use of this program should be mandatory before prescribing or dispensing controlled substances.

Referrals to multidisciplinary pain programs should be made in a timely fashion for patients on opioids for chronic pain for evaluation, treatment recommendations and if necessary, reasonable medication management and monitoring.

To curtail the prescription opioid epidemic, all stakeholders need to come together and act quickly to address this national health crisis.

Thank you for your invitation and the opportunity to discuss this important issue.

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PREPARED STATEMENT OF SHARI M. LING, M.D., DEPUTY CHIEF MEDICAL OFFICER, CENTERS FOR MEDICARE AND MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUAMN SERVICES

Chairman Toomey and members of the subcommittee, thank you for inviting me to discuss the Centers for Medicare and Medicaid Services' (CMS) work to ensure that all Medicare and Medicaid beneficiaries are receiving the medicines they need while also reducing and preventing non-medical prescription drug use.

Opioid addiction is taking a real toll on communities, families and individuals both here in Pennsylvania and across the Nation. Deaths from drug overdose have risen steadily over the past two decades and have become the leading cause of injury death in the United States. Prescription drugs, especially opioid analgesics—a class of prescription drugs such as hydrocodone, oxycodone, and morphine used to treat both acute and chronic pain—have increasingly been implicated in drug overdose deaths over the last decade. From 1999 to 2013, the rate for drug poisoning deaths involving opioid analgesics nearly quadrupled. Deaths related to heroin also have increased sharply since 2010, with a 39-percent increase between 2012 and 2013.[1] It is estimated that 12 percent of all Medicaid beneficiaries ages 18–64 and 15 percent of uninsured individuals who could be eligible for Medicaid coverage have a Substance Use Disorder. Given these alarming trends, it is time for a smart and sustainable response to prevent non-medical prescription opioid use and overdose and to treat people with opioid use disorder. The monetary costs and associated collateral impact to society due to Substance Use Disorder (SUD), including opioid use disorder, are high. In 2009, health insurance payers spent $24 billion for treating SUDs, of which Medicaid accounted for 21 percent of spending.[2] The Medicare program, through Part D, spent $2.7 billion on opioids overall in 2011, of which $1.9 billion (69 percent) was accounted for by opioid users with spending in the top 5 percent.[3]

Combating non-medical prescription opioid use, dependence, and overdose is a priority for Department of Health and Human Services (HHS) Secretary Burwell and

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[1] National Center for Health Statistics/Centers for Disease Control and Prevention, *National Vital Statistics Report,* Final death data for each calendar year (October 2014).
[2] Centers for Disease Control and Prevention. Drug Overdose in the United States: Fact Sheet, Home and Recreational Safety, accessed on October 28, 2013 from *http://www.cdc.gov/drugoverdose/index.html.*
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the administration at large. As part of that commitment, the Secretary launched an evidence-based opioid initiative that focuses on three targeted areas: informing opioid prescribing practices, increasing the use of naloxone (a drug that reverses the deadly respiratory effects of opioid drug overdose), and expanding the use of medication-assisted treatment to treat opioid use disorder. As part of our role in these efforts across HHS, CMS released guidance [4] to help States implement comprehensive, evidence-based service delivery approaches to Substance Use Disorder treatment. CMS is establishing a new Medicaid demonstration opportunity for States seeking to undertake significant improvements in the delivery of care to individuals with Substance Use Disorder.

Moving forward, CMS has a responsibility to protect the health of Medicare and Medicaid beneficiaries, here in Pennsylvania and across the Nation, by putting appropriate safeguards in place to help prevent non-medical use and abuse of opioids, while ensuring that beneficiaries can access needed medications and appropriate treatments for SUD.

PREVENTING OVERPRESCRIBING AND ABUSE OF OPIOIDS IN MEDICARE PART D

Since its inception in 2006, the Medicare Part D prescription drug benefit program has made medicines more available and affordable for Medicare beneficiaries, leading to improvements in access to prescription drugs, better health outcomes, and more beneficiary satisfaction with their Medicare coverage.[5]

Despite these successes, Part D is not immune from the nationwide epidemic of opioid abuse. Based on input from the Department of Health and Human Services' Office of the Inspector General (HHS OIG), the Government Accountability Office (GAO), and stakeholders, over the past several years, CMS has broadened from the initial focus of strengthening beneficiary access to prescribed drugs to also address prescription drug abuse and fraud. CMS is aware of potential fraud at the prescriber and pharmacy levels through "pill mill" schemes. This is a term used by local and State investigators to describe a physician, clinic, or pharmacy that is prescribing or dispensing opioids for non-medical and inappropriate purposes. The structure of the program, in which Part D plan sponsors do not have access to Part D prescriber and pharmacy data beyond the transactions they manage for their own enrollees, makes it more difficult to identify prescribers or pharmacies that are outliers in their prescribing or dispensing patterns relative to the entire Part D program. We believe that broader reforms that result in better-coordinated care will help address several issues with the complex health care delivery system, including non-medical use of prescription drugs. CMS has, however, taken several steps to protect beneficiaries from the harm and damaging effects associated with non-medical prescription drug use and to prevent and detect fraud related to prescription drugs.

Initiatives to Strengthen Medicare Part D and Reduce Opioid Overutilization

A centerpiece of our strategy to reduce the inappropriate use of opioid analgesics in Part D is the adoption of a policy and guidance by which CMS encourages case management of Part D enrollees who have potential opioid overutilization that may present a serious threat to patient safety. To strengthen CMS's monitoring of Part D plan sponsors and to prevent overutilization of these medications, the Medicare Part D Overutilization Monitoring System (OMS) was implemented in 2013. The OMS requires Part D sponsors to implement effective safeguards to deter overutilization while maintaining a commitment to provide coverage for appropriate drug therapies that meet safety and efficacy standards. Through this system, CMS provides quarterly reports to sponsors on beneficiaries with potential opioid overutilization identified through analyses of Prescription Drug Event (PDE) data and through beneficiaries referred by the CMS Center for Program Integrity (CPI). Sponsors are expected to utilize various drug utilization monitoring (DUM) tools, including: formulary-level controls at point of sale (such as safety edits and quantity limits); a review of previous claim and clinical activity to identify at-risk beneficiaries, case management outreach to beneficiaries' prescribers and pharmacies, and beneficiary-level point of sale claim edits, if necessary to prevent continued overutilization of

[4] State Medicaid Director Letter, "New Service Delivery Opportunities for Individuals with a Substance Use Disorder,"
http://www.medicaid.gov/federal-policy-guidance/downloads/SMD15003.pdf.

[5] In 2013, more than one million distinct health care providers collectively prescribed $103 billion in prescription drugs under the Part D program. In all, Part D spent $3.9 billion on prescription opioids in 2013, *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-04-30.html.*

opioids. Lastly, sponsors that have concluded such point of sale edits are appropriate are expected to share information with a new sponsor when the beneficiary moves to another plan in accordance with applicable law. To support additional monitoring by the new sponsor, the CMS Medicare Advantage and Prescription Drug System (MARx) notifies a sponsor when a beneficiary targeted for an opioid point of sale edit changes plans.

We believe this Part D overutilization policy has played a key role in reducing opioid overutilization in the program. From 2011 through 2014, the number of potential opioid overutilizers, based on the CMS definition in the OMS,[6] decreased by approximately 26 percent, or 7,500 beneficiaries.[7]

CMS has new tools to take action against problematic prescribers. CMS issued a Final Rule on May 23, 2014, that both requires prescribers of Part D drugs to enroll in Medicare or have a valid opt-out affidavit on file and establishes a new revocation authority for abusive prescribing patterns. CMS is actively working to enroll over 400,000 prescribers of Part D drugs by January 2016, and will enforce the requirement that plans deny Part D claims that are written by prescribers who do not meet the necessary requirements by June 2016. These prescribers will be subject to the same risk-based screening requirements that have already contributed to the removal of nearly 575,000 provider and supplier enrollments from the Medicare program since the enactment of the Affordable Care Act. Requiring prescribers to enroll in Medicare will help CMS make sure that Part D drugs are prescribed by qualified individuals, and will prevent prescriptions from excluded or already revoked prescribers from being filled. Currently CMS is monitoring Part D claims data to identify provider types with a disproportionate number of unenrolled prescribers, such as dentists, and focusing our outreach strategy to target them. As we approach the implementation date, CMS and Part D sponsors will begin to target individual high volume prescribers that remain unenrolled. Upon enforcement of the enrollment requirement, CMS will require Part D plans to use point of sale edits to stop filling and paying for prescriptions from unenrolled prescribers after the affected beneficiaries have received a 3 month provisional supply and written notice from their plans.

Additionally, CMS has established its authority to remove physicians or eligible professionals from Medicare when they demonstrate abusive prescribing patterns. A revocation for abusive prescribing would be based on criteria that demonstrates a pattern of improper prescribing and would address situations where the prescribing was not in compliance with Medicare requirements or where there were patient safety issues involved. CMS may also revoke a prescriber's Medicare enrollment if his or her Drug Enforcement Administration (DEA) Certificate of Registration is suspended or revoked, or the applicable licensing or administrative body for any State in which a physician or eligible professional practices has suspended or revoked the physician or eligible professional's ability to prescribe drugs. These new revocation authorities provide CMS with the ability to remove problematic prescribers from the Medicare program and prevent them from treating people with Medicare.

Proposals to Further Fight Opioid Overutilization in Medicare Part D

In addition to these initiatives, the FY 2016 President's Budget[8] includes several proposals that would provide CMS with additional tools to prevent inappropriate use of opioids. One proposal to prevent prescription drug abuse in Medicare Part D would give the Secretary of Health and Human Services (HHS) the authority to establish a program that would require high-risk Medicare beneficiaries to only utilize certain prescribers and/or pharmacies to obtain controlled substance prescriptions, similar to requirements in many State Medicaid programs. The Medicare program would be required to ensure that beneficiaries retain reasonable access to services of adequate quality. Currently, CMS requires Part D sponsors to conduct drug utilization reviews, which assess the prescriptions filled by a particular enrollee. These efforts can identify overutilization that results from inappropriate or even illegal activity by an enrollee, prescriber, or pharmacy. However, CMS's statu-

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[6] OMS defines overutilization as the use of opioids with cumulative daily morphine equivalent dose (MED) exceeding 120mg for at least 90 consecutive days with more than three prescribers and more than three pharmacies contributing to their opioid claims.

[7] There were 29,404 potential opioid overutilizers, (or 0.29 percent of all Part D opioid users) in 2011 and there were 21,838 potential opioid overutilizers, (0.18 percent of all Part D opioid users) in 2014.

[8] Fiscal Year 2016 Budget in Brief, *http://www.hhs.gov/budget/fy2016-hhs-budget-in-brief/hhs-fy2016budget-in-brief-overview.html.*

tory authority to take preventive measures in response to this information is limited.

In addition to CMS's existing authority, the FY 2016 President's Budget also proposes to provide the Secretary with new authorities to: (1) suspend coverage and payment for drugs prescribed by providers who have been engaged in misprescribing or overprescribing drugs with abuse potential; (2) suspend coverage and payment for Part D drugs when those prescriptions present an imminent risk to patients; and (3) require additional information on certain Part D prescriptions, such as diagnosis and incident codes, as a condition of coverage. While Part D sponsors have the authority to deny coverage for a prescription drug on the basis of lack of medical necessity, there are currently no objective criteria to inform the medical necessity determination, such as maximum daily dosages, for some controlled substances, especially opioids. Therefore, the only basis for establishing medical necessity in these cases is prescriber attestation. If the integrity of the prescriber is compromised, the finding of medical necessity is compromised as well. If the Secretary had clear authority to intervene in these patterns suggestive of abusive prescribing or harmful medical care, the incidence of coverage and payment of such questionable prescribing could be reduced in Medicare.

Data Analysis Conducted by the Medicare Drug Integrity Contractor (MEDIC)

CMS also contracts with the National Benefit Integrity (NBI) MEDIC, which is charged with identifying and investigating potential fraud and abuse, and developing cases for referral to law enforcement agencies. In September 2013, CMS directed the MEDIC to increase its focus on proactive data analysis in Part D, including producing, at a minimum, quarterly reports to plan sponsors on specific data projects, such as high risk pharmacies assessments.

These assessments contain a list of pharmacies identified by CMS as high risk and provide plan sponsors with information to initiate new investigations, conduct audits, and ultimately terminate pharmacies from their network. For example, one Part D plan sponsor terminated 51 pharmacies from its network as a result of the March 2015 Pharmacy Risk Assessment. Another Part D plan sponsor opened investigations on 16 pharmacies as a result of the September 2014 Pharmacy Risk Assessment. The NBI MEDIC also conducts data analysis and other work to support ongoing law enforcement activities. Examples of the assistance that the NBI MEDIC provides includes: data, data analysis, impact calculations, clinical review of claims and medical records, and prescription drug invoice reconciliation reviews.

Data to Identify Outlier Prescribers

CMS used prescription drug event (PDE) data to identify 1,525 prescribers as outliers of Schedule II controlled substances in the 95th percentile for the number of prescriptions and the number of 30-day equivalent prescriptions. Using this information, CMS developed reports that clearly identified the differences in prescribing patterns for the identified outliers. Similar to CMS's comparative billing report initiatives, the goal is to: (1) proactively educate providers about aberrant prescribing practices; (2) act as a deterrent by making providers aware of the Government's monitoring of their prescribing practices; and (3) reduce inappropriate prescribing. CMS then sent these reports to half of the providers, alerting them about their status as outliers. CMS also shared the list of outlier prescribers with Part D plan sponsors in an effort to augment their current utilization management program. We are further developing this and other approaches, using a similar analysis related to prescribing of atypical antipsychotics.

CONCLUSION

CMS is dedicated to providing the best possible care to beneficiaries while also ensuring taxpayer dollars are spent on medically appropriate care. CMS has broadened its focus from ensuring beneficiaries have access to prescribed drugs to ensuring that Part D sponsors and State Medicaid programs implement effective safeguards and provide coverage for drug therapies that meet standards for safety and efficacy. Although there is still work that needs to be done, CMS is confident that our initiatives will help to reduce the rate of opioid addiction and overdoses in both Medicare and Medicaid.

PREPARED STATEMENT OF ASHLEY POTTS, TEAM LEADER, CRISIS STABILIZATION AND DIVERSION UNIT, SOUTHWESTERN PENNSYLVANIA HUMAN SERVICES, INC.

My name is Ashley Potts and I currently work for Southwestern Pennsylvania Human Services (SPHS) as a Team Leader for the Crisis Diversion Unit. I am currently pursuing my Master's Degree in Social Work, I have a Bachelor's Degree of Arts, and an Associate's Degree in Science. Before accepting my position at SPHS, I worked for the Washington Drug and Alcohol Commission (WDAC) as a case manager for Washington County's Restrictive Treatment Program, Drug Court, for 3 years. However, 9 years ago my life was completely different. At 20 years old I found myself homeless, addicted to heroin, and suicidal. I was facing a State prison sentence and no one in my family wanted to be around me. Telling you about my history will help you understand the importance of treatment, the impact of stigma, the need to have awareness on preventing addiction, and recovery is possible.

I took my first drink of alcohol when I was 9 years old. My mother suffers from addiction issues of her own, so culturally I did not process that it was wrong. When I was 12 years old, I started smoking marijuana and drinking on a more regular basis. At 13, I was given my first Oxycontin. This is where my love for prescription pain pills started. I started having behavioral issues in school, getting suspended on a regular basis, receiving multiple fines, and eventually, I was expelled from high school in the ninth grade. This is the first time I thought that maybe I should stop using drugs. I quit abusing cocaine and prescription pain pills; however, I still did not seek treatment or therapy for the issue. I was able to remain abstinent from these substances for the remainder of my ninth grade year.

At the beginning of my sophomore year of high school, I was allowed to return to my old school. Things were going well in the beginning, but eventually I fell back into old habits. This is the year I began using crack. My life started to spiral out of control and I began running away from home. I was apprehended by the police several times, yet I still continued to run away. Eventually, I assumed they were no longer looking for me. I quit going to school and just continued to use drugs. Someone once told me, "Ashley if you play with fire long enough, eventually you will get burned." I did not understand what that meant at that moment but later it all made sense. My entire life I was determined never to be a heroin addict, I hated heroin addicts, I was better than them. The price of prescription pills were very expensive. The price for Oxycontin on the street was $1.00 a milligram; an 80 milligram pill was $80.00. I could not financially support this habit despite a life of crime, and eventually I gave into heroin; it was only $10.00 a bag. I was 17 years old.

After breaking into my father's home and stealing some of his belongings, I was sentenced to juvenile probation for 6 months. During this time I was ordered to an outpatient program and my probation officer would come to school to visit me. I had moved in with my mother. I was able to graduate from high school despite my drug abuse and lack of attendance. The summer after high school graduation, I was 18 years old, and I had not spoken to my father in quite some time. I called him repeatedly and told him if he did not pick me up that I was going to kill myself.

My father came to pick me up. I returned to his house and went through the physical withdrawals of heroin. With every agonizing breath I said to myself, "I am never going to use again." At this time, I still had not received any inpatient treatment; therefore, none of my behaviors were changing. After a short time of living there, I found out that I was pregnant and I was able to remain abstinent the duration of my pregnancy. Once I had my daughter Riley, everything changed. I was determined to be the best mom I could be; everything was going to be great.

A few weeks after I had my daughter, I thought I could just drink alcohol. This lead to just snorting bags of heroin, which ultimately led to me having a needle in my arm again. Things were worse this time, worse than ever before. I took my daughter and left my father's house. A few weeks later, there was a knock at the door where I was staying with my daughter, it was my father. He begged me to let him have temporary custody of Riley and for me to go to rehab. I agreed. This was the first time I was going to go to an inpatient rehabilitation facility. I remember the car ride there, laying in the back seat, too sick to even sit up, the agonizing pain was back and with every breath I said, "I am never going to use again." The rehabilitation stay was short, only 24 days, even though my family begged them to keep me. I refused a halfway house and returned home; it was May 13th. Riley had her first birthday party on May 20th, but on May 17th I was using, nowhere to be found. All the dreams I had of being the best mother I could be were shattered and

enslaved to a needle. My father informed me to never step foot on his property again or I would be arrested.

I was living in my car. I started selling all the things I had that were worth any amount of money: clothes, cell phone, and eventually my car. I had nowhere to stay. I moved in back in with my mother. I began writing fraudulent checks to support my drug habit. I stole my mother's checkbook and wrote fraudulent checks in her name. I broke into an innocent person's home and stole their belongings. I had become the exact thing I hated most in this world. I felt like a zombie, a hollow corpse. My mother had me walked out of her home in handcuffs. Everyone was done with me. I had several warrants out for my arrest and no desire to live anymore. In my head, there were only two options: go to treatment and stop using or kill myself.

I decided to try treatment one more time. Again, going through the physical withdrawals and with every agonizing breath saying, "I am never going to use again." I spent 7 long days in a detoxification unit and then 29 days in an inpatient rehabilitation program. The time came again where they offered me a halfway house, this time I said yes. This time I was homeless and had no place to return to. I transitioned to a halfway house in Washington, Pennsylvania; it was October 16, 2006. Making the decision to go to a halfway house was the best decision I had ever made. I spent 216 days in treatment; those were the best days of my life because those 216 days saved my life.

When I arrived at the halfway house, the first thing I did was turn myself into all the municipalities that were searching for me. They told me to stay where I was, and the court process would be started. I listened. For the first time in my life, I listened. While I was there, I was encouraged to participate in the Intensive Vocational Rehabilitation Program (IVRP), a program to assist with job development. I took an I.Q. test and scored at a sixth grade level; I was 20 years old. Several months went by and it was time for me to go to my sentencing court hearing. I had 7 months clean at the time and was prepared to face my consequences and go to jail that day. However, when I stood in front of the judge, he granted me 216 days time served and immediate parole. I finally felt like I had a second chance at life and was ready to take full advantage of it. Something happened this day, though; I became a convicted felon.

I returned to Washington and continued with my recovery process. I had decided I wanted to go to college. Due to my low education scores, I first attended Careerlink to take some refresher courses. I enrolled at Community College of Allegheny County (CCAC), I still had to take prerequisite courses; however, I was just so excited to be in college. It was surreal, the girl everyone said couldn't make it, the girl that was told she was not college material. I was in college. I transferred to a technical school as I wanted to pursue a career in the medical field. I attended 6 hour classes, 4 days a week. It became time to participate in an internship; however nowhere in Ohio, Pennsylvania, or West Virginia would accept me due to my criminal record. I was forced to quit the program.

This was my first true encounter with stigma. The decisions that I had made during my active addiction would haunt me for the rest of my life. It was a hard internal battle to continue to pursue a college education. I took a year off from school, but then I decided to go back. I returned to CCAC to finish my associate's degree and then I decided to go further. I enrolled at California University to obtain a bachelor's degree. I was sure to select a program that did not require an internship, so I would not have to face that stigma again. I was able to move forward with my career and obtain a job at the Washington Drug and Alcohol Commission. An employee there had vouched for my character due to my record. This had happened several times while employed there. To be able to work with the Restrictive Treatment Program and complete assessments at the jail, the executive director had to speak with people individually and let them know that I was not the person that I had appeared to be on a piece of paper.

While assessing individuals for the Restrictive Treatment Program applications for Medicare/Medicaid would be completed. Most of these individuals were eligible to receive Medicaid to assist with treatment for their addictions. It is important to have policies in place to continue to assist these individuals to gain access to the treatment that they need. It is also important to have policies in place that monitor the distribution prescription pain pills. Speaking from personal experience having easy access to prescription pain pills can have a devastating impact on one's life.

During my 3 years of employment with WDAC, I had the opportunity to learn about the individuals on the Restrictive Treatment Program and what had led them

to the criminal justice system. In some cases their stories began by receiving a "harmless" prescription from their doctor for pain. These scenarios could include a sports injury or even child birth, either way they had the same outcome, drug court. Despite the fact that prescription painkillers are approved by the Food and Drug Administration, it is important to understand that does not make them safe. While working for WDAC, I also learned that medically assisted treatments such as Suboxone were being identified by individuals as a drug of choice rather that a treatment method. The Restrictive Treatment Program had individuals who were utilizing Vivitrol as a medical assisted treatment and they were diligently working to create more specialty tracks to include other medical assisted treatments and address the various issues attached to them.

During my recovery process, I have had several encounters with stigma. My felony convictions have affected every decision I have made from employment, to housing, to schooling. I have not been hired for several positions due to my criminal record: laughed at by landlords when seeking rental properties; and forced out of school. No matter how hard society tried to bring me down, I was determined not to let it. I have spent several years rehabilitating my life and I never gave up on my dreams. I went from testing at a sixth grade education level to being enrolled in graduate school maintaining a 3.8 GPA. I went from being a client in the IVRP to sitting on their Board of Directors. I went from volunteering at the Washington Drug and Alcohol Commission to being an employee. Recently I was promoted within SPHS to be a team leader for their crisis diversion unit and join their management team. I have filed for a Governor's Pardon for my felony convictions and have devoted my life to helping others. I am proof that treatment works, I am proof of being a good person with much to offer beyond my history of addiction, and finally, I am proof that recovery does happen.

