

VA OPIOID PRESCRIPTION POLICY, PRACTICE, AND PROCEDURES

HEARING

BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS

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VA OPIOID PRESCRIPTION POLICY, PRACTICE, AND PROCEDURES

THURSDAY, MARCH 26, 2015

U.S. SENATE,
COMMITTEE ON VETERANS AFFAIRS,
Washington, DC.

The Committee met, pursuant to notice, at 10:09 a.m., in room 418, Russell Senate Office Building, Hon. Johnny Isakson, Chairman of the Committee, presiding.

Present: Senators Isakson, Moran, Boozman, Cassidy, Tillis, Blumenthal, Brown, Hirono, and Manchin.

Also present: Senators Johnson and Baldwin.

OPENING STATEMENT OF HON. JOHNNY ISAKSON, CHAIRMAN, U.S. SENATOR FROM GEORGIA

Chairman ISAKSON. I would like to call this meeting of the Veterans' Affairs Committee to order. I want to thank our panelists for coming today to talk about a very important subject. Dr. Clancy, particularly, we welcome you again and thank you for all the help you have given the Committee and the Veterans Administration. We appreciate it very much.

We have new rules for this Senate Committee this year. The Ranking Member and the Chairman will make opening remarks. Any members that want to make an opening remark can make it at the closing of the hearing, because we came to hear from those testifying, not from other members of the Senate. Yet, anybody is welcome to file a statement if they would like.

We have two additional members that will sit in today, Senator Johnson and Senator Baldwin from the State of Wisconsin, which obviously has been a focal point of the over-prescription of opiates. I think it is important they have the opportunity to participate in the questioning of our witnesses.

In the absence of opening statements, I will make a brief one. I will turn it over to our Ranking Member, Richard Blumenthal, then we will go straight to our distinguished panelists.

Let me just say this: one of our panelists was going to be Dr. Tom Frieden or his designee from the CDC, which is doing an awful lot of work on the over-prescription of opiates. He could not be here, but we talked by phone for about 15 minutes prior to this hearing. There are two facts that he told me that I think make the point as to why this is an important hearing.

One, 145,000 Americans have died in the last 10 years from an over-prescription or over-consumption of opiates, 145,000. The rate of prescription has become so great that there were enough pre-

scribed last year to provide one in every six Americans with a prescription for a year. That is 15 percent of the population with a year's prescription. That is how much of a supply is coming out.

Two, the CDC has recognized that it is such a prominent problem for health care in America that they have a task force working on guidelines for their prescriptions which will be published some time at the end of December for public comment, and hopefully by April 1 it will become policy of the CDC and the United States of America.

This is a serious problem. Abuse and over-prescription of opiates is bad for the recipient, it is bad for the country, and it is a bad way to mask problems rather than treat problems, which is what we are all about in terms of the Veterans Administration.

With that opening preface and the gravity of the situation, as illustrated by the statistics from the CDC, I am happy to welcome our Ranking Member for his opening remarks.

Senator Blumenthal.

**STATEMENT OF HON. RICHARD BLUMENTHAL, RANKING
MEMBER, U.S. SENATOR FROM CONNECTICUT**

Senator BLUMENTHAL. Thank you, Mr. Chairman, and thank you, our witnesses, all of our witnesses for being here today, and thank you to Senator Baldwin for sharing with us. I know of her very strong interest in the tragic experience, and very responsible involvement in making sure there is proper oversight at the Tomah facility in Wisconsin where an instance of over-prescription occurred.

I want to thank the Chairman for having this hearing. I do not know of any topic that is more important in our VA health care system. We talk a lot about inadequate care in the sense of inadequate quantities of care. Here is an instance of excessive quantities of a particular drug doing absolutely horrific damage to our Nation's heroes.

We know that 22 veterans every day commit suicide, and many of them have suffered from over-prescription of opioids. Plain and simple, the current system is abysmally inadequate. It is like Swiss cheese, riddled with gaps and holes that permit and, in fact, enable, sometime even encourage over-prescription, deadly over-prescription of opioids.