PREPARED STATEMENT OF HON. PATRICK J. TOOMEY,
A U.S. SENATOR FROM PENNSYLVANIA

Thank you to John Paul and Allegheny Health Network for hosting this field hearing, and thank you for my fellow Finance Committee member, Senator Casey, for being here, too. He and I care deeply about how an epidemic of prescription opioid and heroin abuse is affecting Pennsylvania's families.

More Pennsylvanians will die this year from overdoses and misuse of heroin and prescription painkillers than from influenza or homicide. And unlike past drug epidemics that skewed younger and were felt in specific locales, today, heroin and painkiller abuse are spread across all age, demographic groups, and regions.

As the Senate Finance Subcommittee on Health Care will hear today from our witnesses, sadly, southwestern Pennsylvania has been hit severely hard by this epidemic.

Stopping this epidemic and healing our communities will require a three-prong approach that I am pursuing as chairman of the Senate Finance Subcommittee on Health Care:

1. Stopping the illegal diversion of prescription painkillers;
2. Reducing the overuse of opioids for treating long-term pain; and
3. Helping those battling addiction receive appropriate treatment.

Our witnesses will discuss those issues. Joining us are: Dr. Shari Ling, Deputy Chief Medical Officer, Centers for Medicare and Medicaid Services at the United States Department of Health and Human Services; Dr. Neil A. Capretto, Medical Director, Gateway Rehabilitation Center; Mr. Gene Vittone, District Attorney for Washington County; Dr. Jack Kabazie, System Director, Division of Pain Medicine, Allegheny Health Network; and Ms. Ashley Potts, Team Leader, Crisis Stabilization and Diversion Unit, Southwestern Pennsylvania Human Services.

First, let's consider how we arrived at this point. The seeds of this crisis were planted 2 decades ago with the advent of readily available painkillers like hydrocodone and oxycodone. While these drugs can help produce immediate pain relief, they are also easily abused, highly addictive, and commonly diverted.

Nearly 80 percent of heroin users previously abused prescription opioids.

Despite the crackdown on many so-called "pill mills" where unethical physicians prescribed large amounts of powerful opioids in exchange for cash, the problems of diversion and overprescribing still exist.

In fact, the nonpartisan Government Accountability Office has found there are more than 170,000 Medicare enrollees who are actively engaged in "doctor shopping" for physicians who will unknowingly write redundant opioid prescriptions.

When other insurance plans, including Medicaid, spot this kind of fraud, the insurer limits or "locks" the individual to a single doctor or pharmacy to stop pill diversion and help control access to the addictive medication.

Unfortunately, Medicare doesn't have this tool. That's why I've authored the bipartisan Stopping Medication Abuse and Protecting Seniors Act. My legislation, which Senator Casey has cosponsored, will not only help individuals battling addiction get treatment, it will also save taxpayers $79 million by stopping the illegal diversion of pain pills.

Medicare and other insurers must also work with physicians to stop the medically unnecessary use of opioids to treat pain. This year, about 260 million painkiller prescriptions will be filled, enough for every American adult to have their own bottle of pills. While opioids can help control intense pain immediately after a surgery or a visit to the dentist, long-term opioid use becomes less effective in most patient populations, and is associated with higher rates of substance abuse, emergency room visits, accidental overdoses, and falls, especially in senior citizens.

Medical specialty societies have begun developing new guidelines that reduce both the dosage and the length of time prescription opioids can safely be taken. For instance, the American Academy of Neurology now says that the risks of opioid use outweighed any benefits for treating headaches, lower back pain, and fibromyalgia.

And, when opioids are used in combination with other narcotics like Valium or Xanax, the combination is deadly. To help providers know the panoply of medications a patient is taking, there must be broader usage of robust prescription drug monitoring programs. Making them interoperable across State lines will also help physicians, as well as law enforcement, to spot diversion and abuse.

Finally, we must also explore ways to improve access to, and the quality of care. While addiction to an opioid or alcohol is often viewed as a moral failing, in many ways it is a chronic disease like diabetes and heart disease. The medical profession continues to debate the optimal approach, but everyone agrees that opioid addiction can be treated with professional help. Congress and my subcommittee are closely examining a number of legislative proposals in this area.

Ending the epidemic of heroin addiction will require changes in the practice of medicine, government regulation, and societal views. There are steps we can and should take today that end diversion, reduce non-medical use of opioids, and approach addiction like a treatable disease.

I thank all of you for being here today. It shows there is a commitment and desire in southwestern Pennsylvania to end this epidemic. By working together at the Federal, State and local level, I am confident that opioid abuse is an enemy we can defeat.

PREPARED STATEMENT OF EUGENE A. VITTONE II, M.B.A., M.H.A, J.D., DISTRICT ATTORNEY, WASHINGTON COUNTY, PA

INTRODUCTION

Good afternoon. I would like to thank the chairman, Senator Pat Toomey, for the honor and opportunity to provide testimony to the committee. I first met the Senator last year when he convened a working panel in Washington County to address the increasing problem of addiction in our country. He is truly a champion in this area, and I thank him for his recognition and dedication to resolving this deadly national problem.

I would be remiss if I did not also thank our local United States Attorney, David Hickton, for his leadership and assistance on the problem of opiate abuse. Mr. Hickton is also a champion and a great partner for law enforcement, who are on the front lines fighting the epidemic of opiate drug abuse.

It is no secret that our Nation is in the midst of an epidemic of drug-related deaths caused by prescription drug abuse. This is both a public health and a public safety crisis. Many thousands have died due to overdoses caused by opiate drugs and heroin. Washington County is not immune from this peril. Since 2011, more than 230 Washington County residents have lost their lives due to accidental poi-

soning caused by opiate drugs. In August of this year, we had a spate of drug overdoses caused by fentanyl-laced heroin which claimed several lives and placed Washington County in the national news. This epidemic however goes beyond the overdose deaths caused by opiate abuse. The epidemic also significantly impacts the area where I work, which is the criminal justice system.

I recently conducted a statistical review of the criminal case filings for 2014 and discovered that at least 75 percent of the filed cases had a connection to drugs and alcohol. Thirty percent of our cases were directly linked to opiate abuse, both pills and heroin. This is roughly equivalent to the number of cases that we have arising from alcohol, including driving under the influence. From my 17 years working in the Washington County District Attorneys Office, I can assure you that this is a new event. Not too long ago, it was rare to see a heroin case in court—now it is rare not to have a case involving heroin or someone in opiate addiction.

Our coroner, Tim Warco, has been very good about documenting the toll arising from this epidemic. A review of his data about the deaths over the past 5 years indicates that this is a problem not just for young people but for all age ranges. Forty-one percent of our deaths were people over the age of 40. Forty-six percent were from a combination of two or more drugs and, why we are here today, 57 percent were from prescription medications.

The connection between opioid medication abuse and heroin is well established. As local law enforcement professionals, we have had to become educated in many different areas of the law—which were not known to us—in order to fight the abuse of these medications. We have responded in Washington County with numerous drug educational summits at local schools to warn children of the dangers of abuse of pharmaceuticals. We have drop boxes for unwanted medications in our police stations, we have embedded a Federal prosecutor in our office to aggressively go after drug dealers, and we have heightened and promoted treatment for non-violent criminal offenders. These measures are designed to work on both the supply side and demand side of the epidemic. While I am proud of what we have done thus far, I fear that these measures will not be sufficient alone to eliminate the problems of rampant opiate addiction.

Last fall, the Pennsylvania General Assembly enacted legislation providing for an improved Prescription Drug Monitoring Program (PDMP). This legislation was sorely needed as our old system was inadequate to inform health care providers of who was receiving what opiod medications. Since that legislation was passed, the PDMP has not come into being largely due to the fact that no money was set aside for its development. State Representative Brandon Neuman has indicated to me that some Federal funding has become available to initiate the work of development of the PDMP. S.B. 480, which reauthorizes the National All Schedules Prescription Electronic Reporting Reauthorization Act would help Pennsylvania's PDMP. This would also provide for improved communication with neighboring States to prevent prescription medication diversion. It is imperative that this be done as soon as possible as Pennsylvania has become a source location for those coming from other States looking to acquire opioid medications through diversion.

Washington County sits in the southwestern corner of Pennsylvania and is close to Maryland, Ohio, and abuts West Virginia along its western edge. Due to our geographical location we are an easy drive for those looking to acquire medications, whether they are looking to use forged prescriptions or prescriptions acquired through doctor shopping. In 2012, my office in combination with other law enforcement agencies arrested 12 individuals who were acquiring pills in 7 different Pennsylvania Counties. They were traveling as far north as the New York State line and to the east as far as Chambersburg. That scheme wasn't too sophisticated—they would simply go to different physicians—claim pain and obtain prescriptions which they would then alter. They were also manufacturing prescriptions utilizing a scanner and computer. They operated for at least a year and acquired tens of thousands of pills of Opana, OxyContin and other medications before they were arrested. There is no doubt that they would had been detected sooner had a PDMP been in place. They also would not have been able to utilize third-party insurance to pay for the medications if a "lock" had been in place to prevent them from doctor shopping.

There is also an emerging trend we are seeing in the diversion of Suboxone which is a drug utilized in medication-assisted treatment of people with opiate addiction. Traditionally, methadone was utilized to wean people off of heroin. Suboxone is also an opiate but is prescribed to people in an attempt to lessen the effects of withdrawal and help them in recovery. I have heard reports of increased criminal activ-

ity near Suboxone clinics, and recently we have made arrests of individuals selling Suboxone on the street.

In 2012, a physician, Oliver Herndon, was arrested and charged with dispensing powerful opiate drugs, oxycodone and oxymorphone. According to DEA Agents who investigated, Dr. Herndon was one of the largest suppliers of diverted Opana in the eastern United States. His parking lot had cars from many different States and individuals came from out of State to get prescriptions filled. Many pharmacies independently refused to fill the large prescriptions that were written. During one visit by an undercover agent, when asked where his prescription could be filled, he was told by Herndon the further away that he could get the prescription filled the easier it would be. Investigators learned that many of the pills were being sold on the street and were surprised to learn that once Herndon was arrested the price of Opana doubled on the street. Herndon provided a letter to his patients denying that he was under DEA investigation and indicating that he was the medical director for a hospice organization and two nursing homes. Herndon was successfully prosecuted in Federal Court for the Drug Act violations and also for insurance fraud from the hundreds of thousands of dollars that were fraudulently submitted as claims.

I indicated earlier that over 50 percent of the people who die from overdoses are over the age of 40. I just spoke about a doctor who was supplying pills to people of all ages and was also medical director for two nursing homes and a hospice organization. These facts emphasize the need for a lock provision in health insurance policies, particularly Medicare, which require a patient with a drug abuse medical history to "lock in" with a particular physician and pharmacy. This would help eliminate diversion of medications, and the prescribing patterns may be clearly evaluated. This would reduce Medicare fraud attributable to the filing of false claims and diversion of medications. This lock-in provision is the centerpiece of S.B. 1913 entitled the Stopping Medication Abuse and Protecting Seniors Act sponsored by Chairman Toomey.

In closing, I am thankful for the opportunity to address the committee today and talk about this important challenge which is facing Washington County and our Nation. In the 4 years during which I have been learning about the epidemic and attempting to develop the means to fight this problem, I have learned many things. Much of what we have learned has been put into practice as an ever-evolving plan of action. I have had to accept that as a law enforcement professional, I cannot make this problem go away by myself. I cannot stop the accidental overdose deaths and devastation caused by the addiction sweeping our Nation. I need the help of all levels of government in combating this problem. I pray for consistency in the various regulatory agencies involved with the regulation of these powerful medications, and I look for a faster response to problems once they are identified. I am just one district attorney in a county in Pennsylvania, but there are many more like me facing the same crisis, and we need the ability to do our jobs and maintain the criminal justice system in the wake of the increased demands created by the opiate epidemic. Those of us in law enforcement, who are on the front lines of the opiate epidemic, will continue to enforce the law and do our best to protect the public we serve.

Thank you.

STATISTICAL REVIEW OF CRIMINAL CASE FILINGS IN WASHINGTON COUNTY

Study Design—A statistical sample representing a 95 percent confidence interval was taken from the 3,377 criminal cases filed in Washington County in 2014. The goal was to determine within a measure of certainty the number of cases driven by drugs and the specific drugs which drove the criminal case. The sample size was 345 cases. 345 numbers were drawn randomly from an Internet randomization service and criminal complaints and affidavits of probable cause for each of the specific cases corresponding to the randomly generated numbers were reviewed. Note was made of the charges filed, the police department and any mention of a drug in the original criminal complaint. These results were tallied and are given below.

Limitations—In many cases, a specific drug may not be named in the criminal complaint as the use of a drug may not be relevant to the crime charged. For example, in a possession case the type of drug would be relevant; in a theft case, the fact that the offender had a drug problem would not be an element of the crime charged. This limitation on the study design would mean that the results demonstrated are more likely than not higher than indicated below.

Results—A tabulation of a statistically valid sample of criminal case filings for Washington County in 2014 yielded the following results:

Offenders use of a drug—	74.78 percent of the cases	(258/345)
Type of drug		
Prescription medication—	7.25 percent of the cases	(25/345)
Heroin	22.61 percent of the cases	(78/345)
Cocaine	2.9 percent of the cases	(10/345)
Alcohol	32.17 percent of the cases	(111/345)
Cannabis	9.86 percent of the cases	(34/345)

Discussion: The results demonstrate that alcohol is still the most commonly abused drug resulting in criminal charges. DUIs and alcohol based crimes account for almost a third of the criminal cases filed in Washington County. Heroin is the second most commonly implicated drug in criminal cases. Use of an illicit drug other than alcohol resulted in 42.6 percent of the criminal cases filed in Washington County. The correlation between offender drug use and criminal activity has been well documented and the data produced in this statistical review of the filings in Washington County serves to support this correlation.

Other results:		
Felony charge filed	25.79 percent	(89/345)
Misdemeanors	74.21 percent	(256/345)
Domestic violence crime	5.5 percent	(19/345)
Child Abuse	3.18 percent	(11/345)

ACCIDENTAL OVERDOSE DEATHS IN WASHINGTON COUNTY

2011–2015

Year	2011	2012	2013	2014	2015	Total	
Total deaths	46	40	58	36	50	230	
Combined drugs	29	22	12	19	25	107	46.52%
Prescription meds	33	22	26	27	23	131	56.96%
Number of drugs found on toxocology							
1	17	22	46	17	19	121	53.07%
2	14	7	6	9	18	54	23.68%
3	15	7	0	5	6	33	14.47%
4	0	4	6	4	1	15	6.58%
5 or more	0	0	0	1	0	1	0.44%
Gender							
Male	30	23	36	23	35	147	65.04%
Female	16	13	22	13	15	79	34.96%
Age							
<19	14	2	1	2	1	20	9.09%
<29	0	3	25	5	10	43	19.55%
<39	10	12	10	12	15	59	26.82%
<49	13	13	16	6	10	58	26.36%
<59	7	5	5	8	8	33	15.00%
>60	2	1	1	3	0	7	3.18%

Source:
Washington County Coroners Office
Timothy Warco, Coroner
http://www.co.washington.pa.us/index.aspx?NID=386.

COMMUNICATIONS

AMERICAN ASSOCIATION FOR THE TREATMENT OF
OPIOID DEPENDENCE (AATOD)
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Recommendations on Increasing Access to Effective Treatment for Opioid Addiction from the American Association for the Treatment of Opioid Dependence (AATOD)

My name is Mark Parrino, and I am writing on behalf of the American Association for the Treatment of Opioid Dependence (AATOD), which represents 1,000 Opioid Treatment Programs throughout the United States, treating 340,000 patients on any given day. These are the treatment programs that treat opioid addiction under certification through the Substance Abuse and Mental Health Services Administration. All of these programs must comply with SAMHSA's operating requirements, which were promulgated during 2001. All of the Opioid Treatment Programs (OTPs) must also comply with the Drug Enforcement Administration's security requirements. Finally, all of the OTPs are regulated by the State Opioid Treatment Authorities, which have different and at times more stringent, standards of regulation.

The Senate Finance Subcommittee on Health Care and its members understand that our country is experiencing a public health crisis of untreated opioid addiction. It is useful to reference a recent article on this topic, which was published in the *New England Journal of Medicine* on January 15, 2015, "Trends in Opioid Analgesic Use and Mortality in the United States." Dr. Richard Dart is the lead author in this article, which made the following point: "Whatever the measure, the past few decades have been characterized by increasing use and diversion of prescription drugs, including opioid medications, in the United States. An estimated 25 million people initiated non-medical use of pain relievers between 2002 and 2011."

As the subcommittee knows, there have been a number of national reports from the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Centers for Disease Control and Prevention (CDC), documenting the increase in the use of prescription opioids. SAMHSA has also documented the fact that 80% of new heroin addicted individuals report using prescription opioids as a gateway drug.

Need for Public Education

One of AATOD's primary recommendations, which has been made to the representatives at the Department of Health and Human Services and other federal agencies which have jurisdiction in this area, is the need to provide a meaningful and clear public education campaign for Americans, underscoring the dangers of opioid abuse and addiction. There has been a loss of intergenerational knowledge given the fact that people do not understand how they can get into trouble when abusing prescription opioids. Additionally, Americans need to understand that heroin use is not a safe alternative when they do not have access to prescription opioids. We recommend that the Department of Health and Human Services (HHS), in conjunction with its agencies, work with the White House Office of National Drug Control Policy in developing these clear messages to the American public. This would need to be a sustained campaign, since it took years for the American people to get to the current place of prescription and heroin abuse.

AATOD supports a number of the elements in Congressman Bucshon's legislation, especially in providing guidance to medial practitioners who work under the aegis of the Drug Abuse Treatment Act of 2000. Such practices need to provide greater education to their patients about the available medications to treat their illness.

Recommended Policy Initiatives

At the present time, 49 states have either enacted or implemented statewide Prescription Drug Monitoring Programs (PDMPs). These programs need to be utilized by physicians in general practice in addition to dentists and substance abuse treatment providers. It is understood that not all of these PDMPs are easy to use and should also be utilized by other clinical/administrative support personnel in a medical practitioner's office. Ultimately, medical practitioners must utilize these databases as a method of treating their patients with a greater margin of safety. Increasing such utilization of PDMPs will help in better treating individuals who are abusing opioids. However, it is part of a solution, not the only solution.

The Use of Medications to Treat Chronic Opioid Addiction

There are three federally approved medications to treat chronic opioid addiction in the United States: methadone, buprenorphine, and Vivitrol/Naltrexone. It is recommended that all three medications be used in conjunction with other clinical support services, including counseling. Methadone is primarily offered through OTPs, while buprenorphine is primarily offered through DATA 2000 practices. Injectable Naltrexone products may be used in any medical setting including OBOTs and OTPs.

The National Institutes on Drug Abuse (NIDA) has funded numerous studies in support of the use of these medications in treating chronic opioid addiction. There are guidelines for the use of such medications through the Treatment Improvement Protocol series, published by SAMHSA, in addition to recently released guidelines for the use of medications in treating opioid addiction through the American Society of Addiction Medicine. Physicians need to be trained in how such medications are used and when opioid addicted people would benefit from each of the three medications, as stated above.

Opioid Overdose Prevention Toolkits

AATOD agrees with the recommendations of ONDCP and HHS in increasing the utilization of opioid overdose prevention tool kits. We have already seen the benefits of widespread availability through emergency responders and police forces in different cities of the United States. The key recommendation is to ensure that individuals who receive such overdose prevention tool kits get access to emergency room care once they have been revived. The Vermont Hub and Spoke model provides even more support in how such treatment is coordinated once the individual is saved, brought to an emergency room, and then referred to treatment through the available resources.

Recommendations to Increase Access to Medication Assisted Treatment for Opioid Addiction

Congress passed the Drug Abuse Treatment Act of 2000 and subsequently amended it so that physicians who are DATA 2000 waived could treat up to 100 patients per practice. It is understood that a few congressional offices and HHS are considering how to increase access to such care under the aegis of DATA 2000. For the record, our Association has opposed the elimination of this patient limit as proposed by the TREAT Act.

- Before federal agencies and congressional offices proceed with recommendations to increase access to such treatment options, there needs to be a better understanding of what treatment is offered through DATA 2000 practices at the present time.
- If there is going to be any consideration in adjusting this patient number, there should be clear conditions placed on practices that wish to treat a greater number of patients. Illustratively, physicians should be offering counseling services and conducting toxicology profiles on patients to better guide success in treatment.
- Such practitioners also need to be accessing PDMP databases before and during the patient's care.
- The practitioner needs to assess the patient for their clinical needs, which may include counseling and other ancillary support services to treat co-morbidities such as infectious diseases (Hepatitis C) or psychiatric co-morbidity (depression, anxiety).
- Patient outcomes need to be followed as a method of better understanding the success of such treatment interventions. In this case, physicians need to be able to provide information about the length of time a patient remains in treatment and relapse rates.

Increasing Access to the Use of Medications in Opioid Treatment Programs

At the present time, SAMHSA has certified approximately 1,300 OTPs, which operate in 49 states. Approximately 350,000 patients are treated through theseOTPs at any given point in time. AATOD has identified the lack of Medicaid reimbursement for OTP services as a major impediment in l7 states in this country. AATOD has also learned that utilization of such services increases by a factor of 25 percent when Medicaid reimbursement is available. Accordingly, AATOD is working with a number of policy partners to address this impediment.

If the experience of OTPs provides any guidance to Congress and this Subcommittee in its deliberations, the following illustration provides an important reference. OTPs expanded quickly in the late 1960s without any operating requirements. Congress passed legislation that created a regulatory oversight structure for these OTPs in 1972. The House Select Committee on Narcotics Abuse and Control directed the United States General Accounting Office to develop a report on Methadone Maintenance Treatment. This report was published in March 1990: "Methadone Maintenance—Some Treatment Programs Are Not Effective; Greater Federal Oversight Needed." SAMHSA published its first Treatment Improvement Protocol in 1993 "State Methadone Treatment Guidelines" as a method of responding to the recommendations of the GAO report. The FDA asked the Institute of Medicine to evaluate the federal regulation of methadone treatment. The IOM released its findings in 1995, laying the foundation for the FDA to end its oversight of the OTPs and transition the oversight to SAMHSA. This was finalized in 2001. SAMHSA also published more detailed guidelines for OTPs in 2007 and these were revised during March 2015. The point in siting these references is to advise Congress that it took these interventions to improve the quality and practices of OTPs.

Conclusion

In summary, AATOD is pleased to work with members of Congress on the best methods of increasing access to treatment for opioid addiction and in educating America about the dangers of opioid abuse. This will take a sustained and coordinated effort so that federal policy and legislation need to be based on evidence and what is known to be effective. We have learned a great deal over the past 50 years of the most effective methods of treating opioid addiction. It is clear that our nation got into this problem in major part as a result of the improper and unsupervised prescribing of opioids for pain management. The way out is not to provide a different medication without appropriate supervision and the provision of essential services, which must be used in support of opioid addicted individuals. This explains our opposition to the element of the TREAT Act which completely eliminates the existing 100 patient restriction. Additionally, we are asking Congress to expand access to OTPs through Medicaid and Medicare to remove the existing impediments as stated above. We look forward to working with the House and other members of the legislature as these issues move forward.

AMERICAN PSYCHIATRIC ASSOCIATION

AMERICAN ACADEMY OF ADDICTION PSYCHIATRY

AMERICAN OSTEOPATHIC ACADEMY OF ADDICTION MEDICINE

The Honorable Sylvia M. Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Burwell,

We are writing on behalf of three of the foremost nationally recognized addiction medical specialty associations, representing more than 60,000 physicians, to express our concerns regarding proposals to raise the patient limits currently reflected by the Drug Addiction Treatment Act of 2000 (DATA 2000). Because our organizations are entrusted by the law to train prescribers and health professionals on the front lines of treating this public health crisis, we are in eager to work with the Department of Health and Human Services in order to develop recommendations.

As you are well aware, addiction to prescription drugs and heroin is a public health crisis. Yet, as the number of people addicted to these opioids increases, there continues to be a shortage of physicians who are appropriately trained to treat them.

The shortage severely complicates and impairs our ability to effectively address the epidemic, particularly in many rural and underserved areas of the nation.

We sincerely value and appreciate your interest in addressing this growing and complex problem. While we are aware of proposals to raise patient limits, the potentially adverse consequences of increased patient limits are of significant concern, including:

- proliferation of "pill mills" and the erosion of evidence-based treatment;
- inadequate safety monitoring to protect against diversion; and
- underutilization of evidence-based mental health and substance abuse counseling services.

As organizations authorized to train physicians to treat opioid use disorders, we strongly believe that all aspects of the problem and possible solutions should be fully evaluated and considered before moving forward with any proposed policy changes.

We believe that:

- There is a need to address this public health matter as a priority.
- The real complexities of addressing this issue go beyond increasing the patient limit.
- Simply increasing the per-prescriber patient limit is problematic even for addiction specialists; handling 100 buprenorphine-maintained patients in a clinically adequate manner is challenging. There must be frank discussions of multidisciplinary and other models that might better address the issue without adding undue risk for patients, or increasing regulatory scrutiny for all providers, which is against the spirit of DATA 2000.
- The right balance between patient volume and clinical responsiveness must be determined.

Our members are among the leading clinical experts in the treatment of opioid use disorders and are uniquely positioned to address these issues. We are currently formulating more specific recommendations and welcome an opportunity to work with you on how to effectively confront this public health crisis.

Sincerely,

Saul Levin, MD, MPH
CEO and Medical Director
American Psychiatric Association

Laurence M. Westreich, MD
President
American Academy of Addiction Psychiatry

Margaret Kotz, DO
President
American Osteopathic Academy of Addiction Medicine

Cc: Pamela Hyde, J.D., Administrator, SAMHSA
Elinore McCance-Katz, M.D., Ph.D., Chief Medical Officer, SAMHSA
H. Westley Clark, M.D., J.D., M.P.H., Director, Center for Substance Abuse Treatment
Michael Botticelli, Acting Director, ONDCP

Recommendations of the
American Psychiatric Association,
American Academy of Addiction Psychiatry, and the
American Osteopathic Academy of Addiction Medicine on
Revisions to the Drug Addiction Treatment Act of 2000

1. **Replace practice limits of 30/100 patients with a 3 tiered system:**

- **Tier 1: Small Primary Care or Psychiatry practices: physicians can follow up to 30 patients at one time, as with the present system.** There will be *NO DEA INSPECTIONS* unless DEA or single state agency review of state PDMP data suggests the 30 patient limit has been exceeded (or other violations of standard clinical practice regulations have occurred).

  Comment: DEA inspections are frequently mentioned as a reason for physicians not prescribing. This change should expand the number of small pre-

scribers. Data groups and SAMHSA should notify all individuals who have taken waiver training of this new option and widely publicize the change.

- **Tier 2:**
  - ***OPTION ONE—SOLO PRACTICE MODEL* (this practice can occur in a group setting, or multiple physicians can practice within the same system)**
  - **After 1 year of practice, physicians can apply to go up from the 30 patient limit to 150 patients.**
  - Prescribers in this group would be required to:

    1. take 3 hours of approved addiction related CME annually,
    2. certify that they follow a nationally recognized set of standard evidence-based guidelines for the treatment of patients with substance use disorders, and
    3. would be subject to occasional DEA inspections as in the current system.

    Comment: This tier is comparable to the current system. The increase to 150 patients would immediately address identified need for additional services but not increase the numbers in individual practices to a range that is incompatible with good clinical practice.

  - ***OPTION TWO—MULTIDISCIPLINARY PRACTICE***
  - **After 1 year of practice, a physician can apply to go from the 30 patient limit to a range of up to 340 patients with the addition of up to three physician extenders to the practice (Physician Assistant, Nurse Practitioner).** The physician would be capped at **100** patients, each physician extender would be capped at 80 patients, with the total practice capped at 180 to 340 patients depending on the number of physician extenders in the group. This group of practitioners would be required to:

    1. take 3 hours of approved addiction related CME/CEU annually,
    2. certify that they follow a nationally recognized set of standard evidence-based guidelines for the treatment of patients with substance use disorders, and
    3. be subject to occasional DEA inspections as in the current system.

    Physicians in this type of practice would be **required to be certified** in Addiction Psychiatry by the ABPN or in Addiction Medicine by ABAM or ASAM, or have subspecialty board certification in addiction medicine from the American Osteopathic Association (AOA), unless SAMHSA grants an exemption for non-specialists practicing in high-need rural areas.

    Comment: In this type of multidisciplinary practice the physician would be required to supervise the physician extenders. ***To allow for the time for required supervision, should the physician be capped at 80 patients? This would drop the total maximum number for the practice to 320.***

- **Tier 3: Practices that are over 340 patients would require separate registration as a specialized Opioid Treatment Program, and would be monitored accordingly** with varying staffing requirements related to the number of patients being treated, much more specific regulation of practice, and would be subject to periodic reviews by DEA and CARF or The Joint Commission. Physicians working in such a setting would be required to be certified in Addiction Psychiatry by the ABPN or in Addiction Medicine by ABAM or ASAM or have subspecialty board certification in addiction medicine from the American Osteopathic Association (AOA). SAMHSA/CSAT should call a meeting of the DATA groups, the DEA, CARF, The Joint Commission to work out the details of regulations for this class of OTP. Practices of this type could be staffed by one or more physicians and a mix of RNs, MSWs, PhDs, Pharmacists and drug counselors comparable to the staffing in a methadone maintenance program, or they could follow the staffing guidelines described for Tier 2/Option Two above.

  Comment: While this model is inconsistent with the intent of DATA 2000, it recognizes the need for expanded services and protects the integrity of the DATA 2000 system, which is much better suited for providing services that are integrated into standard mental health and primary care settings under the ACA.

2. **Permit buprenorphine prescribing by Physician Assistants and Nurse Practitioners** in those states or jurisdictions where such practice is permitted. Prescribers will be required to take a standard 8 hour face-to-face waiver course,

practice under the supervision of a physician certified in Addiction Psychiatry by the American Board of Psychiatry and Neurology (ABPN) or Addiction Medicine by the American Board of Addiction Medicine (ABAM) or the American Society of Addiction Medicine (ASAM) or have subspecialty board certification in addiction medicine from the American Osteopathic Association (AOA), (unless exempted by SAMHSA for non-specialists working in high-need, rural areas), and take 3 hours of approved addiction related CME/CEU annually. See Tier 2/Option Two above.

3. **Explore options under telemedicine that would permit delivery of buprenorphine services in rural or underserved areas.** Those telemedicine programs treating more than 340 patients will be held to Tier 3 standards.
4. **Additional Federal funds are needed for buprenorphine training for physicians and physician extenders, and for ongoing CME programs to enhance the clinical skills of treatment providers. Additionally, set-aside funding is recommended for residency training programs to provide training in Medication Assisted Treatment and would also provide physician training in MAT through funding additional ABPN-approved addiction psychiatry fellowships, as well as general practice addiction medicine fellowships.**
5. **Funds are also needed to cover the costs for an expanded treatment system for uninsured individuals with opioid use disorders, as well as those covered under Medicaid programs.**
6. **This program should be enacted for a trial period and re-evaluated in three years to determine if it is successful in expanding treatment capacity and whether increasing the number of patients treated by each waivered physicians has a negative impact on the quality of treatment, or a negative impact on public health associated with increased diversion of buprenorphine or other unanticipated negative consequences.**

BEACON HEALTH OPTIONS

Senate Finance Health Care Subcommittee

Investigation into opiate abuse epidemic

Field Hearing

Thursday, October 15, 2015

Allegheny General Hospital—Magovern Auditorium

320 E North Avenue, Pittsburgh, PA 15212

Testimony of Steve Bentsen, MD, MBA, DFAPA, Regional Chief Medical Officer, Board Certified in Addiction Medicine, Beacon Health Options.

Senator Toomey and members of the Subcommittee, my name is Steve Bentsen, MD, DFAPA, and I serve as Beacon Health Options' Regional Chief Medical Officer and I am certified by the American Board of Psychiatry and Neurology in Addiction Psychiatry. Thank you for the opportunity to testify before the Subcommittee today to discuss actions we are taking to address the opioid crisis.

About Beacon Health Options (Beacon).

Beacon is the largest mental health specialty company in America. We operate in 13 counties in western Pennsylvania as Value Behavioral Health of Pennsylvania in the HealthChoices managed Medicaid program. Overall the company serves 47 million people across all 50 states and the United Kingdom, including more than 13 million Medicaid and other publicly funded members across 26 states and the District of Columbia through direct-to-state contracts and 50 health plan partnerships.

Substance abuse is a chronic illness and should be treated through a chronic care model.

Beacon proposed in a recent White Paper that a chronic disease model of care is required to treat opioid addiction. This framework has been applied to other chronic conditions, such as diabetes and cancer. The White Paper is available online at

http://beaconlens.com/wp-content/uploads/2015/07/Confronting-the-Crisis-of-Opioid-Addiction.pdf. The six tenets set forth in the paper are as follows:

1. *Increase community resources and policies:* To really have impact, providers need to create partnerships with local groups including state agencies, courts, schools etc. to link resources and promote better health.
2. *Increase collaboration between payers and providers:* The relationship between purchasers and providers must prioritize chronic care over episodic care through alternative payment methods.
3. *Improve access to resources for self-management:* Promote verbal and written explanation of treatment options, alternatives, risks and benefits of all evidence-based treatments including Medication-Assisted Therapies (MAT)
4. *Improve design of delivery system:* Build a continuum of care based on the chronic care model; including ASAM's 10 levels of care and pain management services.
5. *Increase decision support:* Apply evidence-based clinical practice guidelines to MAT, including real time support for prescriber such as the MCPAP model for adults with substance use disorders.
6. *Implement clinical information systems:* Improve care coordination through EHRs. Create registries of MAT recipients and prescribers.

These tenets are summarized in chart below:

Element	Key components
Community resources and policies	▪ **Partnerships** in the community linking resources and bridging service gaps ▪ **Increased access** to providers trained in addiction ▪ **Workforce development** and **education** to shift public perception ▪ Community involvement in **prevention**
Health care organization	▪ **Alternative payment models,** with reimbursement tied to outcomes and chronic disease management ▪ Use of the **episode bundle**
Self-management support	▪ **Individuals as members of their own treatment team** ▪ Reinforcement of informed consent to support individual's **choice of treatment options**, including MAT
Delivery-system design	▪ An effective **continuum of care** ▪ **Care managers** to coordinate diverse providers and payers ▪ Adherence to **ASAM 10 levels** of care to determine effective care settings
Decision support	▪ **Provider education** on SA disorder services ▪ Engagement of **primary care community,** including early identification through screening and recognition of risk factors
Clinical information systems	▪ **Coordination of care through registries and EHR**, especially anonymous registries to track outcomes without deterring individuals from seeking treatment

Accepting opioid addiction as a chronic illness provides an evidence-based framework for a chronic care model that includes changes at all levels—clinical, social, legislative etc. We strongly support the increased use of evidence based practices in the treatment of substance abuse, such as cognitive-behavioral therapy, medication assisted therapy and contingency management interventions. Additional steps need to be taken to recruit, train and retain a strong workforce of treatment professionals to provide needed therapies for substance abuse treatment. At Beacon, we are working with various stakeholders to turn chaos into order in an organized, step-by-step fashion.

Scope of the substance use disorder problem in Pennsylvania.

We are in the midst of a national "Substance Abuse" crisis. The United States averages 110 overdose deaths from legal and illegal drugs every day. The heroin death toll has quadrupled in the decade that ended in 2013, according to the Centers for Disease Control and Prevention. By all accounts, it has only grown worse since. In Washington County, Pennsylvania there have been more than 50 fatal overdoses this year with a number occurring in a single 24 hour period, according to local news accounts. Unfortunately there are similar stories in other counties in Pennsylvania as well as nearby states.

Opioids, both in prescription drug form as well as illicit sources such as heroin, are taking an enormous toll on all of our communities. A recent report published by the Trust for America's Health and the Robert Wood Johnson Foundation showed that Pennsylvania is near the top in the nation for drug overdose deaths. In fact, death from drug overdoses now exceeds death from car accidents in Pennsylvania (and 35 other states). No socio-demographic group is being spared. We see reports of young, middle-aged and older people dying of these drugs. The demand for substance abuse services in the communities we serve has sky-rocketed. And unfortunately, many of the people who need treatment are still not seeking it due to a lack of information about treatment or the negative stigma that is still attached to drug abuse and addiction. We are working closely with local counties, providers, oversight groups, state officials, law enforcement, education and consumer advocates to help confront this crisis. We believe that a concerted and cooperative effort is one of our strongest weapons.

One example of a successful initiative we undertook involved helping people stay in treatment once they were admitted. We have seen a number of people leaving rehabilitation programs without the ongoing transitional services or resources in place to sustain recovery or leaving before program completion due to lack of engagement. This can lead to early relapse and readmission or death. Through a cooperative effort with counties, oversight bodies and providers, an innovative series of initiatives were implemented including: the use of motivational interviewing, focusing more on individuals early in treatment when the against medical advice (AMA) rate is high, improving weekend programming, better matching with therapists, better use of peers, family members, and other social supports to name just a few. Our work showed improvements in treatment retention with significant decreases in individuals leaving against medical advice including: a 39% decrease in premature discharges from short term residential treatment, a 46.5% decrease on long term residential treatment and a 50% decrease in premature discharges among individuals in short term dual diagnosis residential treatment programs. This demonstrates that we can make a difference when we focus on specific areas in need of improvement and when we work cooperatively. We have also provided substance abuse trainings to emergency departments and mental health units. In addition, we have recently completed a best practice guidelines for Suboxone prescribers.

Recommendations for federal action.

Increasing access to treatment—including MAT services.

There are currently three FDA-approved medications for the treatment of opioid dependence and relapse prevention. Scientific research has shown that these medications are an effective component of treatment, decrease the risk of future overdose and should be made available to all patients as part of a comprehensive treatment plan that includes counseling and behavioral interventions. In addition we support availability of rescue naloxone. Congress has already taken some steps to increase the use of MAT, appropriating $12 million in the FY 2015 budget for states to expand access to opioid treatment services where MAT is an allowable use. SAMHSA has already released a Request for Application for this grant, and states have applied. The Administration has proposed doubling this funding to $25 million in FY 2016. I encourage Congress to consider appropriating this additional funding given the serious challenges that states face in responding to this epidemic.

Better Physician training, member awareness, and increased efforts that promote alternative pain strategies to opioid prescription for pain management.

We need to focus on function (rather than pills), cognitive and behavioral approaches, and non-opioid medications and devices. Physicians receive little to no training about substance use disorders during medical school. As a result, it is reasonable to believe that this lack of understanding has likely contributed to the significant increases we've seen in prescriptions for opioid pain relievers during the last decade despite their significant risks. We need to include primary care physicians in the screening of individuals and educate them on recognizing the signs of addiction. Members should also be messaged regarding the appropriate non-opiate treatments available for acute pain. Providers who say no to opiate medications should not risk negative patient satisfaction ratings. Beacon proposes that addiction be deemed a primary care specialty. In addition, there needs to be better training in the areas of diagnosis, treatment and referral of individuals with opioid dependence. Moreover, Beacon recommends that changes be made to the 42 CFR Part 2 confidentiality regulation to allow sharing of addiction-related information about patients for the purposes of care management and coordination.

Linkage to treatment.

In many cases identification of substance use does not result in treatment engagement. Use and provision of rescue naltrexone is an opportunity for engagement but rarely occurs. Frequently health care providers are unsure how to refer a member for substance use treatment when overuse is identified. In addition, as mentioned above, a significant number of patients who complete detoxification services do not engage in recommended treatment post discharge. We have found in pilot programs provision of case management and/or community peer supports significantly increases engagement and retention in treatment with resulting decrease in hospital readmissions. Due to fragmentation in the current substance use treatment system, Beacon recommends use of case management and peer support services for treatment engagement. Case management services can also enable care linkages for medical and psychiatric co-morbidities which are common in members with substance use conditions.

Innovating in reimbursement models that focus on quality, rather than quantity, of service.

Relative to the treatment of hypertension or diabetes, there is a significant disparity in the provision of best practice care for those receiving substance use services. Reimbursement models can improve this disparity. The specifications for provider performance would target outcomes, member engagement and movement along the continuum to less restrictive, intensive, community-based services, and ultimately, maintenance treatment. An "episode bundle" would pay a provider a flat set amount for a continuum—for example, detox, rehabilitation step-down and two months of outpatient treatment, followed by a year of follow-up care. Over that continuum, the provider would be held to quality outcomes, such as detox readmission, therapy completion and self-reports by members. Beacon would like to see the use of more flexible payment strategies used to support better treatment and outcomes.

Conclusion

We commend Senator Toomey for identifying the opioid issue as a top priority and appreciate Congress' commitment to holding this hearing to continue this important dialogue. Our current health care system needs to recognize the chronic disease of opioid addiction and combat the opioid crisis with solutions like those set forth above. Support by all stakeholders is required to confront and address this crisis. Thank you.

LETTER SUBMITTED FOR THE RECORD BY
ALLAN W. CLARK, M.D.

October 7, 2015

The Honorable Pat Toomey
Chairman, Senate Committee on Finance
Subcommittee on Health Care
248 Russell Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
Ranking Member, Senate Committee on Finance
Subcommittee on Health Care
731 Hart Senate Office Building
Washington, DC 20510

Dear Chairman Toomey and Ranking Member Stabenow,

I submit this statement for the record on behalf of the patients and families in southwestern Pennsylvania, northern West Virginia, and eastern Ohio. I have been providing psychiatric care to adults, children and their families in this small part of our country for 30 years. As a result of the current epidemic in opiate drug misuse and overdose deaths, I have focused my medical practice to treatment of Opiate Use Disorders and the other mental health problems frequently associated with substance use disorders for the last 8 years.

Through the determined work of our patients, dedicated physicians, and legislators in the House and Senate, these patients are recovering the quality of life lost. It reminds me that Americans have always overcome national crises through their selflessness and unity of purpose.

The passage of the DATA 2000 Act delivered an effective, evidenced-based and accessible treatment (buprenorphine products) for Opiate Use Disorders to the medical office. The position paper I submit to the Subcommittee describes a model of care for these patients informed by current research, practical experience in service delivery and patient response to interventions. I suggest that this model which minimizes the problems that have arisen with the use of buprenorphine in the medical office while keeping those interventions which have shown great promise. It is my intent, through submission of this paper, to do my part as a citizen and expert in the treatment of addiction, in providing the Senate Subcommittee on Health Care with testimony which may assist members in the important decisions which lie ahead in the area of the treatment of Opiate Use Disorders and resolution of the current opiate misuse crisis.

In the spirit of disclosure, I attest that I receive no money from any company, agency or insurance group which may or may not benefit from the model of treatment for Opiate Use Disorder described. As an Air Force veteran, I believe service to country is its own reward.

Respectfully submitted,

Allan W. Clark, M.D.

Quality and Outcomes Management in the Treatment of Opiate Use Disorder with Buprenorphine Products

Allan William Clark, M.D.

ABSTRACT

In the U.S. we face yet another public health crisis. Although smoking and obesity related deaths far surpass all other causes of death in this country, death rate due to prescription opiates increased 3-fold from 2001 to 2013, and heroin overdoses increased 5-fold during the same time period.

At the same time, recent legislative actions (Affordable Care Act 2010, Mental Health Parity and Addiction Act of 2008) are reshaping they way in which mental health care and addiction treatment are delivered in the U.S.

The Mental Health Parity and Addiction Act of 2008 "requires group health plans and health insurance issuers to ensure that financial requirements (such as co-pays, deductibles) and treatment limitations (such as visit limits) applicable to mental health or substance use disorder (MH/SUD) benefits are no more restrictive than the predominant requirements or limitations applied to substantially all medical/surgical benefits. MHPAEA supplements prior provisions under the Mental Health Parity Act of 1996 (MHPA), which required parity with respect to aggregate lifetime and annual dollar limits for mental health benefits."

The Affordable Care Act 2010 (ACA) empowered the Department of Health and Human Services (HHS), under Congress oversight, to develop a National Quality Strategy (NQS) to better meet the promise of providing all Americans with access to health care that is safe, effective, and affordable.

The author will review current efforts and strategies developed thus far by SAMSHA as part of a NQS as they may apply to the use of buprenorphine products in treatment of Opiate Use Disorder. Specifically, the author suggests a quality management strategy that links providers with these national strategies.

INTRODUCTION

Opiate Use Disorder is defined in the DSM–V as "a maladaptive pattern of substance use leading to clinically significant impairment or distress" as manifested by 2 or more symptoms from a list of 11 core symptoms. Buprenorphine and buprenorphine/naloxone for the treatment of DSM–V Opiate Use Disorder in the outpatient medical office has been controversial. Despite promising data regarding efficacy and safety, concerns about misuse, diversion, and quality of care persist. Clinics that specialize in the care of patients with Opiate Use Disorder are viewed with suspicion (New York Times 2013). Insurance companies, private and public, concerned over the cost of treatment, restrict dose or duration of the buprenorphine treatment in an effort to control costs and increase profit. Pharmacists feel new pressures to verify prescriptions in the wake of legal consequences faced by Wallgreens and other pharmacies sanctioned for their role in the development of Florida "pill mills" (*Wall Street Journal,* April 2012). Physicians and hospitals are reluctant to use buprenorphine in the outpatient setting due to the requirement for

DEA inspections without "probable cause." The DATA 2000 amendment requires physicians to comply with random inspections by agents of the DEA to verify compliance with the law. Normally, law enforcement would not be allowed to inspect a physician's practices unless they were able to obtain a warrant by a judge.