This Committee had a hearing during the last session on this very problem and I want this hearing to be different, to produce much more adequate action by the VA. We are in this issue together and I know that the VA shares our alarm and outrage, but action is absolutely necessary because over-prescription and overdose of opioids is an epidemic and a scourge in this country.

I am going to ask that the remainder of my opening statement be put in the record, if there is no objection—

Chairman ISAKSON. Without objection.

Senator BLUMENTHAL [continuing]. Because I do provide some of the other background. I just want to say I am grateful to John Gadea of our State Drug Control Division as well as Jonathan Harris, our Consumer Protection Commissioner for being here today. John Gadea and I have worked for many years on this topic.

I helped to lead the initiation in Connecticut of our prescription monitoring program which computerized prescriptions so as to keep track and prevent over-prescription and overdosing. This was in 2006. It was started in 2008. So, this problem has been around for a long time. We cannot claim that it has snuck up on us or surprised us.

This epidemic has been with us for years and years, and that is one reason, from my anger and astonishment, that the VA system is not better than it is. It is a problem that is nationwide. It is not limited to Tomah or any other single facility.

I plan to begin efforts in Connecticut to make sure that the problem that existed in Tomah is not endemic to Connecticut as well. I am going to be commenting later on an invention that a young lady from Connecticut, Lily Zyszkowski told me about that she initiated, announced, and presented to the White House recently at the White House Science Fair called the Pill Minder, which is a microchip with touch sensors designed to remind people how to take their pills and to alert care givers when the pills have not been taken.

A high school student has a system for helping to stop overdoses. Think of it for a moment. A high school student is telling us how to stop a problem that has been with us for more than a decade and has actually killed people. I am very proud of young inventors like Lily. I am grateful to our Chairman for having this hearing today and for his commitment.

Needless to say, it is a bipartisan commitment to make sure that we end this scourge and that we make sure that this kind of systemwide problem is addressed and stopped and that we all take whatever action is necessary to do so. Thanks, Mr. Chairman.

[The prepared statement of Senator Blumenthal follows:]

PREPARED STATEMENT OF SENATOR RICHARD BLUMENTHAL, RANKING MEMBER

Prescription drug overdose has become an epidemic in this country.

According to the Agency for Healthcare Research and Quality, the hospitalization rate for overuse of opioids doubled between 1993 and 2012 and drug overdose death rates in the United States have more than tripled since 1990.

This is a problem that requires the attention of policymakers from the local to the Federal levels, law enforcement as well as health care providers to come together and come up with creative ways to get ahead of the scourge of suffering and addiction that tragically all too often leads to death.

There are few areas when drug addiction is more tragic than when veterans who have served our country return home with serious medical conditions, and seek treatment but end up in a spiral of pain and drug addiction.

I'm pleased that Chairman Isakson has chosen to have another hearing on this important topic. Last year, I participated in then-Chairman Sanders' hearing that focused on complementary and alternative treatments that could serve as an alternative to opioid treatment.

It's vital that we continue to address this topic within this Committee—and especially to discuss the best practices that are utilized within VA and throughout the private sector in partnership with state agencies.

I look forward to hearing the testimony from VA as well as the Inspector General to inform us on the status of VA's internal efforts at avoiding diversion and over-prescription of painkillers.

While the rates of opioid misuse have been steadily increasing, this is not altogether a new problem. I led a hearing on Prescription Drug Abuse as Attorney General of the state of Connecticut over a decade ago as we worked at putting a prescription drug monitoring system in place. It took many years to get the system set up, but Connecticut now has a very robust system and I am especially looking forward to hearing the testimony of John Gadea, Connecticut's Director of State Drug Control Division. John and I have worked together for years and I value his insight

as well as his leadership and partnership in developing the Connecticut Prescription Monitoring and Reporting System.

Veterans deserve to have the best systems in place for drug delivery as well as information on all options available to them. This includes having appropriate access to strong painkillers when necessary, but also access to screening systems, prevention tools and monitoring programs to ensure that treatment for pain does not lead to devastating pain, suffering and possibly death.

While the problem is nationwide, VA must be at the forefront of making sure that its physicians, pharmacists and all of its health care team are committed to best practices in the area and each facility must be confident that doctors like the so-called "Candy Man" at the Tomah VA facility are identified and those practice corrected. I am pleased that my colleagues from Wisconsin are joining our conversation today to lend some insight into what their constituents in Wisconsin experienced and to assist us with our oversight in this area.