Quality of service management and outcome assessments could provide the relevant clinical information needed to address the current dilemmas. In fact, the development of quality delivery measures and strategies for outcomes research form the foundation of the current U.S. healthcare reform. In 2010, the Patient Protection and Affordable Care Act (PPACA—or ACA) charged the U.S. Department of Health and Human Services (HHS) with developing a National Quality Strategy (NQS) to better meet the promise of providing all Americans with access to health care that is safe, effective, and affordable. The Secretary of HHS reported to Congress in March 2011 on a National Strategy for Quality Improvement in Health Care. Over the last 2 years, the Substance Abuse and Mental Health Services Administration (SAMHSA), using the National Strategy for Quality Improvement (NQS) as a model, has developed the National Behavioral Health Quality Framework (NBHQF). The NBHQF has been noted in the NQS Report to Congress as an important effort in development of credible research on the critical concern over availability and safety of current treatments for mental health and substance use disorder.

In this draft, SAMSHA, "recognized that relatively few acceptable outcome measures exist that are endorsed through NQF or other relevant national entities for mental health disorders." The current leadership in behavioral health care quality encourages a collaborative relationship between all stakeholders in the development of new measures as evidence accrues. They add, "over time, it is expected that a rich catalog of behavioral health outcome, process, and structural measures will be endorsed and/or accepted as achieving the appropriate level of evidence by the field and payers."

By contributing to development of new quality measures in our treatment of patients with Opiate Use Disorder, we add much needed clinical expertise to the critical process of "achieving the appropriate level of evidence" acceptable to all stakeholders.

REVIEW

Medication-Assisted Treatment of Opiate Use Disorder with buprenorphine is an emerging treatment born out of the DATA 2000 Act allowing buprenorphine and buprenorphine/nalaxone combination use in outpatient medical practice. Led by an unusual public/private partnership between SAMSHA and Reckitt Benckiser (drug manufacturer), this project's aim was to improve accessibility and decrease stigma for patients seeking treatment of Opiate Use Disorder. Twenty-four randomized controlled trials (RCTs) comparing buprenorphine to methadone in the maintenance treatment of opioid dependence with a total number of 4,497 participants were included in a 2008 Cochrane systematic review and meta-analysis. The main outcome measures were treatment retention and suppression of illicit opioid use. Results indicate buprenorphine is more effective than placebo and as effective as methadone with both drugs being more effective at higher doses. As part of a comprehensive treatment program, MAT (medication-assisted treatment) has been shown to: [1]

- Improve survival.
- Increase retention in treatment.
- Decrease illicit opiate use.
- Decrease hepatitis and HIV seroconversion.
- Decrease criminal activities.
- Increase employment.
- Improve birth outcomes with perinatal addicts.

An analysis of French overdose deaths between 1995 and 1998 found an average annual death rate of 0.47% for patients taking methadone, compared with 0.05% for buprenorphine. In the United States, the danger of overdose was addressed by the addition of nalaxone to the formulation. When injected, buprenorphine/naloxone may cause an initial dysphoria due to brief opiate receptor blockade. Buprenorphine/naloxone combination was the preferred formulation to avoid problems with intravenous use and death found in Europe.

Physicians who use these medications in the office for opiate dependence must follow specific protocols in the course of treatment. For example, the DATA 2000 Act acknowledges the importance of psychosocial interventions in the treatment of ad-

[1] See reference number 1.

diction. DATA 2000 states, "the physicians must attest that they have the capacity to refer addiction treatment patients for appropriate counseling and other non-pharmacologic therapies." The "assisting" treatments typically include substance abuse counseling, group therapy, 12 Step self-help groups, and other social supports. The guidelines for the use of buprenorphine for Opiate Use Disorder published by the World Health Organization states, "psychosocial interventions can add to the effectiveness of treatment." Further, they recommend that psychosocial services should be made available to all patients, although patients who decline these services should not be denied access to medication.

The NBHQF framework has identified six NQS health priorities or goals (evidence-based practice, person-centered care, coordinated care, reduction of adverse events, and cost reductions) that will be tracked via a set of core behavioral health quality measures. SAMSHA specifically intends that this document be a "guiding document" for the delivery of behavioral healthcare. SAMHSA has been working with the HHS Assistant Secretary for Policy and Evaluation, CMS (Center for Medicare and Medicaid Services) and NQF to develop measure concepts and to vet and validate measures or instruments for measure development.

The NQF (National Quality Forum) is a non-profit, non-partisan public service organization. NQF reviews, endorses and recommends use of standardized healthcare performance measures. Performance measures, also called quality measures, are essential tools used to evaluate how well healthcare services are being delivered. NQF endorsed measures that "are often invisible at the clinical bedside but quietly influenced the care delivered to millions of patients everyday." The participation by groups such as the NQF, representing a wide range of stakeholders, insures outcome measures can fulfill the stated expectation of this collaborative group to "seek meaningful, real life outcomes for people who are striving to attain and sustain recovery; build resilience, and work, learn, and participate fully in their communities."

At this early phase of behavioral health quality measurement development, it is understood that the available measures are insufficient to provide meaningful information in all behavioral health care settings.

Most of the currently approved NBHQF quality measures are "process measures." "Processes" are specific patient interventions performed by health care professionals that result in an particular outcome. Process measures are frequently used in performance measurement. Process measures are generally much easier to construct, require less data collection and analysis to produce, and are easier for both clinicians and non-clinicians to understand. Many performance measurement systems, such as the Health Plan Employer Data Information Set (HEDIS), are primarily measures of process of care. Process improvement, when linked to processes proven by randomized clinical trials to improve outcomes, is an important part of continuous quality improvement (CQI). Implementation of CQI programs based on process improvement can reduce variation and enhance patient care.

Practice guidelines for the treatment of illness were developed for this purpose. Many practice guidelines (Federation of State Medical Boards, American Psychiatric Association, American Society of Addiction Medicine) use a grading system to link the strength of the empirical data to the specific guideline. Recommendations to initiate and monitor a process (intervention) are made based upon the strength and quality of the research linking the intervention to desired outcome.

In these systems, an "I" (Roman numeral I) or "A" is given to those guidelines, or process measures, that are recommended "with substantial confidence" to produce desirable outcome based upon large randomized clinical trials. For example, one of the NBHQF process measures looks at the percentage of patients diagnosed with a new episode of major depression, treated with an antidepressant medication, and who remained on an antidepressant medication treatment for 6 months. Several large random clinical trials support this strongly indicates quality outcome defined as reduction of depressive symptoms.

A "II" (Roman numeral II) or "B" rating is given to guidelines, or process measures, that have support from observational studies or small randomized clinical trials. An example of this type of guideline is the Management of Substance Use Disorder published in 2009 by the VA/DoD. They recommend that identifying and addressing other biopsychosocial problems may be more effective than increasing the intensity of addiction focused treatments when a patient has a lapse or minor "slip."

Finally, a "III" rating denotes those guidelines or process measures that are developed from expert opinion but which have little scientific evidence to support the process indicators (*e.g.,* the Agency for Healthcare Policy and Research's low back

pain guidelines, most of which is supported by expert opinion). Essentially, practice guidelines such as those described above and the NBCQF constitute a outcome management strategy.

In his classic article, Ellwood coined the term outcomes management as "a technology of patient experience designed to help patients, payers, and providers make rational medical care-related choices based on better insight into the effect of these choices on the patient's life." Further, he states that this technology "consists of a common patient-understood language of health outcomes; a national data base containing information and analysis on clinical, financial, and health outcomes that estimates as best we can the relation between medical interventions and health outcomes, as well as the relation between health outcomes and money; and an opportunity for each decision-maker to have access to the analyses that are relevant to the choices they must make."

Further guidelines have been published by SAMSHA to aid in the development of relevant measures. To the extent possible, measures included in the NBHQF will:

1. Be endorsed by NQF or other relevant national quality entity where possible;

2. Be relevant to NQS and NBHQF priorities;

3. Address "high-impact" health conditions;

4. Promote alignment with program attributes and across programs, including health and social programs, and across HHS;

5. Reflect a mix of measurement types: outcome, process, cost/appropriateness, and structure;

6. Apply across patient-centered episodes of care; and

7. Account for population disparities.

With the above background, we now may begin to consider useful measures for the outpatient medical office using buprenorphine products for the treatment of Opiate Use Disorder. I will organize this discussion around the five health care priorities designated by the U.S. Department of Health and Human Services.

The first priority is to ensure healthcare interventions are effective. The goal specifically aims to "promote the most effective prevention, treatment, and recovery practices for behavioral health disorders." SAMSHA places a heavy emphasis on the inclusion of interventions shown to be effective in large randomized clinical trials. Measures within this group focus on processes or clinical interventions strongly linked to substantial empirical evidence for quality outcome. An example of outcomes management in action is the currently approved COMS process measure involving treatment of major depression. There is substantial clinical evidence that proper use of an antidepressant results in a desirable outcome for patients suffering from major depression. In all practice guidelines, this recommendation is categorized as I or A. As such, given the high prevalence and impact of major depression, this was chosen and approved as a process measure. In this case, the NBHQF targets percentage of patients diagnosed with major depression who receive antidepressant treatment.

Several different accrediting bodies have developed practice guidelines for use of buprenorphine in the office using the above described grading system. These guidelines organize current empirical evidence demonstrating reduction of opioid use, reduction of opioid-related health and social problems, and better engagement and retention in treatment with the use of buprenorphine. As with the use of antidepressants for Major Depressive episodes, a patient who presents with depression may choose cognitive behavioral therapy or other treatments which have been shown empirically to reduce depressive symptoms instead of an antidepressant. Other patients may chose to take an antidepressant and engage in one of theses other psychosocial treatments. The point is not that every patient suffering from Opiate Use Disorder take buprenorphine, but that they are given a choice of interventions based upon empirical evidence. The ability to provide buprenorphine treatment to any patient for which it is indicated is a measure of quality care.

A second "high impact" and well researched process is the identification and treatment of co-morbid psychiatric diagnosis in persons suffering from Opiate Use Disorder. Coexisting psychiatric disorders are present in 20% to 60% of the persons entering addiction treatment, especially older individuals, those living in urban areas, patients who are incarcerated, or patients of a lower socioeconomic status. Presence of major depression is linked to poor outcome in patients suffering from Opiate Use

Disorder, as well as many other indicators of health (heart disease, stroke).[2] Regularly monitoring of depressive and anxiety disorders in patients with Opiate Use Disorder allows the providers to identify and address these potential obstacles to satisfying recovery. Unless comorbidity is taken into consideration, measures of the outcome of treatment for opiate addiction will fail to tease apart the possibility of better outcomes of patients with no comorbidity, thereby compromising a fair test of treatment effects. The identification, monitoring, referral and/or treatment of comorbid conditions signals quality of care in the treatment of Opiate Use Disorder for the above reasons as delineated in the practice guidelines.

As we have discussed, the NQF has challenges providers to develop outcome measures which "seek meaningful, real life outcomes for people who are striving to attain and sustain recovery; build resilience, and work, learn, and participate fully in their communities." Several promising surveys to measure this concept are being developed by the WHO (World Health Organization). The WHO Quality of Life instruments define health as "a state of complete physical, mental, and social well-being, not merely the absence of disease." WHO, with the aid of 15 collaborating centers around the world, has developed 2 interments for measuring quality of life (the WHOQOL–100 and the WHOQOL–BREF), that can be used in a variety of cultural settings while allowing the results from different populations and countries to be compared. Both instruments show good discriminant validity, content validity, and test-retest reliability. The routine use of the QOLBREF in the treatment of Opiate Use Disorder and comorbid conditions provides crucial data with which to ensure that the interventions which the patients chooses are effective.

In summary, under the priority of effective care, we attach measures to processes which have substantial clinical evidence supporting our outcome goals.

- Percent of patients diagnosed with Opiate Use Disorder offered buprenorphine as part of their overall treatment.
- Percentage of patients presenting for Opiate Use Disorder who receive a comprehensive psychiatric evaluation to identify comorbid diagnosis.
- Monthly assessment using PHQ–9 and GAD–7 to monitor for these syndromes as treatment progresses.
- Monthly urine drug analysis.
- QOL BREF every 6 months.

The second healthcare goal identified is person-centered care. Morris Chavez, M.D. in the 1950s at the Massachusetts General Hospital Alcoholism Clinic was able to dramatically improve engagement and retention in treatment of alcoholics presenting to the MGH emergency room using novel interventions considered patient-centered. He concluded that these patients achieved better outcome when they received "caring and organized" treatment. The concept of person-centered care has gained considerable momentum in current healthcare reform. This has become a key determinate of quality care. Large randomized clinical trials have shown that engagement and retention are crucial to the recovery process from mental illness and substance use disorders.

SAMSHA's Working Definition of Recovery from Mental Disorders and Substance Use Disorders revised in 2011 describes 10 Guiding Principles of Recovery. These person-centered concepts were vetted by SAMSHA with consumers, persons in recovery, family members, advocates, policy-makers, administrators, providers and others. In this manner, concept validity was established for this dimension of quality care. The Patient Assessment of Care for Chronic Conditions published by Group Health (PAIAC) measures patient engagement in care. It is a self-administered assessment asking questions about were they given a written list of things they could do to improve their health, were they encouraged to go to a group to help them cope better with a their chronic condition, and asked how the chronic condition effects their life. It consists of 20 questions answered on a Likert scale. Higher scores signify better engagement. The problem with this measure is that it is designed to be scored by an independent agency for reasons of confidentiality and candor. As an alternative one could gather this extremely useful data while preserving confidentiality. This would allow for outside agency review in an HIPAA compliant manner when requested.

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[2] See reference number 2.

The inclusion of a competent family/social network assessment at onset of treatment is recommended in the NBHQF draft. Again, this is an evidenced based process indicator strongly linked to better outcome in several large randomized trials and has been included as a recommendation in two practice parameters addressing buprenorphine use for Opiate Use Disorder.[3] The stronger the link between family/social network assessment and targeted intervention aimed to strengthen resiliency and mitigate vulnerabilities the better the outcome. Thereby, presence of this assessment in the EHR signals a quality process linked to quality outcome.

Recommended measures targeting the evidence base currently available would include:

- PAIAC every 6 months.
- Presence of competent family/social network assessment at onset of treatment in the EHR.

The third priority is "to encourage effective coordination within behavioral health care, and between behavioral health care and community-based primary care providers, and other health care, recovery, and social support services."

One process in the treatment of those with Opiate Use Disorder that we may chose to monitor relates powerfully to this aspect of care is ensuring that those suffering from addiction is ensuring that care is coordinated with other mental healthcare providers. With high percentages of co-occurring psychiatric disorders, these patients often seek and are engaged in mental health treatment which may include prescription of potentially abusable medications. For example, patients may fear telling the physician prescribing buprenorphine of their alprazolam prescription because they think the doctor will take it away abruptly. At times of crisis, patients may see their PCP for "emergency" medication contraindicated in the treatment of the Opiate Use Disorder. For these reason, the following process measures appear to have the most support.

- Percent of patients who have had co-treating physicians notified of their ongoing treatment for Opiate Use Disorder.

The fourth priority is to "assist communities to utilize best practices to enable healthy living." One of the NBHQF measures involves the presence of an assessment of tobacco use and, if indicated, a tobacco cessation intervention. These measures are included to promote preventive care across the broad spectrum of health care services. Body mass index at onset of treatment and at regular intervals has also been included in the NBHQF under this goal for similar reasons. Obesity is the major preventable cause of illness in the U.S.[4] Regular monitoring of weight in behavioral health care is quite common given the propensity of many psychiatric medications to cause weight gain. Patients seeking treatment for Opiate Use Disorder with buprenorphine often come with a long list of psychiatric medication, and have trouble maintaining a healthy weight. One could debate the wisdom of initiating treatment for Tobacco Use Disorder, Obesity, and Opiate Use Disorder at the same time. However, assessment and monitoring of these high impact problems allows for the discussion to be postponed until the patient may be better equipped or motivated to address these health concerns. The recommended measures under this priority would be:

- Presence of screening or intervention/treatment for tobacco use in EHR.
- Body Mass Index on intake and every 6 months.

The fifth priority is safety. The goal aims to "make behavioral healthcare safer by reducing harm caused in the delivery of care." NBHQF measures include presence of suicide risk assessments, patients discharged on multiple psychiatric medications, and percentage of patients engaged in behavioral health treatment hospitalized for overdose.

Diversion and misuse of buprenorphine is a major safety concern in the treatment of Opiate Use Disorder to individuals and the community. Some patients attempt to use buprenorphine intravenously. This practice may lead to the addition of intravenous benzodiazepines, overdose and death. Another danger of buprenorphine treatment is diversion. Patients who falsely present for treatment of Opiate Use Disorder with the intention of selling this medicine for profit and fund further illicit drug use. One could make an argument for inclusion of pill counts into the treat-

[3] See reference number 3.
[4] See reference number 4.

ment process. Pill counts can aid in determining compliance with medications in the absence of reliable blood levels. Pill counts are a reasonable method to detect diversion of medication prescribed to a patient. This allows for investigating suspicions in higher risk patients and routine monitoring of the patient population as well. Pill counts can go along way to reassure partners in the treatment of our patients that diversion is being effectively addressed. Pill counts done at the pharmacy dispensing the prescription for buprenorphine is particularly helpful in reassuring pharmacists the provider is responsible addressing diversion.

Should all patients enrolled in a clinic be given regular random pill counts? Until further information is available perhaps we may track the percentage of patients in the practice receiving pill counts in a month. Standardizing pill count practices and procedures would give the practitioner and other stakeholders critical data in the quest for safely delivered care. For example, a written office protocol where in clinic staff members ask the patient to go to their pharmacy for the count within a short period of time (1 hour). We take into consideration factors like the patient needing to go after work, distance to pharmacy and other related obstacles. We have found it essential to verify claims that a patient must wait until after work to comply with the pill counts. We have found instances where the patient was not at work as they said. This process, in conjunction with patient cross referencing to State Prescription Monitoring Programs, provides a formidable defense against diversion. In the absence of vetted and validated measures, the following is recommended:

- Percentage of active patients pill counted per month.
- Use of State Prescription Monitoring programs.

Although listed as the last criterion, the importance of affordability is critical. The NBHQF goals' stated purpose is to "foster affordable high-quality behavioral healthcare for individuals, families, employers, and governments by developing and advancing new and recovery-oriented delivery." Methadone treatment studies since 2006 have shown cost-effectiveness when compared with other treatments, and cost effectiveness for HIV prevention. Buprenorphine has been studied much less, but available studies are very encouraging as this medication appears to be cost-effective as well.[5] With the development and wide spread use of outcome measures which better capture the quality of life outcomes achieved via different interventions, cost/benefit data will become increasingly relevant. Until that time, aggregated data regarding the cost per patient per month or year maybe the most useful and easily provided data that can be shared with all stakeholders.

CONCLUSIONS

Wisely chosen quality measures as part of an outcome management strategy can guide us through the treacherous waters of health care reform. SAMSHA and other thought leaders have developed the NBHQF as a way to coordinate efforts nationally in this arena. This framework allows for the development of a common language or method to report data satisfying to all stakeholders. The current efforts in behavioral health care reform are designed to be a cooperative process. We have a choice between focusing on the current controversies in the use of buprenorphine in the medical office, and perhaps abandon efforts to increase access and availability of this promising approach, or we may use the legitimate questions posed by stakeholders as a stimulus to find workable solutions. In either case, we must recognize that we have an critical role in healthcare reform. Joining the current efforts appears to be the way forward in the second decade of use of buprenorphine in the outpatient medical office.

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Tuesday, October 13, 2015

Senator Pat Toomey
C/O Katelyn King Lamm
Regional Manager for Southwest Pennsylvania
Landmarks Building
100 W. Station Square Drive, Suite 225
Pittsburgh, PA 15219

Dear Senator Toomey:

Thank you for hosting the Senate finance Subcommittee on Health Care Field Hearing in Pittsburgh. I would like to take this opportunity to address the opiate addiction epidemic in western Pennsylvania and specifically the Greater Johnstown region.

I am a family physician and serve as Chair of the Department of Family Medicine and direct the Conemaugh Memorial Medical Center Family Medicine Residency. Within our office, we provide a Ryan White funded HIV clinic and a suboxone program.

Each day I see our patients suffering from the ravages of opiate abuse. As I rounded today, a patient wanted to make sure she could be discharged tomorrow to attend the funeral of a friend's son who just died of an overdose. This is becoming evermore-common. Within our practice we are frequently admitting patients with infected injection sites. One patient had her finger amputated as the infection traveled to her bone.

In our Level 3 NICU, generally 60% or more of the babies are being treated for methadone or heroin withdrawal. These children are so jittery. Parenting a newborn is always a challenge; I cannot imagine how these parents struggling with their own addiction now try to parent these extremely fussy newborns. From a health care utilization perspective, the cost of treating these babies is enormous.

As physicians are trying to limit prescription drug access we are seeing patients turn to cheaper heroin. It is not uncommon that users of heroin share needles or engage in unprotected sex. These practices may result in transmission of HIV or hepatitis C. Such practices could result in an epidemic in our region similar to the ongoing situation in Austin, Indiana where a drug fueled outbreak has led to 153 confirmed HIV cases. As you are likely aware, the Centers for Disease Control and Prevention recently issued a health advisory alerting states, health departments, and doctors nationwide to be on the lookout for clusters of HIV and hepatitis C among intravenous drug users and take steps to prevent them. Our region has little access to hepatitis C treatment. We are seeing many young people who are infected and likely spreading the infection to their peers. We are also seeing Hepatitis C in our pregnant mothers.

We need help to combat this problem. Our drug treatment facilities are overburdened. Even law enforcement struggles to keep up. Needle exchanges are not legal in our state.

I thank you for the opportunity to share my experiences and concerns.

Sincerely,

Jeanne Spencer, MD, FAAFP, AAHIVS
Chair of Family Medicine
Program Director, Family Medicine Residency Program
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TESTIMONY

Before The

UNITED STATES SENATE

COMMITTEE ON FINANCE

SUBCOMMITTEE ON HEALTH CARE

FIELD HEARING

On

OPIATE ABUSE IN SOUTHWESTERN PENNSYLVANIA

On

OCTOBER 15, 2015

Mr. Chairman and committee members, I would like to thank you for the opportunity to speak with you about opioid addiction. My name is Cindy Pigg. I am a Pharmacist and Vice President of Pharmacy at Gateway Health Plan and serve on the Board of the Academy of Managed Care Pharmacy. Headquartered in Pittsburgh, PA. Gateway Health is a Managed Care Organization that has served the Commonwealth's Medicaid and Medicare Advantage population for over 20 years. Our mission embraces quality, innovation, and financial soundness. We are the second largest participating plan in the statewide Medicaid *HealthChoices* Program delivering quality care to more than 300,000 PA Medicaid beneficiaries in 40 counties. Gateway Health's[SM] robust provider network encompasses more than 9,000 physicians and 100 hospitals. We also serve over 50,000 Pennsylvanians in 32 counties who are qualified for Medicare Advantage Special Needs Plans (SNPs). These individuals are those who are either dually eligible for Medicare and Medicaid or have chronic conditions such as diabetes, cardiovascular disorders or chronic heart failure. Many have physical disabilities as well as behavioral health issues.