I will turn back to the Chairman in a second, but I just want to share one last thing with the Committee. Earlier this week, I went to the White House for the White House Science Fair. We had two representatives from Connecticut there, and one of the young ladies, Lily Zyszkowski, was there with three inventions, one of which she calls the PillMinder.

I am probably not doing justice to the invention, but the basic idea is that the PillMinder is a microchip with touch sensors designed to remind people to take their pills and to alert caregivers when the pills had been taken. Now I don't know if Lily was thinking about how this could be used to prevent and deter drug overdoses, but that seems like a pretty interesting use of her invention to me.

I bring this up today partially because I am very proud of young inventors from my state like Lily, but primarily because this is the type of smart, creative thinking that we need from all sectors to be able to properly tackle the problem of prescription drug abuse. I hope this hearing today will result in implementing more of the good ideas that I know are out there.

Chairman ISAKSON. Thank you, Senator Blumenthal.

We have our first panel, which consists of Dr. Carolyn Clancy, who is the interim Under Secretary for Health, Veterans Health Administration, Department of Veterans Affairs. Thank you for being here.

You are accompanied, I believe, by Dr. West and Mr. Valentino. Is that correct? From the Inspector General's Office, John—is it Daigh?

Dr. DAIGH. Daigh, sir.

Chairman ISAKSON. Daigh. Thank you. Dr. Daigh, is Assistant Inspector for Healthcare Inspections, Office of the Inspector General, Department of the Veterans Affairs. We will start with Dr. Clancy.

STATEMENT OF CAROLYN CLANCY, M.D., INTERIM UNDER SECRETARY FOR HEALTH, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS; ACCOMPANIED BY GAVIN WEST, M.D., SPECIAL ASSISTANT FOR CLINICAL OPERATIONS, AND MICHAEL VALENTINO, CHIEF CONSULTANT OF PHARMACY BENEFITS MANAGEMENT SERVICES

Dr. CLANCY. Thank you. Good morning, Chairman Isakson, Ranking Member Blumenthal, Members of the Committee. We appreciate the opportunity to participate in this hearing and to discuss VA's pain management programs and the use of medications, particularly opioids, to treat veterans' experiencing chronic pain. As the Chairman noted, I am accompanied by Dr. Gavin West and Mike Valentino.

I would like to begin today by addressing the situation at Tomah. We are continuing to investigate the accusations at Tomah and we will keep you up to date on our findings. We will not tolerate an

environment where intimidation or suppression of concerns occurs and we welcome input from all employees and whistle blowers.

If employee misconduct is identified, we will take the appropriate action and hold those responsible accountable. These investigations are an opportunity to get to the bottom of any issue so that moving forward, these issues are not repeated at Tomah or elsewhere in our system.

Unfortunately, many of our Nation's veterans suffer from chronic and acute pain. About 60 percent of returning veterans from the Middle East and more than 50 percent of older veterans live with some kind of chronic pain. The treatment of veterans' pain is often very complex.

Many of our veterans have survived severe battlefield injuries, some repeated, resulting in lifelong moderate to severe pain related to musculoskeletal problems and permanent nerve damage. This can impact not only their physical abilities, but also their emotional health and brain structures.

Our efforts to reduce high dose opioid-prescribing have been successful initially in patients with uncomplicated chronic pain. However, veterans with complex chronic pain, such as those with one or more combinations of Traumatic Brain Injury, Post Traumatic Stress Disorder, and so forth may have relied on opioids for pain control.

Tapering their doses to safer levels and instituting more comprehensive pain practices must go much more slowly and carefully to be both safe and to assure control of their suffering and quality-of-life. Veterans are particularly challenged by chronic pain, but as the Chairman mentioned, having heard from my former colleague, Tom Frieden, chronic pain is a national public health program.

As identified in a study by the Institute of Medicine several years ago, 30 percent of the Nation's adult population experience chronic pain. This country is now in the midst of an epidemic of misuse and overuse, as has been very clearly stated. The safe and appropriate use of opioids is particularly important for VA due to the number of veterans who have musculoskeletal injuries, nerve damage, and other conditions associated with their pain.

Making positive changes in our prescribing practices has required providers and veterans to change the ways in which pain is managed, including other pain treatments available to rely less on opioids. These changes to pain management have to be done carefully and in a measured fashion to avoid the possibility that veterans will receive inadequate pain care.

Our data and studies in the medical literature show that we are making progress in pain management. We have adopted several initiatives to advance the goal of safe, effective pain management. One of these is called our Opioid Safety Initiative, or OSI, which was first launched in August 2013. This combines feedback to providers and facilities on their prescribing practices with education and training to ensure that these medications are used safely, effectively, and judiciously.

This initiative holds considerable promise for minimizing harm among veterans, promoting provider competence in promoting of veteran-centered, evidence-based, and coordinated multi-disciplinary pain care.

We recently produced a risk report for individual clinicians so that they could look at their entire panel of patients. Academic detailing, which is another one of our programs, combines the expertise of individuals specialized in pain management and prescribing. It has been tested in three of our networks with pretty big successes.

Last year we encouraged all of our networks to adopt this approach, and about a third did. I am now mandating that all of our networks adopt this approach and have it fully implemented by the end of June 2015, and that they begin reporting quarterly data to the Under Secretary's office by the end of September 2015.

We are also leveraging the capabilities of our telehealth to extend specialty expertise in safe, effective pain management for clinicians who care for veterans in rural communities for whom travel to pain management experts can be pretty challenging. It has been particularly successful in Ohio.

While we know our work to improve pain management programs and the use of these medications will never truly be finished, we believe we have been at the forefront of dealing with pain management and will continue to do so to better serve the needs of veterans. We appreciate this Committee's support and encouragement in identifying and resolving challenges as we find new ways to care for veterans.

On the subject of overdose, I will say that since May, we have instituted a program and prescribed 2,700, I believe, Narcan-prescribing kits, which we have a couple of samples to show you here. These can be administered by a family member, a friend, or a clinician to prevent an overdose if they suspect that has happened in someone close to them. And since last May, 41 people have a second chance at life. I wanted to make that all clear as well and look forward to your questions.

[The prepared statement of Dr. Clancy follows:]

PREPARED STATEMENT OF DR. CAROLYN CLANCY, M.D., INTERIM UNDER SECRETARY FOR HEALTH, VETERANS HEALTH ADMINISTRATION (VHA), DEPARTMENT OF VETERANS AFFAIRS (VA)

Good morning, Chairman Isakson, Ranking Member Blumenthal, and Members of the Committee. Thank you for the opportunity to participate in this hearing and to discuss VA's pain management programs and the use of medications, particularly opioids, to treat Veterans experiencing acute and chronic pain. I am accompanied today by Dr. Gavin West, Clinical Operations, Veterans Health Administration (VHA) and Dr. Michael Valentino, Chief Consultant, Pharmacy Benefits Management, VHA.

I would like to begin by saying that clearly we are deeply concerned about the allegations of improper opioid prescribing practices and retaliatory behavior at the Tomah VA Medical Center (VAMC). To deliver high-quality health care, we rely on the integrity, observations, and recommendations of VA's front-line staff, who work professionally and compassionately with Veterans each and every day. We recognize the toll this situation is taking on all involved, and we are quickly and thoroughly investigating these issues.

CHRONIC PAIN ACROSS THE NATION

Chronic pain affects the Veteran population, but this is not an issue limited to Veterans. Chronic pain is a national public health problem as outlined in the 2011 study by the Institute of Medicine (IOM). At least 100 million Americans suffer from some form of chronic pain. The IOM study describes in detail many concerns of pain management, including system-wide deficits in the training of our Nation's health care professionals in pain management; the problems caused by a fragmented health care system; the general public's lack of knowledge about pain leading to inadequate

self-management; and the need for care planning that is personalized for the individual patient. While about 30 percent of the Nation's adult population experiences chronic pain, the problem of chronic pain in VA is even more daunting, with almost 60 percent of returning Veterans from the Middle East and more than 50 percent of older Veterans in the VA health care system living with some form of chronic pain. The treatment of Veterans' pain is often very complex. Many of our Veterans have survived severe battlefield injuries, some repeated, resulting in life-long moderate to severe pain related to damage to their musculoskeletal system and permanent nerve damage, which cannot only impact their physical abilities but also impact their emotional health and brain structures.