AMCP is a national professional association of 7,000 pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to assist patients in achieving positive therapeutic outcomes. In Pennsylvania alone, we have over 480 active members. AMCP's members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

Studies and reports document the opioid abuse problem in Pennsylvania and nationwide

According to the Centers for Disease Control and Prevention (CDC), deaths associated with prescription medications have increased more than 300 percent since 1998, while prescribing rates for these drugs quadrupled between 1999 and 2010. Deaths connected to prescription drug misuse now exceed those from heroin and co-

caine combined.[1] The Pennsylvania Medical Society reports that more Pennsylvanians die from drug overdoses than from any other type of injury, including car accidents.[2] In 2014, that's 2,400 deaths attributed to drug overdoses, or 7 people a day in Pennsylvania.[3] Moreover, the economic costs of prescription drug abuse are substantial. The nonmedical use of controlled substances amounts to $73 billion annually in unnecessary costs, including lost productivity, increased costs to the criminal justice system, and health care expenditures.[4, 5, 6]

Rates of prescription drug abuse related to emergency department visits and treatment admissions have reached epidemic levels in the United States. All too often, many of us know someone who is battling drug addiction. There is a definite need for action on many fronts to address this growing concern. Patients, providers, patient family members, health plans, community based organizations, employers, and government must all work together to formulate and implement solutions.

S. 1913—a solution that addresses a program where abuse has been documented

One area where change can be affected is in the Medicare Part D program. That Program does not currently permit the use of a drug management program (DMP) by prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MA–PD) to limit patients with a history of abuse, misuse or diversion to a single prescriber and/or pharmacy.

In terms of the impact to beneficiaries, a 2012 CMS study found that less than 1% of beneficiaries would be directed into a DMP. The study further found that only 0.7% of Medicare Part D beneficiaries received opioids from at least 4 prescribers and 4 or more pharmacies, signaling a high-risk patient.[7] (Those beneficiaries in hospice or those with a diagnosis of cancer were excluded from the study.) In essence, DMP programs help to mitigate the issues associated with doctor or pharmacy shopping and may reduce the number of inappropriate controlled substance prescriptions.[8] The limited number of beneficiaries that may be included in the DMP is encouraging because it is an indicator that the majority of beneficiaries in the Program will not have any change in their prescriber or pharmacy. On the other hand, that small group of beneficiaries that are at-risk, will have an opportunity to receive better coordination of care by the prescriber, pharmacy and PDP working together through the DMP.

Senator Toomey's bill S. 1913, Stopping Medication Abuse and Protecting Seniors Act of 2015, would allow PDPs and MA–PDs to proactively identify individuals at risk for controlled substance abuse, misuse or improper utilization. The Secretary of Health and Human Services (HHS) would determine the criteria for the "at risk" designation. The plans would work with a beneficiary's prescriber and give the beneficiary notice that they had been identified as a potential participant for enrollment in a drug management program (DMP). The beneficiary has appeal rights and can submit their preference of a specific prescriber and pharmacy. The use of DMPs may improve continuity of care among at-risk plan beneficiaries, while ensuring beneficiaries with legitimate medical needs have continued access to effective pain control. Furthermore, at risk beneficiaries are still able to receive non-controlled prescriptions at other pharmacies and from other prescribers. Another advantage of a DMP is that it works as prospective identification program allowing the plan to act in real time; as opposed to a retrospective program which combs through past data to find anomalies.

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Prospective Drug Management Programs (DMPs) are more beneficial to the patient

In 2013, CMS launched a federal initiative called Medicare Part D's Overutilization Monitoring System (OMS) to partner with PDPs and MA–PDs to identify Medicare beneficiaries who may be misusing or abusing controlled substances. OMS uses a *retrospective approach,* whereby a contractor is utilized to identify beneficiaries who receive certain quantities of controlled substance prescriptions on a monthly basis. Reports are then provided to Part D plans on a quarterly basis. While OMS has been successful in reducing inappropriate controlled substance utilization, plans must rely on reports from the contractor to identify beneficiaries and then assign case managers to work with the beneficiary.

The DMPs we are talking about today, such as the one defined in Senate bill 1913, is a *prospective program* and allows Part D plans to directly identify beneficiaries, provide notice to enroll and select a prescriber and pharmacy, and then take additional actions necessary to reduce the risk of inappropriate controlled substance utilization. This type of program is proactive and highly desirable. In addition, the plans must provide the beneficiary with information on other organizations that can provide them with contact information regarding drug management programs. The prospective approach allows the identification of at-risk beneficiaries earlier and PDP and MA–PD's can offer them assistance sooner.

DMPs have been successfully utilized by state Medicaid programs. On the state level, 46 state Medicaid programs have successfully implemented DMPs with positive results.[9] An evaluation of state Medicaid DMPs, performed by a CDC expert panel, concluded that these programs have the potential to reduce opioid usage to safer levels and thus save lives and lower health care costs.[10]

A few examples from other states:

- In 2012, the State of North Carolina, announced $5.2 million in savings from their state Medicaid DMP program.[11]
- In 2009, the Oklahoma Medicaid department found that its lock-in program reduced doctor shopping, utilization rates of controlled substances, and emergency room visits with a savings of $600 per person in costs.[12]
- Florida reported 1,315 individuals had been placed into their Medicaid PRR between October 2002 and March 2005. During this time period, cumulative savings for medical and pharmaceutical expenses topped $12.5 million.[13]

Prescription Drug Monitoring Programs

Another area that we believe would assist PDPs and MA–PDs to help an at-risk beneficiary is to allow pharmacists in those plans access to information in the Prescription Drug Monitoring Program (PDMP). In order for a DMP to be successful, AMCP recommends real-time data sharing of information compiled in PDMPs with prescribers, pharmacies, managed care organizations, and pharmacy benefit management companies (PBMs). In Pennsylvania, where access was recently amended, data in PDMPs is generally available to prescribers, pharmacists and other health care providers, and law enforcement personnel, but not PDPs, and MA–PDs and PBMs. Congress could help to encourage PMP data sharing by passing legislation to require states to adopt this practice and increase funding of existing PDMP programs.

Many inappropriate controlled substance prescriptions are purchased through cash-based transactions and not adjudicated to a private insurance plans, Medicare Part D, or Medicaid.[4] This means that PDPs, MA–PDs or PBMs may be unaware of certain controlled substance prescriptions for some individuals and thus do not have all the information necessary to establish a basis for inappropriate utilization or

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[9] Roberts AW, Cockrell Skinner A. Assessing the Present State and Potential of Medicaid Controlled Substance Lock-in Programs. J Manag Care Pharm. 2014;20(5):439–46.

[10] CDC; National Center for Injury Prevention and Control. Beneficiary review and restriction programs. Lessons learned from state Medicaid programs (2012), *http://www.cdc.gov/homeandrecreationalsafety/pdf/PDO_beneficiary_review_meeting-a.pdf.* Accessed on August 25, 2015.

[11] North Carolina Department of Health and Human Services. 2.3 million pills off the streets, $5.2 million saved by narcotics lock-in. May 14, 2012.

[12] SoonerCare Pharmacy Lock-in Program Promotes Appropriate Use of Medications. September 9, 2009 [press release], *http://okhca.org/about.aspx?id=10973.* Accessed on August 25, 2015.

[13] Centers for Disease Control and Prevention; National Center for Injury Prevention and Control. Patient review and restriction programs. Lessons learned from state Medicaid programs (2012), *http://1.usa.gov/1UJuEag.* Accessed on August 25, 2015.

abuse. Allowing access by PDPs, MA–PDs and PBMs could help to reduce inappropriate utilization or abuse by implementing systems to flag inappropriate utilization and provide other interventions to ensure appropriateness of the prescription prior to dispensing.

Managed care pharmacists are well-positioned to help reduce prescription opioid abuse, misuse, and diversion in two distinct ways. First, we have been managing programs on the commercial side and in state Medicaid programs. Through specific modeling tools unique to the industry, we have been able to identify beneficiaries at-risk for abuse, misuse or diversion and offer them the help they need. Secondly, through these same tools, the long-term results of having fewer at-risk beneficiaries involved in the misuse, abuse, or diversion of controlled substances will ultimately result in reduced costs to the overall health care system.

On behalf of Gateway Health Plan and AMCP, we strongly support S. 1913 and your tireless efforts to address this important societal problem. In our opinion, S. 1913 strikes the appropriate balance by preserving the beneficiaries' rights to be notified, submit their preferences for prescriber and pharmacy and exercise appeal rights. On the other hand, the PDPs and MA–PDs will have the authority to identify at-risk beneficiaries in a prospective manner and help them obtain the necessary treatment sooner and improve their ability to address their addictions. Earlier this year, legislative language contained in another bill creating a drug management program in Medicare Part D for at-risk beneficiaries received a score from the Congressional Budget Office as saving $115 million over 9 years. Prescribers and pharmacies will also be aware of the at-risk beneficiaries' need for assistance. This concludes my testimony. Thank you again for inviting me to speak here today. Please feel free to contact me, or my colleagues at AMCP as a resource in tackling this very important issue. We will continue to work with you to enact this legislation.

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TESTIMONY

Submitted for the record of the

UNITED STATES SENATE FINANCE

HEALTH CARE SUBCOMMITTEE

FIELD HEARING

On

OPIATE ABUSE IN SOUTHWESTERN PENNSYLVANIA

On

OCTOBER 15, 2015

Mr. Chairman and committee members, I would like to thank you for the opportunity to submit comments for the record of the field hearing on opioid abuse. My name is Karen Geary. I am a Pharmacist, a life-long resident of western Pennsylvania and a member of Academy of Managed Care Pharmacy.

AMCP is a national professional association of 7,000 pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to assist patients in achieving positive therapeutic outcomes. In Pennsylvania alone, we have over 480 active members. AMCP's members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

Opioid abuse is a problem in Pennsylvania and nationwide and needs to be addressed

According to the Centers for Disease Control and Prevention (CDC), deaths associated with prescription medications have increased more than 300 percent since 1998, while prescribing rates for these drugs quadrupled between 1999 and 2010. Deaths connected to prescription drug misuse now exceed those from heroin and co-

caine combined.[1] The Pennsylvania Medical Society reports that more Pennsylvanians die from drug overdoses than from any other type of injury, including car accidents.[2] In 2014, that's 2,400 deaths attributed to drug overdoses, or 7 people a day in Pennsylvania.[3]

Rates of prescription drug abuse related to emergency department visits and treatment admissions have reached epidemic levels in the United States. All too often, many of us know someone who is battling drug addiction. Moreover, the economic costs of prescription drug abuse are substantial. The nonmedical use of controlled substances amounts to $73 billionannually in unnecessary costs, including lost productivity, increased costs to the criminal justice system, and health care expenditures.[4, 5, 6]

There is a definite need for action on many fronts to address this growing concern. Patients, providers, patient family members, health plans, community based organizations, employers, and government must all work together to formulate and implement solutions. One area where change can be affected is in the Medicare Part D program. That Program does not currently limit patients with a history of abuse, misuse or diversion to a single prescriber and/or pharmacy. The use of a drug management program (DMP) by prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MA–PD) is a managed care pharmacy solution to control access to addictive medicines.

Senator Toomey's bill S. 1913, Stopping Medication Abuse and Protecting Seniors Act of 2015, would allow PDPs and MA–PDs to proactively identify individuals at risk for controlled substance abuse, misuse or improper utilization. The Secretary of Health and Human Services (HHS) would determine the criteria for the "at risk" designation. The plans would work with a beneficiary's prescriber and give the beneficiary notice that they had been identified as a potential participant for enrollment in a drug management program (DMP).

The beneficiary has appeal rights and can submit their preference of a specific prescriber and pharmacy. The use of DMPs may improve continuity of care among at-risk plan beneficiaries, while ensuring beneficiaries with legitimate medical needs have continued access to effective pain control. At risk beneficiaries are still able to receive non-controlled prescriptions at other pharmacies and from other prescribers. In essence, DMP programs help to mitigate the issues associated with doctor or pharmacy shopping and may reduce the number of inappropriate controlled substance prescriptions.[7]

In terms of the impact to beneficiaries, a 2012 CMS study found that less than 1% of beneficiaries would be directed into a DMP. The study further found that only 0.7% of Medicare Part D beneficiaries received opioids from at least 4 prescribers and 4 or more pharmacies, signaling a high-risk patient.[8] (Those beneficiaries in hospice or those with a diagnosis of cancer were excluded from the study.)

The limited number of beneficiaries that may be included in the DMP is encouraging because it is an indicator that the majority of beneficiaries in the Program will not have any change in their prescriber or pharmacy as a result of S. 1913. On the other hand, that small group of beneficiaries that are at-risk, will have an opportunity to receive better coordination of care by the prescriber, pharmacy and PDP working together through the DMP.

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[1] CDC. Vital Signs: Overdoses of Prescription Opioid Pain Relievers—United States, 1999–2008. MMWR 2011; 60: 1–6.

[2] *http://www.pamedsoc.org/opioids.*

[3] Pennsylvania Medical Society, August 11, 2015: *http://bit.ly/1PguMyI.* Accessed October 6, 2015.

[4] Centers for Disease Control and Prevention. Prescription painkiller overdoses in the U.S. November 2011. Available at: *http://www.cdc.gov/vitalsigns/painkilleroverdoses/*. Accessed on August 25, 2015.

[5] Ghate SR, Haroutiunian S, Winslow R, McAdam-Marx C. Cost and comorbidities associated with opioid abuse in managed care and Medicaid beneficiaries in the United States: a comparison of two recently published studies. J Pain Palliat Care Pharmacother. 32010;24(3):251–58.

[6] Hansen RN, Oster G, Edelsberg J, Woody GE, Sullivan SD. Economic costs of nonmedical use of prescription opioids. Clin J Pain. 2011;27(3):194–202.

[7] Peirce GL, Smith MJ, Abate MA, Halverson J (2012) Doctor and Pharmacy Shopping for Controlled Substances. Medical Care 50:7. *http://bit.ly/1i3C8Zm* Accessed September 11, 2015

[8] Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Centers for Medicare and Medicaid Services, April 2, 2012. Available at

http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=15078. Accessed September 4, 2015.

Managed care pharmacists are prepared to work with at-risk Medicare beneficiaries

Managed care pharmacists are well-positioned to help reduce prescription opioid abuse, misuse, and diversion in two distinct ways. First, we experience with DMPs on the commercial side and in state Medicaid programs. Through specific modeling tools unique to the industry, we have been able to identify beneficiaries at-risk for abuse, misuse or diversion and offer them the help they need. Secondly, through these same tools, the long-term results of having fewer at-risk beneficiaries involved in the misuse, abuse, or diversion of controlled substances will ultimately result in reduced costs to the overall health care system.

On behalf of myself and AMCP, we strongly support S. 1913 and your tireless efforts to authorize a program that will address this important societal problem. In our opinion, S. 1913 preserves the beneficiaries' rights to be notified, to submit preferences for prescriber and pharmacy and to exercise appeal rights. However, the PDPs and MA–PDs will be able to identify at-risk beneficiaries sooner and help them obtain the necessary treatment and improve their ability to address their addictions. Prescribers and pharmacies will also be aware of the at-risk beneficiaries' need for assistance.

I unfortunately will be out of town during the October 15th field hearing but this is an important issue to me and I wanted to provide input for the record. Thank you the opportunity to be included. Please feel free to contact me, or my colleagues at AMCP as a resource in tackling this very important issue. We will continue to work with you to enact this legislation.

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Testimony of Michael J. Consuelos, M.D.

Senior Vice President for Clinical Integration
The Hospital and Healthsystem Association of Pennsylvania (HAP)

The U.S. Senate Committee on Finance
Subcommittee on Health Care

"Examining Heroin and Opiate Abuse
in Southwestern Pennsylvania"

October 15, 2015

Chairman Toomey, Ranking Member Stabenow, and members of the Subcommittee, my name is Michael J. Consuelos, M.D., and I am the senior vice president for clinical integration for The Hospital and Healthsystem Association of Pennsylvania (HAP). HAP represents and advocates for the nearly 240 acute and specialty care hospitals and health systems across state. We appreciate the opportunity to describe how HAP and Pennsylvania hospitals are working to reduce opioid addiction and opioid related deaths.

Opioid abuse is a terrible problem in Pennsylvania, and only coordinated efforts across sectors of public and private stakeholders can increase the chance of stemming what has become a public health epidemic. In 2014, in the State of Pennsylvania, approximately 2,500 people died from drug overdoses, more than double the 1,200 people who died from motor vehicle accidents.

HAP has joined the Pennsylvania Medical Society (PAMED), the Pennsylvania Department of Health (DOH), the Pennsylvania Department of Drug and Alcohol Programs (DDAP), and other stakeholders on the Safe and Effective Prescribing Practices and Pain Management Task Force. This taskforce has prepared three guidelines for providers who regularly prescribe opiate pain medications. These include prescribing guidelines for:

- emergency departments;
- dental practices; and
- the treatment of chronic non-cancer pain.

We are now working on guidelines for geriatric patients and obstetrical patients.

The taskforce is also collaborating on providing professional continuing education programs for physicians, nurses, and pharmacists. This important education supports the written prescribing guidelines and promulgates the use of naloxone under Pennsylvania Act 139. Act 139 provides liability protections for first responders administering life-saving opioid reversal medication.

Individual hospitals are assessing the impact of opioid dependency and related deaths in the communities they serve. Many are identifying opioid abuse as a major community health issue as they develop their most recent Community Health Needs Assessments. Emergency departments are seeing a growing number of opioid overdoses and working closely with local emergency medical services personnel and police on the proper use of naloxone by first responders.

Lastly, the HAP Behavioral Health Taskforce is evaluating Pennsylvania's existing laws, policies, and regulations addressing the treatment of drug abuse. Hospitals primarily rely on DDAP and country treatment and prevention programs. Better alignment between medical and behavioral health regulations can provide better transitions to, and adherence with, treatment services.

This activity is just a start and requires sustained support and additional resources to truly make an impact on this public health problem. HAP supports the following:

- Implementation of Pennsylvania's Achieving Better Care by Monitoring All Prescriptions (ABC–MAP) Prescription Drug Monitoring Program (POMP) to improve safe prescribing practices and identification of drug-seeking patients so they can receive the proper treatment.
- Federal legislation, such as S. 480, the National All-Schedules Prescription Electronic Reporting (NASPER) Reauthorization Act of 2015, introduced by Senators Shaheen (D–NH) and Toomey (R–PA), could support Pennsylvania in implementing ABC–MAP. Importantly, NASPER goes beyond providing grant support to states to establish prescription drug monitoring programs, but also ensures interoperability between state monitoring programs and within health information technology systems.
- Increasing the use of naloxone and supporting the development and distribution of the life-saving drug, to help reduce the number of deaths associated with prescription opioid and heroin overdose. S. 707, the Opioid Overdose Reduction Act, would expand important liability protections for the emergency administration of an opioid overdose drug.
- Expanding the use of Medication-Assisted Treatment (MAT), a comprehensive way to address the needs of individuals, which combines the use of medication with counseling and behavioral therapies to treat substance use disorders.
- Proliferating drug take-back programs, which provide safe and efficient means to destroy prescribed pain medications, thereby removing them from the streets.
- Assessment and evaluation of prenatal opioid abuse and neonatal abstinence syndrome, as outlined in S. 799, the Protecting Our Infants Act, introduced by Senators McConnell (R–KY) and Casey (D–PA), will initiate positive steps to decrease the number of infants suffering from opioid dependency.

In conclusion, HAP and Pennsylvania hospitals are working diligently with other stakeholders to address the epidemic of opioid abuse and overdose deaths. This good work requires continued support and collaboration to fully make an impact on the future health and wellbeing of Pennsylvanians.

LETTER SUBMITTED FOR THE RECORD BY JULIE KMIEC, D.O.

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Senator Pat Toomey
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October 14, 2015

Dear Senator Toomey,

I am an addiction psychiatrist and treat patients primarily who are addicted to opioids. Today's opioid epidemic stems back to the mid 1990s. In 1995, Purdue Pharma released OxyContin, which is an extended release oxycodone tablet, which was initially billed by the pharmaceutical company to have low abuse potential. Around the same time, there was a focus developing on assessing and treating pain. A joint consensus statement from two pain societies published in 1996 stated that development of addiction is low when opioids are used for pain and withholding opioids based on concerns about respiratory depression is unwarranted. Judicious use of opioid pain medications was encouraged to alleviate suffering. As you are aware, prescribing of opioid pain medications increased. From 1991 to 2013, the number of opioids prescribed in the United States went from 76 million to 207 million per IMS Health, Vector One prescription records.[i] In that same period of time, deaths from prescription opioids tripled.[ii]

Today, it is estimated 1.9 million Americans abuse or are addicted to pill opioids.[iii] In Allegheny County, the SAMHSA National Survey on Drug Use and Health found that the prevalence of pill opioid use from 2010–2012 was 4.05%.[iv] About 75% of those using opioid pills will go on to use heroin due to cost.[v] My patients tell me that they buy pills for $1 per milligram, whereas heroin costs $10 per stamp bag. Patients usually start out using heroin intranasally, then as their tolerance grows, they need to use more and more to get the same effect, so they switch to injecting it in order to use less and get a greater effect. However, with time, they become tolerant to the effects of the injected heroin as well, and again start using more and more. Currently, there are 517,000 Americans addicted to heroin.[iii] Each day, 46 Americans die from prescription opioid overdoses[vi] and 22 die from heroin overdoses.[vii] In 2014, there were 299 overdose deaths in Allegheny County alone.[viii]

I see patients in all phases of their addiction, actively using, in detoxification, and in recovery. Sadly, I have treated several patients who have overdosed on opioids and died. About 50% of my patients have survived or witnessed an accidental overdose at some time in their lives.

To address the opioid epidemic, addiction physicians have recognized to effectively treat this opioid and overdose epidemic, we need to take a multifaceted approach. We need to:

1. Emphasize prevention. Encourage patients to discard of all unused medications, especially narcotic medications, by returning them to participating take-back pharmacies, police departments, or utilizing drug take-back days so unused drugs are not used by unintended recipients.
2. Educate medical students, residents, and physicians about addiction and proper opioid prescribing. An organization, Physicians for Responsible Opioid Prescribing *(www.supportprop.org)* provides continuing medical education on responsible opioid prescribing. In addition to physicians, dentists, advance practice nurses, and physician's assistants also need basic and continuing education on proper opioid prescribing. All healthcare professionals need more training in recognizing signs and symptoms of addictive disorders and effectively working with patients with addictive disorders. I am a member of The Coalition on Physician Education in Substance Use Disorders (COPE) and we are working on encouraging the integration of increased education on addiction into allopathic and osteopathic medical school curricula.
3. Use prescription drug monitoring databases to ensure we have as much data available to us as possible to make sound clinical decisions. Of note, Pennsylvania's prescription drug monitoring database which was signed into law on October 27, 2014, and anticipated to take effect June 30, 2015, is still not available due to budget constraints. Hence, physicians in Pennsylvania still do not have this resource available to possibly inform prescribing.
4. Use FDA-approved medications to treat opioid use disorder, including methadone, buprenorphine, and naltrexone. These medications are effective in reducing opioid use, preventing relapse, reducing transmission of HIV and hepatitis C from injection drug use, and reducing emergency room visits and hospitalizations.[ix] These medications, however, are underutilized currently.
5. Provide overdose prevention training and co-prescribe naloxone when prescribing opioids in case of accidental overdose.