CURRENT VHA PAIN MANAGEMENT COLLABORATION

To implement effective management of pain, VHA's National Pain Program office oversees several work groups and a National Pain Management Strategy Coordinating Committee representing the VHA offices of nursing, pharmacy, mental health, primary care, anesthesia, education, integrative health, and physical medicine and rehabilitation. Working with the field, these groups develop, review and communicate strong pain management practices to VHA clinicians and clinical teams. For example, the VHA Pain Leadership Group, consisting of Pain Points of Contact for the Veterans Integrated Service Networks (VISNs) and facilities, meets monthly with the National Pain Program office to discuss policy, programs and clinical issues and disseminate information to the field as well as to provide feedback to VACO leadership about these programs. Several of these groups are chartered to promote the transformation of pain care in VHA at all level of the Stepped Care Model: the Pain Patient Aligned Care Team (PACT) Initiative Tactical Advisory Group focuses on primary care issues; the Pain Medicine Specialty Team Workgroup builds capacity for specialty pain services; the Interdisciplinary Pain Management Workgroup focuses on developing CARF certified tertiary care pain management programs for complex patients. Opioid Safety Initiative (OSI) Toolkit Task Force has published and promoted 16 evidenced-based documents and presentations to support the Academic Detailing model of the OSI. More information on the OSI Toolkit can be found via the follow link: (<http://vaww.va.gov/PAINMANAGEMENT/index.asp>). The Department of Defense (DOD)-VA Health Executive Council's Pain Management Workgroup (PMWG) oversees joint projects with the DOD, including the two Joint Investment Fund (JIF) projects, the Joint Pain Education and Training Project and the Tiered Acupuncture Training Across Clinical Settings, and other projects that aim to standardize good pain care across DOD and VHA.

Academic Detailing is a proven method in changing clinicians' behavior when addressing a difficult medical problem in a population. Academic Detailing combines longitudinal monitoring of clinical practices, regular feedback to providers on performance, and education and training in safer and more effective pain management. Our pain management programs, including the Specialty Care Access Network-Extension for Community Healthcare Outcomes (SCAN-ECHO) and the OSI, have been designed to integrate into the Academic Detailing model.

VA'S PROGRESS IN PAIN MANAGEMENT

Chronic pain management is challenging for Veterans and clinicians—VA continues to focus on identifying Veteran-centric approaches that can be tailored to individual needs that may also include physician therapy, acupuncture, chiropractic treatments, and other modalities in addition to medications. Opioids are an effective treatment, but their use requires constant vigilance to minimize risks and adverse effects. VA launched a system-wide OSI in October 2013, and has seen significant improvement in the use of opioids as discussed later in the testimony. Most recently, in March 2015, we launched the new Opioid Therapy Risk Report tool which provides detailed information on the risk status of Veterans taking opioids to assist VA primary care clinicians with pain management treatment plans. This tool is a core component of our reinvigorated focus on patient safety and effectiveness.

VA's own data, as well as the peer-reviewed medical literature, suggest that VA is making progress relative to the rest of the Nation. In December 2014, an independent study by RTI International health services researcher, Mark Edlund, MD, Ph.D. and colleagues, supported by a grant from the National Institute of Drug Abuse, was published in the journal *PAIN*¹ the premier research publication in the field of pain management. This study, using VHA pharmacy and administrative data, reviewed the duration of opioid therapy, the median daily dose of opioids, and

¹Edlund MJ et al, Patterns of opioid use for chronic noncancer pain in the Veterans Health Administration from 2009 to 2011. *PAIN* 155(2014) 2337–2343

the use of opioids in Veterans with substance use disorders and co-morbid chronic non-cancer pain. Dr. Edlund and his colleagues found that:

- First, half of all Veterans receiving opioids for chronic non-cancer pain, are receiving them short-term (i.e.: for less than 90 days per year);
- Second, the daily opioid dose in VA is generally modest, with a median of 20 Morphine Equivalent Daily Dose (MEDD), which is considered low risk; and
- Third, the use of high-volume opioids (in terms of total annual dose) is not increased in VA patients with substance use disorders as has been found to be the case in non-VA patients.

Dr. Edlund and the other authors concluded “this suggests appropriate vigilance at VA, which may be facilitated by a transparent and universal electronic medical record.” Although it is good to have this information, a confirmation of our efforts for several years, starting with the “high alert” opioid initiative in 2008 and multiple educational offerings, by no means is VA’s work finished. In fact, although we are well along in implementing our plan, VA is also working with other Federal agencies and VAMC experts to implement the National Institutes of Health-Department of Health and Human Services National Pain Strategy, an outgrowth of the IOM study, which recommends a transformation in the education of physicians and other health care professionals in pain management. By virtue of VA’s central national role in medical student education and residency training of primary care physicians and providers, we will be playing a major role in this national effort. But we have already started with our robust education and training programs for primary care, such as SCAN-ECHO, Mini-residency, Community of Practice calls, two JIF training programs with DOD, and dissemination of the OSI Toolkit.

The Opioid Safety Initiative

The OSI was chartered by the Under Secretary for Health in August 2012. The OSI was piloted in several VISNs. Based on those results of the pilot programs, OSI was implemented nationwide in August 2013. The OSI objective is to make the totality of opioid use visible at all levels in the organization. It includes key clinical indicators such as the number of unique pharmacy patients dispensed an opioid, unique patients on long-term opioids who receive a urine drug screen, the number of patients receiving an opioid and a benzodiazepine (which puts them at a higher risk of adverse events), and the average MEDD of opioids. Results of key clinical metrics for VHA measured by the OSI from Quarter 4, Fiscal Year 2012 (beginning in July 2012) to Quarter 1, Fiscal Year 2015 (ending in December 2014) are:

- 91,614 (13%) fewer patients receiving opioids (679,376 => 587,762);
- 29,281 (24%) fewer patients receiving opioids and benzodiazepines together (122,633 => 93,352);
- 71,255 more patients on opioids that have had a urine drug screen to help guide treatment decisions (160,601 => 231,856);
- 67,466 (15%) fewer patients on long-term opioid therapy (438,329 => 370,863);
- The overall dosage of opioids is decreasing in the VA system as 10,143 (17%) fewer patients are receiving greater than or equal to 100 MEDD (59,499 => 49,356); and
- The desired results of OSI have been achieved during a time that VA has seen an overall growth of 75,843 (2%) patients who have utilized VA outpatient pharmacy services (3,959,852 => 4,035,695).

The changes in prescribing and consumption are occurring at a modest pace and the OSI dashboard metrics indicate the overall trends are moving in the desired direction. OSI will be implemented in a cautious and measured way to give VA time to build the infrastructure and processes necessary to allow VA clinicians to incorporate new pain management strategies into their treatment approaches. A measured process will also give VA patients time to adjust to new treatment options and to mitigate any patient dissatisfaction that may accompany these changes.

While these changes may appear to be modest given the size of the VA patient population, they signal an important trend in VA’s use of opioids. VA expects this trend to continue as it renews its efforts to promote safe and effective pharmacologic and non-pharmacologic pain management therapies. Very effective programs yielding significant results have been identified (e.g., Minneapolis, Tampa), and are being studied as strong practice leaders.

State Prescription Drug Monitoring Programs

Another risk management approach to support the Veterans’ and public’s safety is VHA participation in state Prescription Drug Monitoring Programs (PDMP). These programs, with appropriate health privacy protections, allow for the interaction between VA and state databases, so that providers can identify potentially vulnerable at-risk individuals. VA providers can now access the state PDMP for in-

formation on prescribing and dispensing of controlled substances to Veterans outside the VA health care system. When fully deployed, non-VA providers will also be able to identify their patients who may be receiving controlled substances from VA. Participation in PDMPs will enable providers to identify patients who have received non-VA prescriptions for controlled substances, which in turn offers greater opportunity to discuss the effectiveness of these non-VA prescriptions in treating their pain or symptoms. More importantly, information available through these programs will help both VA and non-VA providers to prevent harm to patients that could occur if the provider was unaware that a controlled substance medication had been prescribed elsewhere already.