Opioid use disorder, also known as opioid addiction, is a chronic, relapsing, life-threatening, but treatable disease of the brain. Addiction is not a choice or lack of willpower. It is not a time-limited illness. Yet, the patients I see each day are given these messages by their friends, family, the media, healthcare workers, and insurance providers.

Patients with addictive disorders face barriers when trying to seek medications for treatment of opioid use disorder, including wait-lists to get into methadone maintenance programs and buprenorphine clinics, difficulty finding physicians who accept Medicaid who will prescribe stabilizing medications,[x] difficulty getting into rehabilitation programs, rigorous prior-authorization requirements[xi] which set up barriers to patients being able to afford medications.

Eleven states have implemented lifetime limits for how long their Medicaid programs will pay for buprenorphine,[xii] 14 states have implemented buprenorphine dose limits,[xiii] and one state (*i.e.,* Maine) has implemented a 2-year lifetime limit for Medicaid payment for methadone. These limits have restricted patients' access to treatment and put them at risk for relapse and overdose, and there is no evidence behind these practices.[xiv]

Fortunately, Pennsylvania has not instituted a lifetime limit for buprenorphine treatment but Pennsylvania Medicaid does have a dose limit of 16 mg daily. Patients on buprenorphine treatment need their treating physician to submit prior authorizations documenting participation in psychosocial therapy, urine drug testing, relapse status, every 6 months. Some managed care companies require patients who want to use extended release naltrexone for treatment to use the immediate release naltrexone first, as part of a step therapy requirement. The patient is required to "fail" this treatment in order to be approved for the more expensive treatment. This puts the patient at risk for relapse and overdose. In fact, I had one patient for whom the insurance company refused to authorize the extended release naltrexone and required him to take the naltrexone tablets first. The patient took the tablets for a short time and relapsed on heroin and then overdosed. Fortunately he survived the overdose, underwent detoxification again, and then started the extended release naltrexone and began a long period of recovery.

Despite The Mental Health Parity and Addiction Equity Act of 2008, there are still private insurers in the southwest Pennsylvania region that do not pay for outpatient detoxification. These patients who have this insurance company who come to the program have to pay out-of-pocket or try to find an inpatient detoxification facility.

In Pennsylvania, patients with opioid use disorders have to complete several hurdles in order to get lifesaving medications authorized by their insurance companies as described above. These same patients could get prescriptions for most immediate release (*e.g.,* oxycodone) and several extended release opioids (*e.g.,* oxymorphone ER, Fentanyl patch), without any step therapy requirements, prior authorizations, and/or requirements for additional treatment such as physical therapy.

In closing, patients with addiction need to be treated as all other patients with chronic diseases. A patient with high blood pressure is not expected to stop blood pressure medications once his/her blood pressure is stabilized or to maintain the gains made by medication through lifestyle changes (*e.g.,* diet and exercise) if these haven't been successful treatments previously. Likewise, limits on medications to treat opioid and other addictions should not be time limited. Once patients stabilize on methadone or buprenorphine, they should not be expected to stop the medications and maintain their recovery with therapy alone. Patients with opioid addiction should not need to "fail" a treatment before their insurance will pay for a more expensive medication, especially since "failure" could be a matter of life and death.

I am hopeful that you will find my comments helpful in understanding the opioid epidemic and barriers those with the disease of opioid addiction are facing in Allegheny County, Pennsylvania, and also in the greater United States.

Respectfully submitted,

Julie Kmiec, D.O.
Addiction Psychiatrist

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[i] IMS Health, Vector One: National, Years 1991–1996, Data Extracted 201. IMS Health, National Prescription Audit, Years 1997–2013, Data Extracted 2014.

[ii] Mack, K.A. Drug-induced deaths—United States, 1999–2010. MMWR Surveill Summ. 2013 Nov 22;62 Suppl 3:161–3. CDC.

[iii] In 2013, the *National Survey on Drug Use and Health* (NSDUH) estimated that 1.9 million Americans live with opioid pain reliever addiction and 517,000 are addicted to heroin. *http://www.samhsa.gov/data/sites/default/files/NSDUH-SR200-RecoveryMonth-2014/NSDUH-SR200-RecoveryMonth-2014.htm.*

[iv] *http://www.samhsa.gov/data/sites/default/files/substate2k12-StateTabs/NSDUHsubstateStateTabsPA2012.htm.*

[v] Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. The changing face of heroin use in the United States: a retrospective analysis of the past 50 years. JAMAPsychiatry. 2014 Jul 1;71(7):821–6. doi: 10.1001/jamapsychiatry.2014.366. PubMed PMID: 24871348.

[vi] According to the Centers for Disease Control and Prevention (CDC), 46 Americans die every day from opioid prescription drug overdoses: that translates to almost 2 deaths an hour and 17,000 annually. CDC Vital Signs, July 2014 *(http://www.cdc.gov/vitalsigns/opioid-prescribing/).*

[vii] According to the Centers for Disease Control and Prevention (CDC). more than 8,000 Americans die annually from heroin overdoses. *http://www.cdc.gov/nchs/data/databriefs/db190.htm.*

[viii] *http://www.achd.net/pr/pubs/2015release/052115_nalaxone.html.*

[ix] *http://www.asam.org/docs/default-source/2015-conference-epk/asam-impact_cce-4-02-14.pdf?sfvrsn=4#search="proven clinical and cost effectiveness opioid use".*

[x] A shortage of Medicaid-eligible physicians or organizational providers who prescribe addiction medications has developed—one state has only one Medicaid-eligible methadone clinic. This can be especially harmful when low-income opioid addiction patients are unable to find/access Medicaid-eligible providers in their area, according to The Avisa Group (*Availability without accessibility? State Medicaid coverage and authorization requirements for opioid dependence medications;* Rinaldo, S. and Rinaldo, D. 2013).

[xi] Rigorous prior-authorization requirements for continued use of medications, sometimes within as little as 6 months. Prior authorization requirements can also change substantially over time, without notice, and severely restrict or deny access to medication, according to research conducted by The Avisa Group (*Availability without accessibility? State Medicaid coverage and authorization requirements for opioid dependence medications;* Rinaldo. S. and Rinaldo, D., 2013).

[xii] Eleven states impose preset "lifetime" medication limits on buprenorphine, according to The Avisa Group (*Availability without accessibility? State Medicaid coverage and authorization requirements for opioid dependence medications;* Rinaldo, S. and Rinaldo, D. 2013).

[xiii] *http://www.asam.org/docs/default-source/2015-conference-epk/asam-impact_barriers4-02-14.pdf?sfvrsn=4#search="medications for the treatment of opioid use disord".*

[xiv] Stabilizing medications for patients living with chronic opioid addiction disease are uniquely controlled, with insurance limitations not supported by medical knowledge, according to Treatment Research Institute findings (*FDA approved medications for the treatment of opiate dependence: Literature reviews on effectiveness and cost effectiveness;* Chalk, M. et al., 2013).

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Statement

Of

The National Association of Chain Drug Stores

For

United States Senate

Committee on Finance

Subcommittee on Health Care

Field Hearing on:

"Opiate Abuse in Southwestern Pennsylvania"

October 15, 2015

The National Association of Chain Drug Stores (NACDS) thanks Chairman Toomey, Ranking Member Stabenow, and members of the Senate Finance Subcommittee on Health Care for the opportunity to submit a statement for the hearing on Opiate Abuse in southwestern Pennsylvania. NACDS and the chain pharmacy industry are committed to partnering with federal and state agencies, law enforcement personnel, policymakers and others to work on viable strategies to prevent prescription drug diversion and abuse. Our members are engaged daily in activities aimed at

preventing drug diversion and abuse. Since our members operate pharmacies in almost every community in the U.S., we support policies and initiatives to combat the prescription drug abuse problem in southwestern Pennsylvania and nationwide. We believe that holistic approaches must be implemented at the federal level.

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS's 115 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.2 million individuals, including 179,000 pharmacists. They fill over 2.9 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 850 supplier partners and nearly 60 international members representing 22 countries. For more information, visit *www.nacds.org*.

Background

First enacted in 1970, the federal Controlled Substances Act (CSA) regulates the manufacture, importation, possession, use, and distribution of prescription drugs that have a potential for diversion and abuse and are collectively known as "controlled substances." The CSA creates a closed system of distribution for controlled substances; the Drug Enforcement Administration (DEA) often refers to this as "cradle-to-grave" control over controlled substances. DEA has implemented a very tight and comprehensive regulatory regime pursuant to the CSA. States have followed this lead and have implemented similar, sometimes duplicative regimes. This matrix of regulation has created a multi-layered system of checks and balances to protect Americans from the dangers of prescription drug abuse. Pharmacists and other pharmacy personnel are all trained to understand and comply with this complex regulatory matrix.

Chain Pharmacy Initiatives

To comply with DEA's "cradle to grave" regulatory regime, chain pharmacies have created a variety of loss prevention and internal security systems that are in place from member prescription drug distribution centers right down to the point of dispensing to the patient. Our members undertake initiatives to ensure that prescription drugs are accounted for throughout every step along the way. Some of those initiatives could include conducting background checks before hiring personnel who have access to prescription drugs, training employees on controlled substance laws and regulations within 30 days of hire, maintaining electronic inventories of controlled substances and conducting random audits. Our members work closely with law enforcement to see that perpetrators of crimes relating to controlled substances are brought to justice.

Specifically at the pharmacy level, examples of NACDS-member initiatives include training pharmacy personnel on how to handle suspect prescription drug orders, and exception reporting, in which exceptionally large or unusual orders of controlled substances will trigger an internal investigation. Chain pharmacies also may maintain perpetual inventories of controlled substances that are randomly audited by internal security personnel. Pursuant to DEA and state regulations, pharmacy and chain distribution centers are required to be highly secured with physical barriers and utilize heavy duty safes, secure cages, and complex alarm systems. Some pharmacy chains also utilize cameras and closed-circuit television surveillance to ensure compliance with policies and procedures. Some pharmacies require employees to read and sign "codes of conduct," which commits them to compliance and some will conduct drug testing, including random, for cause, and pre-employment testing.

Chain pharmacies are committed to ensuring that prescription drugs remain under tight control for the purposes of providing care to their patients, and are not diverted for nefarious purposes. Our members' efforts are evidence of this commitment.

Legislative Initiatives

NACDS shares the goals of policymakers to curb the incidence of fraud and abuse and appreciates the work that has been done over the last year, such as with the 21st Century Cures Initiative. NACDS believes that any potential programs aimed at "locking-in" a beneficiary to a certain pharmacy or pharmacies—such as the one included in the 21st Century Cures Initiative or in S. 1913, the Stopping Medication Abuse and Protecting Seniors Act of 2015—must ensure that legitimate beneficiary access to needed medications is not impeded. Policies to reduce overutilization must maintain access to prescription medications by the beneficiaries who need them most.

While the use of a single pharmacy could decrease incidents of fraud, waste and abuse as well as provide the potential for better care coordination, a lock-in provision may actually be a barrier to care as supply chain issues exist around these medications which are beyond the pharmacy's control. Also, patients often legitimately see multiple doctors representing different specialties in different locations. In addition, there are instances due to location and/or services offered (*e.g.,* compounded or specialty drugs) that a single pharmacy may not meet all the needs of a specific patient.

In order to protect legitimate patient access while combatting prescription drug abuse and diversion, mechanisms must be included in any legislation that would allow a pharmacy, in consultation with the prescriber, to fill legitimate prescriptions without needlessly delaying treatment for beneficiaries. This includes ensuring that back-up systems are in place which would allow a beneficiary to obtain needed medication in the event their "locked-in" pharmacy is unable to supply the medication. Without this, the potential for harm from unnecessary delay in obtaining medication is possible.

Additionally, NACDS believes a beneficiary should be able to select a pharmacy location, or number of locations that are under common ownership and that electronically share a real time, online database. The ability to share real-time data will ensure that beneficiaries are only obtaining the necessary prescriptions while protecting beneficiary access and health.

The Role of DEA

According to DEA regulations, the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility also rests with the pharmacist who fills the prescription. An order purporting to be a prescription that is not issued in the usual course of professional treatment is not a prescription within the meaning and intent of section 309 of the CSA (21 U.S.C. 829), and any person knowingly filling such a purported prescription, as well as the person issuing it, is subject to the penalties provided for violations of the CSA.

Community pharmacists are front-line healthcare providers and are one of the most accessible members of a healthcare team. As such, the CSA requires pharmacists to take on diverse and sometimes conflicting roles. On the one hand, pharmacists have a strong ethical duty to serve the medical needs of their patients in providing neighborhood care. On the other hand, community pharmacists are also required to be evaluators of the legitimate medical use of controlled substances.[1] As briefly mentioned above, the CSA requires that a pharmacist, prior to dispensing any controlled substance, make the following determinations-whether the prescription complies with all legal and regulatory requirements, and whether the prescription has been issued for a "legitimate medical purpose" "by a prescriber acting in the usual course of his or her practice."[2] The former obligation is called "corresponding responsibility," and if the two elements are not met, the prescription is not valid. DEA interprets a pharmacist's corresponding responsibility "as prohibiting a pharmacist from filling a prescription for a controlled substance when he either 'knows or has reason to know that the prescription was not written for a legitimate medical purpose.'"[3]

Pharmacies fully understand that controlled substances are subject to abuse by a minority of individuals who improperly obtain controlled substance prescriptions from physicians and other prescribers. Pharmacies strive to treat medical conditions and ease patients' pain while simultaneously guarding against the abuse of controlled substances. The key is to guard against abuse while still achieving our primary goal of assisting patients who need pharmacy services.

The Role of FDA

In 2007, Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA), which provided FDA the authority to impose risk management plans on prescription drugs; this program is known as Risk Evaluation and Mitigation

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[1] In order for a prescription for a controlled substance to be valid, federal law (21 CFR § 1306.04(a)) requires that the prescription be issued for a legitimate medical purpose by a prescriber acting in the usual course of his or her practice. The rule places a ***corresponding responsibility*** upon the dispensing pharmacist to establish the validity of the prescription by ensuring the prescription is written for a legitimate medical purpose.

[2] 21 CFR 1306.04(a).

[3] *East Main Street Pharmacy,* 75 FR 66149, 66163 (Oct. 27, 2010).

Strategies (REMS). A REMS will be imposed if FDA finds that a REMS is necessary to ensure that the benefits of a drug product outweigh the risks of the drug product. Among the numerous REMS that FDA has implemented is a REMS for extended release and long-acting opioid products ("ER/LA opioid drugs"). These are pain relieving medications that have an elevated potential for abuse. The central component of this "Opioid REMS" is an education program for prescribers (*e.g.,* physicians, nurse practitioners, physician assistants) so that ER/LA opioid drugs can be prescribed and used safely. NACDS agrees that prescribers should be properly educated about the risks and benefits of prescription drugs, including those that have elevated abuse potential like ER/LA opioid drugs. It is critical that all prescribers understand the nature of addiction and abuse before issuing prescriptions for these medications. NACDS supports FDA's Opioid REMS.

In 2011, FDA announced a REMS for another class of drugs with elevated abuse potential: transmucosal immediate-release fentanyl (TIRF) products. NACDS and other industry stakeholders worked closely with FDA to design and implement this REMS. We are appreciative of this collaborative effort spearheaded by FDA, and believe such a collaborative effort should serve as a model for similar programs to address prescription drug abuse.

The GAO Report

Numerous groups and state and federal entities are working to reduce the problem of prescription diversion and abuse. Unfortunately, in their efforts to combat prescription drug abuse, federal agencies have not been effectively coordinating their efforts to assure access to prescription controlled substances for patients who legitimately need these medications. In GAO's recent report that examines shortages of prescription drugs that contain controlled substances, GAO found that DEA and FDA have not established a sufficiently collaborative relationship to ensure an adequate supply of controlled substance medications.[4] GAO found that the barriers to coordination prevent DEA and FDA from preventing or alleviating shortages.[5] Although critical to their efforts, a memorandum of understanding (MOU) between the two agencies has not been updated in *40 years.*[6]

Specific to DEA, GAO found that:

- DEA does not meet its requirements due to lack of internal controls for data reliability, performance measures, and performance monitoring;[7]
- Insufficient internal DEA controls lead to errors in its data system;[8]
- DEA has not met required time frames for more than a decade;[9] and
- DEA is not prepared to respond to future prescription drug shortages.[10]

Considering the patient harm that occurs due to prescription drug shortages, the concerns identified by GAO about lack of federal agency coordination, and serious DEA deficiencies, we believe that Congress should act. Federal agencies must come together behind a comprehensive approach and pursue drug abuse prevention policies that are strategically designed to target enforcement efforts while still maintaining access to prescription controlled substances for patients who legitimately need these medications.

Since NACDS and our members are focusing our energies on real, workable solutions that will address the problem of prescription drug abuse while also ensuring that legitimate patients are able to receive their prescription pain medications, we support the "Ensuring Patient Access and Effective Drug Enforcement Act of 2015," which has been introduced in the Senate as S. 483, sponsored by Sen. Orrin Hatch (R–UT) and Sen. Sheldon Whitehouse (D–RI). This legislation would promote cooperation among key government agencies, such as DEA and FDA, to jointly identify obstacles to legitimate patient access to controlled substances, issues with diversion of controlled substances, and how collaboration between law enforcement agencies and healthcare stakeholders can benefit patients and prevent diversion and abuse of controlled substances.

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[4] "Drug Shortages: Better Management of the Quota Process for Controlled Substances Needed; Coordination between DEA and FDA Should Be Improved;" Government Accountability Office; February 2015; pp. 43–51.
[5] Ibid.
[6] Ibid., at 46.
[7] Ibid., at 29.
[8] Ibid., at 47.
[9] Ibid.
[10] Ibid.

S. 483 also facilitates open dialogue on issues related to prescription drug diversion and abuse by directing key federal agencies to consult with patient groups; pharmacies; drug manufacturers; common or contract carriers and warehousemen; hospitals, physicians, and other healthcare providers; state attorneys general; federal, state, local, and tribal law enforcement agencies; health insurance providers and entities that provide pharmacy benefit management services on behalf of a health insurance provider; and wholesale drug distributors.

We believe that bringing together stakeholders to address the problems associated with prescription drug abuse in this manner would provide better solutions than have been developed to date. Improved collaboration and coordination among federal agencies and other stakeholders would benefit all, including the patient, whose legitimate access to medication must be preserved in order for any potential solution to be successful.

Additional DEA Recommendations

Although the GAO report focuses on the quota process for prescription drugs, we have a number of additional concerns about DEA processes and functions that should be brought to light. DEA's enforcement activities include conducting inspections of the entities that are subject to its regulatory oversight. Although such enforcement activities are essential to its mission, DEA has been criticized for an alleged lack of transparency in its inspection and other enforcement actions, and even inconsistency among the actions of its numerous field offices. Such opaqueness and inconsistency impose challenges on the compliance efforts of DEA registrants.

To help address the problems of DEA opaqueness and inconsistency, we support efforts to promote accountability and transparency with respect to DEA's inspection and enforcement programs. The following recommendations, drawn from FDA transparency and oversight and enforcement initiatives, could serve as a model for DEA:

1. *Development of a Comprehensive DEA Investigation Program, Corresponding Inspector Manual and Compliance Policy Guides:* Specifically, DEA would set forth guidance for its oversight of regulated facilities inspections that provide clear and firm direction.
2. *Accountability and Consistency Among Field Offices:* DEA would ensure the uniformity and effectiveness of its inspection program and oversight over field offices. DEA would provide public training for inspectors and develop an audit process to ensure that inspections are carried out consistently across field offices.
3. *Transparency and Communication—DEA Inspection Observations:* DEA would provide substantive and timely feedback to inspected regulated facilities regarding agency observations and facility compliance. Specifically, DEA would provide regulated facilities with substantive written feedback upon completion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the CSA and implementing regulations. Without receiving such information, it is difficult for regulated facilities to implement requisite facility and process improvements and take corrective actions where necessary.
4. *Public Disclosure—Oversight of Inspections:* An important mechanism of accountability is public disclosure of information. Disclosure of final inspection reports of regulated facilities would provide the public with a rationale for DEA enforcement actions and the industry with transparency into agency decision-making, allowing them to make more informed actions to enhance facility compliance.
5. *Ombudsman Office:* An ombudsman office would address complaints and assist in resolving disputes between companies and DEA regarding interactions with the agency on inspections and compliance issues.

We believe these recommendations would greatly increase predictability and transparency in DEA regulation. The adoption of such recommendations would greatly enhance the compliance efforts of DEA registrants, thus leading to more effective DEA regulation and oversight. Enhanced compliance efforts by DEA registrants and more effective DEA regulation and oversight would have highly beneficial impacts on efforts to combat prescription drug diversion and abuse.

Conclusion

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

STATEMENT SUBMITTED FOR THE RECORD BY DEBORAH PARTSCH

Written testimony relative to Senate bill 1913: *Stopping Medication Abuse and Protecting Seniors Act of 2015* to prevent inappropriate access to opioids and improve patient care for at-risk beneficiaries.

Mr. Chairman and committee members, my name is Deborah Partsch, and I am a Pharmacist who has lived and practiced professionally in western Pennsylvania for over 16 years. I respectfully submit a written testimony as an individual and as a member of the Academy of Managed Care Pharmacy. I think it is also important to note that I am an employee of Highmark Inc. a Pittsburgh-based Blue Cross and Blue Shield-affiliated health insurance company. I have held various positions within Highmark which has afforded me the opportunity to develop expertise on insurance-related aspects of pharmacy and health care policy. Briefly:

- Substance abuse has been a problem in this country for decades, and has expanded from illegal to legal substances (prescription medications). I support bill S. 1913, Stopping Medication Abuse and Protecting Seniors Act of 2015, which would allow prescription drug plans and Medicare Advantage prescription drug plans to proactively and prospectively identify individuals at risk for controlled substance abuse, misuse or improper utilization. Many prescription drug plans covering non-Medicare eligible individuals utilize a Designated Pharmacy Program. The program's intent is to deter drug-seeking members from doctor shopping, which is the practice of seeking the same type of prescriptions from multiple physicians. Additionally, the Controlled Substance Act provides the pharmacist an affirmative obligation to only fill prescriptions that are "issued in the usual course of professional treatment,"[i] and prescriptions that do not meet this requirement are considered improper.
- Relative to concerns you may hear of limiting access to a designated pharmacy, I would highlight the pivotal model to reform the health care industry is the creation of Patient Center Medical Home programs and Accountable Care Organizations. Stimulated by Health Care Reform, these centralized health care partnerships seek to better manage an individual's care in a streamlined manner. For the intent of the bill to be successful, I recommend real-time data sharing of information compiled in Prescription Drug Management Programs with key stakeholders including prescribers, pharmacies, managed care organizations, and pharmacy benefit management companies (PBMs).
- Lastly, patients, providers, patient family members, health plans, community based organizations, employers, pharmaceutical companies and government must all work together to formulate and implement solutions. As an employee of Highmark, I wanted to share with you one initiative that Highmark has taken to address the issue of opioid abuse. As a health insurer with over 5 million members, the issue of opioid abuse is certainly of importance to Highmark. Earlier this year, Highmark, through its Foundation, provided a grant of $50,000 to support a state initiative that provides grants to first responders to purchase naloxone, a drug that reverses heroin and opioid overdoses. These grants enable first responders to administer the drug to individuals experiencing an overdose. According to the Pennsylvania Department of Drug and Alcohol Prevention Programs, results to date have been positive—289 drug overdoses have been reversed statewide since the implementation of this initiative. I am proud of my employer and other health insurers for supporting initiatives such as this one and I would like to encourage the drug industry to be a part of the solution by ensuring that the price of treatments like Naloxone remain reasonable.

Thank you again for accepting my written testimony. Please feel free to contact me at 412–544–2489 or deborah.partsch@highmark.com, or my colleagues at AMCP as a resource in tackling this very important issue. We will continue to work with you to enact this legislation.

AMCP is a national professional association of 7,000 pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to assist patients in achieving positive therapeutic outcomes. In Pennsylvania alone, we have over 480 active members. AMCP's members develop and provide a diversified range of clinical, educational and business

[i] SOURCE: "Substances Act." Revised 2010. *http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf.* Accessed June 28th, 2013.

management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

THE PENNSYLVANIA MEDICAL SOCIETY

Written Testimony

By Karen Rizzo, MD, FACS

October 16, 2015

Stopping Medication Abuse and Protecting Seniors Act

The Pennsylvania Medical Society thanks you for the opportunity to present this written testimony regarding the Stopping Medication Abuse and Protecting Seniors Act.

Our nation is unquestionably facing an opioid abuse crisis. According to a report by the Centers for Disease Control (CDC), there were 16,007 opioid overdose deaths in the U.S. in 2012, the most recent year for which statistics were available. Pennsylvania's death rate exceeds the national average, and in 2011 we ranked 21st per capita among the states in opioid prescriptions written. Nationally and in Pennsylvania overdose deaths now exceed motor vehicle deaths. Magnifying the situation, prescription opioids can become gateway drugs to heroin. Indeed, up to 80 percent of heroin addicts started on opioids.

While there is a clear need to act aggressively in response to this epidemic, we must also act prudently, because prescription opioid medications are an essential tool for physicians who treat their patients who are living with chronic pain.

Reducing opioid abuse requires a comprehensive effort, and the Pennsylvania Medical Society has initiated a multi-pronged approach to the problem:

- Our "Pills for Ills, not Thrills" campaign provides physicians with a wide range of information and resources they can use in their practices;
- We secured a grant to host a six-credit Risk Evaluation and Mitigation Strategies Continuing Medical Education (CME) program on extended release and long acting opioids;
- We actively promote Pennsylvania's medication drop box program. Several tons of medications have been turned in since the program was initiated less than 2 years ago;
- We were early advocates for the recently enacted statewide controlled substance database legislation, where prescribers will be able to look to identify patients who might be scammers or have an abuse problem;
- We were strong supporters of Senate bill 1164, now Act 198 of 2014, which provides Good Samaritan protection to those who aid persons who experience a drug overdose, and expands the prescribing of life-saving naloxone to first responders as well as friends and family members of persons at risk of experiencing an overdose.
- Additionally, we initiated a process to create opioid prescribing guidelines, giving prescribers clear, concise guidance as to best practices when utilizing these pain medications. We merged our effort with that of the Commonwealth's own task force, and the chronic, non-cancer pain prescribing guidelines that resulted from that collaboration have been viewed more than 10,000 times on PAMED's website.
- Finally, we actively participated in the Joint State Government Commission's examination of the state's drug laws and regulations, which produced recommendations for further actions.

Of course, much remains to be done. We are currently coordinating an effort by key provider organizations, including the PA Department of Health and the PA Department of Drug and Alcohol Programs, to develop four new continuing education programs focusing on the opioid prescribing guidelines, the new naloxone/Good Samaritan law, the forthcoming ABC–MAP controlled substances database, and "warm

hand-offs," to better direct overdose survivors and abusers to appropriate treatment programs.

While we continue our efforts to combat opioid abuse, we also wish to offer a word of caution. Overzealousness in the campaign to eliminate opioid abuse can also lead to negative consequences. According to published reports, new laws aimed at eliminating Florida's pill mills have left many legitimate chronic pain sufferers scrambling to find pharmacies that have controlled substances, like Oxycodone, and are willing to dispense them.

Additionally, well-meaning legislation which would require physicians and patients to follow a rigid, one-size-fits-all protocol, may be detrimental to patient care by impeding the individualized treatment that is the hallmark of the physician-patient relationship. In that regard, we are concerned that the one prescriber/one pharmacy provisions of the Stopping Medication Abuse and Protecting Seniors Act would create a bureaucratic impediment to that needed clinical flexibility.

There is no question that limiting the number of prescribers and pharmacies from which a patient obtains scheduled drugs is a key element of the campaign to eliminate prescription opioid abuse, and we commend Senator Toomey and his cosponsors for identifying that need. However, we believe this objective can be accomplished without placing additional governmental restrictions on prescribers, patients, and pharmacies.

Pennsylvania's new ABC–MAP controlled substance database will allow prescribers and pharmacies to quickly identify patients who have an abuse problem or are trying to scam the system. One of the system's primary purposes is to flag patients who are obtaining scheduled drugs from multiple prescribers and multiple pharmacies.

Additionally, the legislation authorizes the ABC–MAP board to aid prescribers in identifying those individuals and direct them to treatment programs. Further, the state attorney general's office will have unrestricted access to Schedule II prescribing and dispensing data, and can access Schedule III–V data with a court order.

It should also be noted that Pennsylvania's new opioid prescribing guidelines for chronic, non-cancer pain recommend the use of patient agreements, which typically include restrictions on multiple prescribers and pharmacies, as well as compliance checks involving urine and saliva screening and pill counts.

We believe these new tools will have a major impact on the opioid abuse crisis without reducing practitioners' clinical treatment options or limiting patient access.

Again, we wish to thank you for your leadership on this important public health issue, and for offering us the opportunity to comment on the Stopping Medication Abuse and Protecting Seniors Act.

The Pennsylvania Medical Society is committed to continuing its campaign to eliminate opioid abuse. We look forward to working with the Congress, Governor Wolf, the General Assembly, and other stakeholders in that ongoing endeavor.

THE PEW CHARITABLE TRUSTS

Testimony for the

Senate Committee on Finance, Subcommittee on Health Care

United States Senate

Field Hearing on Opiate Abuse

October 15, 2015

Cynthia Reilly, Director, Prescription Drug Abuse Project

Chairman Toomey, Ranking Member Stabenow, and members of the Senate Committee on Finance, Subcommittee on Health Care, I am submitting testimony on behalf of The Pew Charitable Trusts. Pew is an independent nonpartisan research and policy organization dedicated to serving the public. Pew's prescription drug abuse project works to develop and support policies that will help reduce the inappropriate

use of prescription drugs while ensuring that patients with legitimate medical needs have access to effective pain management. Pew encourages Congress to pursue policy solutions to address the nation's prescription drug abuse epidemic. The Stopping Medication Abuse and Protecting Seniors Act of 2015 is one such proposal that has been introduced in by Senators Toomey (R–PA), Brown (D–OH), Portman (R–OH), Kaine (D–VA), and Casey (D–PA). Pew supports this bill, which authorizes the use of drug management programs in Medicare.

Our testimony makes two key points:

- The use of opioids for non-cancer pain among Medicare beneficiaries is common, with some patients obtaining these prescription from multiple prescribers and pharmacies—a factor that places these individuals at increased risk for overdose and other adverse events, and
- Medicare beneficiaries would benefit from drug management programs that allow plan sponsors to prevent inappropriate access to controlled substances that are susceptible to abuse and better coordinate patient care.

The drug management programs described in the legislation, which are also known as patient review and restriction programs (PRRs), can play an important role in preventing prescription drug abuse by assigning patients who are at risk for drug abuse to pre-designated pharmacies and prescribers to obtain these drugs. Through this mechanism, PRRs allow plan sponsors and providers to improve care coordination and prevent inappropriate access to medications that are susceptible to abuse. The effectiveness of PRRs has led to their adoption in the public and private sector, with major insurers operating these programs in their Medicaid managed care and employer-based plans. In addition, 46 state Medicaid programs currently operate PRRs.[i] An evaluation of state Medicaid PRR programs performed by a Centers for Disease Control and Prevention expert panel concluded that these programs have the potential to reduce opioid usage to safer levels and thus save lives and lower health care costs.[ii]

The need for these programs in Medicare is highlighted by the growing concern about potential overuse of opioids among these beneficiaries. Analyses conducted by the Medicare Payment Advisory Commission (MedPAC), the Centers for Medicare and Medicaid Services (CMS) and the Government Accountability Office (GAO) have sought to quantify the extent of opioid overuse in this population. A MedPAC analysis of 2012 prescription drug event data found that 10.7 million (87 percent) of the roughly 12 million Medicare Part D beneficiaries who were prescribed prescription opioids received these therapies for conditions not associated with cancer treatment or hospice care. Among beneficiaries with the highest expenditures for opioids used for these indications, 32 percent obtained these prescriptions from four or more prescribers and 32 percent used three or more pharmacies. MedPAC also found that these beneficiaries accounted for 68 percent of the program's total gross spending on opioids for non-cancer, non-hospice-related care. On average, these patients filled 23 opioid prescriptions at a cost of $3,500 per beneficiary.[iii]

Evaluations by CMS and GAO found similar trends in the use of opioids for non-cancer, non-hospice-related care and instances in which multiple prescribers and pharmacies were used to obtain these therapies, respectively.[iv] Further, the CMS analysis identified approximately 225,000 beneficiaries who received potentially un-

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[i] Roberts AW and Skinner AC. Assessing the present state and potential of Medicaid controlled substance lock-in programs. *J Manag Care Pharm.* 2014;20(5):439–46c.

[ii] Centers for Disease Control and Prevention; National Center for Injury Prevention and Control (2012). Patient review and restriction programs. Lessons learned from state Medicaid programs. Available at *http://www.cdc.gov/homeandrecreationalsafety/pdf/PDO_patient_review_meeting-a.pdf.*

[iii] Medicare Payment Advisory Commission (2015). Medicare and the Health Care Delivery System, Report to the Congress. Chapter 5. Available at *http://www.medpac.gov/documents/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0.*

[iv] Centers for Medicare and Medicaid Services (2013). Supplemental guidance related to improving drug utilization controls. Correspondence from Cynthia G. Tudor, director, Medicare Drug Benefit and C and D Data Group dated Sept. 6, 2012. Available at *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/HPMSSupplementalGuidanceRelated-toImprovingDURcontrols.pdf.*

safe opioid dosing, which was defined as doses that exceeded 120 mg daily morphine equivalent dose for 90 or more consecutive days.[v]

The Stopping Medication Abuse and Protecting Seniors Act of 2015, which would authorize the use of PRRs in Medicare, would help reduce prescription drug abuse in this population. In addition, the legislation has strong beneficiary protections to ensure that patients with legitimate medical needs have access to effective pain management. Beneficiaries have the right to appeal their identification as at-risk and subsequent enrollment in a PRR. Patient input on the selection of prescribers and pharmacies will also ensure reasonable access, including consideration of geographic location, cost-sharing, travel time, and multiple residencies. Furthermore, patients receiving hospice care, those residing in long-term care facilities, and other beneficiaries the Secretary elects to treat as exempt would be excluded from enrollment in a PRR. This mechanism can be used to avoid enrollment of patients with medical diagnoses that require high doses or combinations of controlled substances to manage their pain.

There is substantial support to advance this policy as an effective tool to decrease opioid abuse. The policy has been proposed in the FY 2016 Budget request for the Department of Health and Human Services. A proposal similar to the Senate bill is part of the 21st Century Cures Act, which passed the House of Representatives with broad bipartisan support on July 10, 2015.

We urge the Senate to help address the nation's prescription drug abuse epidemic by passing legislation that would authorize the use of PRRs in Medicare. We look forward to working with Congress to refine the Stopping Medication Abuse and Protecting Seniors Act of 2015 and other legislative proposals that would expand use of the PRRs to ensure that these programs work as intended to prevent prescription drug abuse in Medicare.

PFIZER

Testimony of Mr. Ken W. Cole
Senior Vice President, U.S. Government Relations, Pfizer Inc.
Before the Senate Finance Subcommittee on Health
Hearing on Opiate Abuse
October 15, 2015

Mr. Chairman and members of the subcommittee,

Thank you for the opportunity to submit testimony for the Senate Committee on Finance Subcommittee on Health Care Field Hearing, "Examining Heroin and Opiate Abuse in Southwestern Pennsylvania." We are including Pfizer's comments, dated January 9, 2015, submitted to the FDA addressing the agency's "Development and Regulation of Abuse-Deterrent Formulations of Opioid Medications; Public Meeting [FDA–2014–N–1359]" for your reference. Further, we appreciate your commitment and attention to the prescription drug epidemic and welcome your request for policy proposals for Congress to consider for addressing this crisis.

Pfizer is a global leader in healthcare, helping change lives for the better by providing access to safe, effective, and affordable medicines and related healthcare services. Pfizer is one of the world's largest research-based biopharmaceutical companies. As part of our mission, we believe we can best ensure that people everywhere have access to innovative medicines and quality healthcare by working in partnership with all stakeholders, including patients, healthcare providers, managed care organizations, governments, and non-governmental organizations.

As you know, abuse of prescription opioids continues to take a devastating toll on individuals, families and communities across the nation. According to the Centers for Disease Control and Prevention (CDC), every day in the United States, 44 people die as a result of prescription opioid overdose. Deaths from overdose of prescription opioid painkillers have tripled since 2001, killing more than 16,000 in the United States in 2013. The rising prevalence of chronic pain and the increasing use and

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[v] Government Accountability Office (GAO) (2011). Medicare Part D: Instances of questionable access to prescription drugs, Report to Congressional Requesters. Available at *http://www.gao.gov/assets/590/585424.pdf.*

abuse of opioid analgesics have created an epidemic of distress, disability, and danger to a large percentage of Americans.

As you examine potential policy proposals to address the prescription drug crisis, we respectfully request that the subcommittee consider the role that abuse-deterrent opioids (ADOs) can play in reducing opioids misuse and abuse. Pfizer is well aware of the urgent need for new, powerful analgesics that are safer than opioids, and we are working to develop them. However, until powerful yet safer alternatives to opioids become available, and possibly even after they become available, opioid analgesics are likely to remain an indispensable component of pain therapy. Pfizer shares the vision of the future articulated by the Food and Drug Administration (FDA) in which most or all opioid analgesics are available to pain patients who need them in formulations that are less susceptible to abuse than the majority of currently available opioids. While no ADO to date can entirely eliminate the risk of abuse, ADOs are an important part of a comprehensive strategy to reduce prescription opioid-related abuse, misuse and overdose.

We are concerned however, that current policies restricting access to these new technologies as they become available could stifle innovation, limit patient access, and only perpetuate the prescription drug abuse crisis. Existing payment structures help illustrate system-wide barriers at both the formulary and provider level to the adoption of new pain therapies and treatment modalities and, more importantly, to the appropriate management of patients with pain. For example, non-opioid analgesics are uniformly recommended as first-line treatments by chronic pain and opioid use guidelines; however, patient access to the branded non-opioid analgesics is often restricted by prior authorization/step-edits and/or higher patient co-pays/co-insurance.[1] In contrast, patient access to currently available, largely generic, and largely non-abuse-deterrent opioid analgesics is unrestricted as they are placed on preferred formulary tiers with lower patient out-of-pocket expenses.[2] These policies, which disadvantage appropriate first-line therapies—either non-opioid alternatives or ADOs—and provide preferential access to the currently available non-ADOs, contribute to opioid overprescribing, and are likely to delay, if not prevent, the adoption of ADOs.

To help ensure patient access for Medicare beneficiaries, Pfizer recommends that the Centers for Medicare and Medicaid Services (CMS) propose a requirement that ADOs be placed in each drug class where ADOs exist. Per the Medicare Prescription Drug Benefit Manual, CMS requires that formularies contain at least two drugs for each category/class, but "may require more than 2 drugs for particular categories or classes if additional drugs present unique and important therapeutic advantages in terms of safety and efficacy, and their absence from the sponsor's formulary would substantially discourage enrollment by beneficiaries with certain disease states."

In addition to proposals to address prescription opioid abuse and misuse through CMS, we would also urge you to consider ways in which policies and programs at other federal agencies could be strengthened. In particular, you may wish to consider how the Food and Drug Administration's regulatory authorities can be utilized to encourage health care providers to consider prescribing ADOs, as appropriate, before prescribing opioids without abuse-deterrent properties, and to not approve new opioids that lack meaningful abuse-deterrent properties, except under limited circumstances.

We have recently seen strides made in the development of ADOs. Since 2010, four such products have been approved by FDA. And in April of this year, FDA issued final guidance establishing a pathway for the development of ADOs, clarifying the types of data required for abuse-deterrent labeling.[3] In Pfizer's view, the labeling of these opioid products should support and guide appropriate opioid prescribing.

We appreciate FDA's actions in 2013 mandating new labeling for extended-release/long-acting (ER/LA) opioids. The changes clarified that these products should only be used for pain severe enough to require daily, around-the-clock, long-term opioid treatment for patients for whom other, lower-risk pain medications are inadequate. These critical labeling changes were an important first step to help ensure that pro-

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[1] NIH Pathways to Prevention Workshop: The Role of Opioids in the Treatment of Chronic Pain, September 29–30, 2014, Draft Statement.

[2] *http://www.fingertipformulary.com//*. Accessed October 2014.

[3] *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM334743.pdf.*

viders are fully aware of the risks posed by these products and, ultimately, they will help save lives.

Yet currently, the labels of extended release opioids fail to provide guidance to physicians that opioids without abuse-deterrent properties should only be prescribed when an abuse-deterrent version is not available, or when an ADO is not appropriate for the patient. Similar to the new safety labeling mandated in 2013, such labeling could have a significant, positive impact on provider knowledge of ADO options and could help ensure that payors, including CMS, are providing access to ADOs.

Additionally, Pfizer recommends that FDA not approve opioids or opioid formulations lacking meaningful abuse-deterrent properties unless the new medicine fulfills an unmet need or provides a unique therapeutic benefit. In fact, FDA should encourage and support, through the development of guidance documents, a transition of all opioid medications, both immediate release and extended release, toward abuse deterrence (since both IR and ER opioids formulations can be abused)—similar processes, guidances, and expectations to those currently in place for extended release opioids should be followed for IR opioids, when and where there is evidence that developing such technologies is feasible.

Pfizer also recommends that FDA implement prominent labeling to distinguish between abuse-deterrent and non-abuse deterrent products, in order to inform patients, providers, and federal and private payers, and to encourage innovation. Please see the attached for Pfizer's full comments to the docket for FDA's October, 2014, public workshop entitled, "Development and Regulation of Abuse-Deterrent Opioid Medications."

Finally, we would respectfully request that you consider ways to ensure a coordinated policy response to the role of ADOs in helping to address the prescription drug abuse epidemic across federal agencies, including CMS, CDC, the National Institutes of Health (NIH) and the Substance Abuse and Mental Health Services Administration. Pfizer would also welcome appropriate recognition and reference updates incorporating the important concepts outlined in the FDA final guidance on the evaluation and labeling of ADOs in policy guidance and educational documents addressing opioids. For example, CMS should acknowledge FDA's final guidance establishing labeling standards for ADOs and levels of abuse deterrence in its 2017 call letter and discuss the potential role of ADOs in reducing the growing problem associated with opioid misuse. Similarly, the NIH's National Pain Strategy, the National Drug Control Strategy, and the Department of Health and Human Services recent initiative on opioid abuse should recognize the importance of ADOs as an emerging treatment option for clinicians and should integrate the concepts in FDA's recent guidance into relevant clinical, policy and research objectives.

Mr. Chairman, thank you again for the opportunity to submit testimony and for your efforts to address this critical public health threat. We look forward to working with you to turn the tide of this epidemic.

PINNACLE TREATMENT CENTERS

U.S. Senate
Committee on Finance
Subcommittee on Health Care
Field Hearing on Opiate Abuse in Southwestern Pennsylvania
Allegheny General Hospital—Magovern Auditorium
October 15, 2015

Statement for the Record

October 14, 2015

The Honorable Pat Toomey
Chairman
U.S. Senate
Committee on Finance
Subcommittee on Health Care
248 Russell Senate Office Building

Washington, DC 20510

The Honorable Debbie Stabenow
Ranking Member
U.S. Senate
Committee on Finance
Subcommittee on Health Care
731 Hart Senate Office Building
Washington, DC 20510

Dear Chairman Toomey and Ranking Member Stabenow,

I appreciate the opportunity to submit a statement for the record to this important hearing.

I am Joe Pritchard, CEO of Pinnacle Treatment Centers. Pinnacle currently operates 29 treatment centers in Pennsylvania, Kentucky, Michigan, New Jersey, and Virginia. On behalf of the Opioid Treatment Program (OTP) Consortium, of which Pinnacle is a member, I would like to thank you for holding this important hearing today. The OTP Consortium is a group of over 300 opioid treatment centers located in 39 states.

As you and your colleagues seek to address our nation's growing opioid abuse epidemic, I want to express our **strong opposition to S. 1455, The Recovery Enhancement for Addiction Treatment (TREAT) Act.**

OTP clinics provide comprehensive treatment to patients suffering from prescription opioid and heroin addiction via Medication-Assisted Treatment (MAT). MAT emphasizes patient-focused care in an individualized and integrated approach that includes counseling, behavioral therapies, drug testing, and the use of medication. OTP clinics are highly regulated by the states and federal government and have very low drug diversion rates. The National Institutes of Health (NIH) finds that our treatment protocols—which involve providing medications including methadone, buprenorphine and vivitrol, medical services, and psychosocial services including counseling for all patients—have "the highest probability of being the most effective of all treatments for opioid addiction." [1]

The TREAT Act seeks to remove the limit on the number of opioid addicted patients that a Drug Addiction Treatment Act (DATA) 2000-waivered physician can treat. Under current law, DATA 2000 physicians can treat 30 patients in the first year and apply for a waiver after the first year to treat up to 100 patients. These caps were put in place in exchange for the lax regulations governing the DATA 2000 program. In order to receive a DATA 2000 waiver, physicians only need to take an 8-hour online course, which focuses primarily on the medication (buprenorphine) that they would be allowed to prescribe to patients. DATA 2000 patients are not required to provide MAT. They are not required to provide counseling or behavioral therapy (or to refer it out), they are not required to administer random testing to determine illicit drug use or guide clinical decision making, they are not required to reference Prescription Drug Monitoring Program databases, and, as a result, most do not. Instead, DATA 2000 patients often receive a 30-day supply of buprenorphine and are told to return in another month or more for a refill. Prescribing more medication is not the answer and it certainly is not MAT. In our opinion, DATA 2000 practices that begin to exceed 100 patients become unregulated addiction treatment services, opening the door for poor practices to set back the gains achieved by highly regulated MAT services.

Medications like methadone and buprenorphine help to stabilize the patient—that's when the real work begins. These medications allow the patient to receive the treatment and services needed to address the underlying issues that led to their addiction in the first place. These patients need counseling and their providers need to be conducting random drug testing to help inform clinical decisions. Providers should be required to consult PDMP databases to prevent diversion. Seeing patients once per month and simply filling out a prescription once every 30–90 days will not address the opioid epidemic. That is why additional requirements should be placed on DATA 2000 physicians who want to treat more than 100 patients for opioid addiction.

The OTP Consortium strongly recommends expanding access to treatment as a key component of addressing the opioid epidemic. However, there is no evidence to sug-

[1] "Confronting an Epidemic: The Case for Eliminating Barriers to Medication-Assisted Treatment of Heroin and Opioid Addiction," Legal Action Center, March 2015.

gest that existing DATA 2000 physicians have reached their patient capacity. According to a June 2015 HHS study, through 2012, just 27.5% of DATA 2000 physicians had a waiver to prescribe to as many as 100 patients.[2] If just one-quarter of DATA 2000 physicians have applied for and received a waiver to go beyond the initial 30-patient limit, it's unlikely that lifting the cap will have an impact on access. Those who want to go above 100 are essentially drug treatment centers rather than a general medical practice and should be regulated as such to ensure their patients suffering from opioid addiction are receiving the evidence-based care they need. Worse yet, without regulation, these practices run the risk of becoming "pill mills."

Additionally, before considering whether to increase the DATA 2000 patient cap, Congress and HHS should seek information about the type of care being provided and patient outcomes in DATA 2000 practices. Specifically, Congress and HHS should measure:

- The number of patients in treatment within each DATA 2000 practice relative to its cap;
- Patient level outcomes and practice performance measures;
- The percentage of practices offering counseling on-site;
- The percentage of physicians referring patients for counseling and other services; and
- The percentage of practices offering toxicology testing to guide therapeutic dosing and decision making and to avoid the widespread diversion of this drug in the general community.

If the cap on DATA 2000 facilities were to be lifted, Congress and HHS should adopt patient safeguards and reforms that have proven to work in the OTP setting. Specifically, DATA 2000 practices should:

- Conduct a minimum amount of counseling per patient, per month;
- Employ prescription drug diversion control strategies;
- Perform drug testing to make sure patients are taking their prescribed medications, are not using illicit drugs, and to guide treatment decisions (*e.g.,* increase or decrease intensity);
- Use Prescription Drug Monitoring Programs to ensure patients are not getting opiates elsewhere; and
- Provide each patient with a comprehensive ASAM Patient Placement Assessment.

These reforms would ensure that raising the cap does not result in significant unintended consequences like greater diversion, drug use, crime, and higher health care spending. Such reforms should be adopted through an open process that engages stakeholders before increasing the patient cap.

At a minimum, these important patient protections should be added to the TREAT Act and apply to any waivered physician seeking to treat more than 100 patients.

We strongly recommend that Congress and HHS expand and increase the availability of treatment to overcome the opiate epidemic via OTPs as OTPs are required to adopt and implement evidence-based MAT. In fact, one study found that those who receive MAT are 75% less likely to have an addiction-related death than those who do not receive MAT.[3] A recent HHS report stated that increasing the number of OTPs would "help address treatment gaps" and that "OTPs are important . . . because they offer onsite medical care for those receiving methodone."[4] The same report found that 82% of OTPs nationally operated at 80% capacity in 2012.[5] Increasing OTP availability would truly increase access. Specifically, Congress should:

- Expand Medicaid coverage of prescription drugs to treat opioid addiction. (Currently, just 28 states cover all three[6]);
- Allow Medicare to pay for methadone to treat opioid addiction; and
- Enforce parity by requiring private insurance to provide methadone as a treatment option.

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[2] Jones, Campopiano, Baldwin, and McCance-Katz, "National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment," American Journal of Public Health, June 2015, page e3.

[3] Miller, T. and Hendrie, D. Substance Abuse Prevention Dollars and Cents: A Cost-Benefit Analysis. DHHS Pub. No. (SMA) 07–4298. Rockville, MD: Center for Substance Abuse Prevention, SAMHSA, 2008.

[4] Jone et al., page 6.

[5] Ibid.

[6] AK, AL, AZ, CA, CT, DE, FL, GA, IL, MA, MD, ME, MI, MN, MO, NC, NH, NM, NV, NY, OH, OR, PA, UT, VA, VT, WA, and WI.

If Congress or HHS chooses to examine lifting the DATA 2000 patient cap, it should first reform DATA 2000 practices for the first time in 15 years to ensure that these physicians who seek a larger addiction practice are, at a minimum, providing counseling, employing anti-diversion programs, and conducting random drug testing.

Thank you for your attention to this important matter. Again, the OTP Consortium and its 300+ treatment centers strongly opposes S. 1455 and instead strongly supports expanding access to treatment that has proven to be the most effective for decades—MAT. The Consortium looks forward to working with you to combat this crushing disease.

Sincerely,

Joe Pritchard
CEO
Pinnacle Treatment Centers

Pittsburgh Tribune-Review
OCTOBER 15, 2015

Senate Health Care Subcommittee Explores Ways of Stopping Addiction

(By Ben Schmitt)

At 13, Ashley Potts popped her first OxyContin pill and immediately fell in love.

Her life spiraled out of control as she became addicted, stole money, got arrested several times, got expelled from high school and graduated to crack cocaine.

Although she made a pact with herself never to inject heroin, she was shooting up by 17. Heroin was much cheaper: $10 a bag instead of $80 for a street prescription pill. Potts found it much easier to obtain.

"I felt like a zombie, a hollow corpse," she said. "In my head, there were only two options: Go to treatment and stop using or kill myself."

Potts, 29, of Washington told her story to a crowd of more than 300 people who packed Allegheny General Hospital's Magovern Auditorium on Thursday for a Senate health care subcommittee field hearing on the national and regional heroin and opioid addiction crisis. U.S. Senator Pat Toomey, a Republican from Lehigh Valley, convened the hearing along with Senator Bob Casey, a Democrat from Scranton.

She described herself as a full-on street junkie, who had cleaned up and relapsed several times by 2006 with a young daughter and not much hope. She contemplated suicide often but decided to try one more stint in detoxification and long-term treatment.

Potts eventually got clean and went to college. She works as a team leader for the crisis diversion unit of Southwestern Pennsylvania Human Services. When she finished her story, the crowd heartily applauded.

Still, Toomey, Casey and a panel of experts pointed out that while Potts' tale inspires, there are many people of all ages, races and demographics losing their battles with heroin and painkillers such as OxyContin, Vicodin and Percocet at startling rates.

Pennsylvanians are more likely to die from an opiate overdose than an auto accident, according to a report from the Trust for America's Health and the Robert Wood Johnson Foundation. A contributing factor is the over-prescribing of addictive painkillers to seniors and others. The Government Accountability Office estimates 170,000 Medicare beneficiaries nationwide may be battling addiction to pain medication, Toomey said.

"Ending the epidemic of heroin addiction will require changes in the practice of medicine, government regulation and societal views," he said.

As chairman of the Senate Committee on Finance Subcommittee on Health Care, Toomey described possible solutions as threefold: halting illegal diversion of prescription painkillers, reducing overuse of opioids for treating long-term pain and helping addicts receive proper treatment. He introduced bipartisan legislation to prevent inappropriate access to opioids and improve patient care for at-risk seniors.

One of the panelists, Neil Capretto, medical director of Gateway Rehabilitation Center, testified that OxyContin, the brand name for oxycodone, is a morphine-like drug

that accelerated the opioid addiction problem in the region "at a level never seen before."

"Of the several thousand heroin users that I have interviewed since 2000, well over 90 percent told me they started with opioid pain pills," he said.

Dr. Jack Kabazie, system director of Allegheny Health Network's Division of Pain Medicine, said Americans consume more opiate painkillers than the rest of the world combined.

"While most doctors prescribe opioids with good intents, once they move down that path, it is an extremely difficult path to reverse," he said. "In addition, physicians who have compensation or employment tied to patient satisfaction scores may feel pressure to prescribe opioids in response to patient pain complaints."

As the hearing was underway, Drug Enforcement Administration officials told the Tribune-Review they plan to hire drug diversion investigators for their Pittsburgh office. The investigators plan to focus on rogue pharmacies and doctors who write prescriptions for narcotic painkillers without cause, said Special Agent in Charge Gary Tuttle, who in July was promoted to head the agency's Philadelphia Field Division, which covers Pennsylvania and Delaware.

The beginning of a statewide prescription-drug database will help DEA agents keep tabs on the distribution of prescription painkillers from doctors and pharmacies, Tuttle said.

The DEA plans to combat the heroin and opiate drug problem through education, outreach and treatment, Tuttle said.

"I'm not saying we have a silver bullet," he said. "But we have to move people away from use, from that disease."

Potts, the recovering heroin addict, said the large turnout at the hearing moved her but highlighted the devastation caused by opiate abuse.

"We're not just statistics—we're real live people," she said. "The problem is astronomical. Every day I wake up grateful to be alive."

Dr. Tony Farah, chief medical officer for AHN, concurred.

"I think everyone saw today the passion and the interest in the audience not only from the medical professionals but from the lay audiences as well," he said. "This really underscores the incredible need for people not only to be educated on this problem but also to understand the role that each of them can play in addressing this major issue."

Ben Schmitt is a staff writer for Trib Total Media. He can be reached at 412–320–7991 or bschmitt@tribweb.com. Staff writer Jason Cato contributed to this report.

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October 7, 2015

The Honorable Pat Toomey
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248 Russell Senate Office Building
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The Honorable Debbie Stabenow
Ranking Member
U.S. Senate
Committee on Finance
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731 Hart Senate Office Building
Washington, DC 20510

Dear Chairman Toomey and Ranking Member Stabenow,

Good afternoon. I would like to thank you for giving me the opportunity to speak to you on behalf of Positive Recovery Solutions (PRS). My name is Amanda Cope. I am a registered nurse and have developed my career to specialize in addiction medicine. I celebrated 9 years sober on May 6th. Addiction medicine has been a passion for me since starting my own journey on the road to recovery. I am so grateful to be a part of this process to reach those in need of help. I have always strived to be an example of sobriety to each of our patients at PRS.

PRS is a private physician group dedicated to helping those with alcohol and opiate dependence. We have two physical locations, one in Pittsburgh, PA and one in Washington, PA. We started out as a suboxone clinic dedicated to helping those suffering from opiate addiction. Through our expansion over the past 20 months we have incorporated Vivitrol to help battle the horrific epidemic of heroin overdose that is taking place in Pennsylvania. We are on the front lines of this battle and work diligently to reach as many underserved populations as possible. Through our suboxone treatment we set into place practices and policies that reduce the rate of diversion and misuse of the medication. Patients are required to have weekly office appointments where they are urine drug screened at each appointment and given a 7 day prescription. The patient will be seen weekly for a minimum of 12 weeks until they have reached 12 consecutive clean urine drug screens. Patients are required to provided monthly verification from their behavioral entities that they are compliant with their drug and alcohol counseling sessions. We stand firmly on the belief that medication alone is not the answer. We also are an insurance based clinic. We do not charge patients cash for their office visits. We have a maxium dose of 16 mg per day of suboxone. After a patient has reached 12 consecutive clean urine drug screens they may then graduate to a biweekly program at the physicians discretion. Month long prescriptions are not given at PRS. Patients are not discharged for positive urine drug screens. PRS makes every possible attempt to get the patient the appropriate level of care. If a patient has 3 positive UDS they will be recommended to receive drug and alcohol counseling at a higher level. We will elevate a patients level of care all the way back into inpatient rehabilitation in an effort not to discharge. We employ every means possible to keep a patient active in treatment and on the road to recovery.

Approximately 1 year ago I had a meeting with a Vivitrol representative named Joanne Kommer. Joanne explained the Vivitrol medication to me and its valuable use in the fight against opiate dependence. PRS immediately incorporated Vivitrol treatment into our practice. We were very excited in the complete abstinence model that it supported. The success stories from people that were already on Vivitrol was a cause of great excitement for us. We added PRS onto the provider locater website for Vivitrol and that is where the idea for a mobile Vivitrol unit formed. Through our addition to the provider locater site one thing became rapidly clear to us. Patients were traveling from very far distances in order to be followed on the medication. Sometimes as far as 4 hours away. We quickly realized that providers were either unable or unwilling to provide follow-up care for these patients. A lot of patients were induced in an inpatient setting then could not follow up with their monthly injections due to lack of providers or the providers that would do the follow-up care would charge a large cash amount to receive their injection. We immediately started researching our idea of a mobile unit. PRS had meetings with local SCA in surrounding counties to establish that they did in fact have a need in their community. Specifically Kami Anderson of Indiana, Armstrong, and Clarion and Judy Rosser of Blair county. These ladies were pivotal in the formation of our pilot program. As mentioned earlier, PRS believes firmly that patients need the whole picture of recovery, not just medication. It is with that philosophy that we have created relationships with local behavioral health entities in order to give the patient the best chance of recovery. Gateway rehab, Cove forge, Pyramid, The Open Door, Arc Manor, Blairdap are just a few of the entities that we work with to provide the patient the appropriate level of care. Our program is designed that when a patient is referred to our services they must consent to allow open lines of communication between PRS and the behavioral health entity. PRS is strictly the medical aspect of treatment. We do not provide drug and alcohol counseling. With that in mind, that is why our program is so enticing to programs that have no ability to provide medication assisted therapy. We work together to complete the picture of a successful road to recovery.

Our mobile unit launched the first week of July 2015 and has been a success from day one. Our mobile unit functions in the exact fashion as our brick and mortar locations. The unit is equipped with a private waiting area, a restroom for urine specimen collection, a private assessment room, and a private injection room. We have

contracted with Blair, Indiana, Clarion, and Armstong counties to be able to provide services to unfunded patients. Once a patient has flipped to Medicaid coverage we then bill the appropriate insurance. Of the 67 counties in Pennsylvania, 37 of those have expressed interest in having our services made available to them. More will be revealed when the budget is passed. PRS had the capability and intention to provide services to the entire state of Pennsylvania. We have applied to programs such as "Pay for success" and up to this point have been privately funded for the purchase of the mobile unit. We look forward to expand and service as much as the patient population as possible.

Current challenges to our program include the Prior authorization process. We have attended meetings in Harrisburg with Secretary Tennis and Secretary Dallas who are working with us to make this mobile unit a success. Currently we are trying to have an agreement similar to the one with the Department of Corrections where we can get a verbal authorization and bypass the faxing of documents which then leads to a wait from anywhere between 24 hours to 3 weeks. Our desire to get these patients safe as soon as possible relies on the ability to be able to administer the medication as soon as the treatment team deems it to be medically appropriate. Our unit is currently available to each county on a biweekly schedule. The first appointment will include their "New patient assessment" where we do a complete drug history, past medical history, medication check, UDS, confirmation of drug and alcohol counseling and other pertinent information is obtained. PRS would like the ability to give the injection at the first assessment when medically appropriate. We continue to work on a daily basis to find new ways to help stop the devastating effects of overdoses in our communities. We appreciate immensely your interest in learning about our innovative program. Together we can help stop this horrific epidemic and assist in bringing back together families, loved ones and communities. I thank you for your time today. God Bless.

Amanda Cope, RN
Positive Recovery Solutions

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October 12, 2015

U.S. Senator Pat Toomey
248 Russell Senate Office Building
Washington, DC 20510

Dear Senator Toomey:

We appreciate your legislative efforts to address the problem of prescription opioid addiction, which is a significant issue in western Pennsylvania as well as other areas of the U.S. We are writing to share our ideas as we both have worked in the field of addiction treatment and research for several decades and have seen firsthand the havoc that opioid addiction creates for affected individuals, families, and society. Here are some of our thoughts about this problem and potential solutions from the perspectives of education and treatment.

The U.S. Attorney in Pittsburgh published a final report and recommendations on prevention, intervention, treatment, and recovery related to drug overdose and addiction (September 29, 2014). Dr. Douaihy served on the committee that generated this report.

Key elements of this report that we believe are relevant to what you wish to accomplish with your legislation include:

1. *Education, prevention and family intervention:*
    a. Develop a public awareness and education plan to reduce overdose deaths.
    b. Coordinate websites containing information on overdose prevention and links to recovery-based resources.
    c. Assure access to and promote a regional hotline dedicated to OD prevention.

d. Promote physician education and intervention programs.

e. Educate buprenorphine providers on the best practice guidelines (Community Care Behavioral Organization in PA published excellent guidelines on "best practices" for treatment of opioid addiction).

2. *Treatment:*

a. Promote efforts to increase the availability of naloxone in the community as a safe antidote to opioid overdose.

b. Support Good Samaritan Laws and Prescription Drug Monitoring Programs.

c. Support measures to increase capacity for treatment of addiction.

d. Implement screening and referral interventions for early identification of drug problems (*e.g.,* in medical settings).

Treatment needs to be long-term since opioid addiction is a chronic condition. Presently, many treatment resources focus on the acute phase of illness (detoxification, rehabilitation, intensive outpatient) and not on long-term or "continuation" treatment.

Recovery from addiction must be emphasized as this is the best antidote for relapse. Engagement in community mutual support programs helps many sustain long-term recovery. Treatment can help prepare an individual for recovery, but is not a replacement for it.

Family involvement in treatment and recovery needs to be emphasized. Many treatment programs DO NOT include families or offer services to them. There is a significant research and clinical literature documenting the adverse impact of opioid addiction on family units and individual members, including children. Addiction contributes to higher rates of family break-up, abuse and neglect, dependence on welfare, and involvement in criminal justice and other social services. Addiction creates a huge emotional and financial burden for families who spend an incredible amount of time, energy and money on their addicted loved one. Children of opioid addicted parents are at higher risk for psychiatric and substance use disorders, behavior problems, and academic problems.

Addressing addiction requires considering multiple perspectives. We wish you well in your attempts to help addicted individuals, families and communities.

Sincerely,

Dennis C. Daley, Ph.D.
Professor of Psychiatry and Social Work
Director, Regional Research and
Training Center of Clinical Trials
Network of the National Institute
on Drug Abuse

Antoine Douaihy, M.D.
Professor of Psychiatry
Medical Director
Addiction Medicine Services

LETTER SUBMITTED BY KEVIN M. WONG, M.D., CMD, FAAFP

October 14, 2015

The Honorable Pat Toomey
Chairman
U.S. Senate
Committee on Finance
Subcommittee on Health Care
248 Russell Senate Office Building
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The Honorable Debbie Stabenow
Ranking Member
U.S. Senate
Committee on Finance
Subcommittee on Health Care
731 Hart Senate Office Building
Washington, DC 20510

Dear Chairman Toomey and Ranking Member Stabenow,

S. 1913—Stopping Medication Abuse and Protecting Seniors Act of 2015 is a laudable effort to help reduce the narcotic abuse. As a practicing family physician

for over 33 years, I have always tried to treat patients to the best of my ability following the adage, "First do no harm." Even with clinical indications for appropriate use of long term narcotics and prescribing, an experienced clinician will eventually be "beaten" by a patient seeking narcotics for inappropriate reasons. If we don't prescribe to some of these patients because they don't fit the typical pattern, we will inadequately treat someone who has a true medical need.

A few years ago, I had an 80 year old frail female patient with documented severe arthritis who had been on a stable regimen of long acting narcotics for her chronic pain. I never suspected that she might be diverting her medications and was greatly surprised to receive a call from the pharmacist saying, "we have a problem!" When we filled Mrs. T's prescription today, she stood at our counter, made us count out the tablets, stating she had been shorted last month. After she was satisfied the count was correct, the bottle was placed in a bag and she left. As soon she walked out to the parking lot, we saw her on our security camera hand the same bag to a man, who handed her cash, which she held up in the sunlight to count each bill (she had poor eye sight). The pharmacist said they wouldn't report her if she didn't show up there again! When I called her family to tell them I would not be prescribing her narcotics anymore, they were livid, claiming I was abandoning her. After I explained she would not be withdrawing from narcotics, since she handed over her entire amount, they calmed down. After that, she transferred to another physician and I eventually found out she continued to get narcotics, until I happened to see that physician and he mentioned her name, saying she came to see him as I had been too busy. After I told him the story, he stopped writing the prescription and she moved onto another doctor.

This bill would eliminate this specific scenario. However there are many more reasons it needs to pass. Even with the current guidelines proposed by organizations to help physicians (American Academy of Family Physicians, American Academy of Pain Medicine, AMA, CDC) without support from the federal and state agencies, the problem of narcotic abuse will continue to grow as witnessed by the current trends. State-based Prescription Drug Monitoring Programs (PDMPs) have been successful in aiding physicians decrease narcotic diversion, however the programs are NOT fully functional in all states (currently 49 states, District of Columbia, and Guam). Even in states where PDMPs have been created, they are NOT all helpful to physicians—Pennsylvania is a perfect example. The registry is currently accessible only to law enforcement. Many states have been happy with the PDMPs, but the next step requires federal help—link all the state PDMPs to prevent migration from state to neighboring states that either don't have a physician accessible database or don't share data.

Other significant improvements for PDMPs:

(1) Require the data be reported by the pharmacist, live to ensure the patient didn't get a narcotic recently from another physician and report it to BOTH physicians, if a concern is discovered, BEFORE filling the prescription.
(2) Require photo IDs for anyone prescribed and picking up a narcotic prescription.

Physicians who are trying to do the best for their patients need as much support as possible. Family doctors find it very hard to follow these appropriate guidelines when they are constantly held to a different standard of care compared to pain clinics who will prescribe narcotics and tranquilizers concurrently, even though there is strong evidence against concurrent use of this combination of medications which can lead to fatalities.

The good news is that there is some preliminary evidence that an insurer in western Pennsylvania trying to aid physicians care for their Medicare patients has found that only 0.13% (~200/150,000) for the first 2 Quarters of this year hit the high dose narcotic threshold. It is hoped with further measures as outlined previously to minimize inappropriate use and diversion, this number can continue to drop.

Thank you for your efforts to protect our vulnerable patients and help doctors care for them appropriately.

Kevin M. Wong, M.D., CMD, FAAFP

Past President, Pennsylvania Academy of Family Physicians

Resources:

http://www.aafp.org/news/health-of-the-public/20150408hhsopioids.html

http://www.aafp.org/news/health-of-the-public/20150408hhsopioids.html

http://www.ama-assn.org/ama/pub/advocacy/topics/preventing-opioid-abuse/opioid-abuse-task-force.page

http://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq

http://www.aafp.org/news/health-of-the-public/20150729opioidtaskforce.html

http://www.cdc.gov/drugoverdose/prescribing/guideline.html

http://www.aafp.org/news/health-of-the-public/20150128nihopioidstudy.html

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