Opioid Therapy Risk Report

In conjunction with the OSI, a population-based provider report and feedback tool has recently been developed and is now available to all primary care providers and their teams. This report, easily accessible through a direct link in the electronic health record, assists the PACTs to manage their entire panel of patients prescribed pharmacotherapy for acute or chronic pain; this tool makes it easy to ensure Veterans receiving safe, quality care. This resource provides a quick but thorough assessment of their patients' opioid risk for adverse outcomes. Included in the report is the current opioid dose, concomitant use of benzodiazepines, and presence of associated high-risk diagnoses such as substance use disorder or Post Traumatic Stress Disorder. Urine drug screens, recent mental health and primary care visits, and the presence of a signed opioid agreement are also tracked. By clicking on the patient's name in the report, the provider can immediately pull up graphs showing the relationship between the patient's opioid dose and pain score over the past 12 months. This tabular and graphical information alerts the provider to situations where closer follow up may be needed or to settings where opioid withdrawal or dose reduction may be opportune. To better inform decisionmaking, links to practical pain presentations and opioid clinical guidelines are also embedded.

This report was developed in late 2014 and released in early 2015. A comprehensive training program for primary care was launched in February 2015 reaching over 2,000 PACT providers and their teams. This tool will also assist in the monitoring of opioid prescribing behavior of our primary care workforce over time.

Complementary and Integrative Medicine

The number one strategic goal of VHA is "to provide Veterans personalized, proactive, patient-driven health care." Integrative Health includes Complementary and Alternative Medicine approaches, provides a framework that aligns with personalized, proactive, patient-driven care. There is growing evidence in the effectiveness of non-pharmacological approaches as part of a comprehensive care plan for chronic pain which includes acupuncture, massage, yoga and spinal manipulation. VA is establishing the Integrative Health Coordinating Center (IHCC) within the Office of Patient-Centered Care and Cultural Transformation to build the infrastructure (e.g. establishing new occupations) to support the delivery of these services.

CLEVELAND VA MEDICAL CENTER'S SUCCESS IN PAIN MANAGEMENT

Providing Veterans excellent care in pain management is taking center stage at the Louis Stokes VAMC in Cleveland, Ohio. The Cleveland VAMC earned the Clinical Center of Excellence Award from the American Pain Society for implementing a model of care where Veterans engage in using interventional procedures and complementary and alternative medicine to lower their reliance on opioids. This model of care required cultural change within the pain management staff; they worked together to embrace clinical and behavioral services in a multi-disciplinary fashion to promote physical rehabilitation and self-management of pain.

It has taken time, but today, the Cleveland VAMC has dedicated support in education for both staff and patients, funding to support their programs, dedicated staffing, improved resilience among their Veteran population, and a demonstrated reduction in the use of opioids among their patients.

The unique program follows a three-level stepped-care model, based on Veteran need:

- Level-I Veterans are managed by primary care providers with pain management training. The specialized training is provided through advanced video teleconferencing, in which the SCAN-ECHO team leads weekly training sessions. Time is protected for the providers to attend weekly 90-minute sessions for at least a year.
- Level-II Veterans are referred to outpatient clinics where they can be seen by specialists in pain medicine, pain psychology, and other allied health professionals to assist them in managing their pain.

- Level-III is the Intensive Outpatient Program (IOP) where more complex cases are referred. In the IOP, Veterans are enrolled in a 12-week, 1-day/week rehabilitation program that features psychological interventions, aquatic therapy, group exercise, occupational therapy, and dietary and vocational rehabilitation.

HYDROCODONE RESCHEDULING AND THE IMPACT ON VETERANS

The new Drug Enforcement Administration (DEA) rescheduling for hydrocodone products became effective on October 6, 2014, and aim to improve medication safety and reduce misuse and abuse of opioid analgesics. Prior to the DEA rule change, a provider could authorize five refills within a 6-month period on hydrocodone combination products. These refills did not require Veterans to have monthly contact with their providers as the refills were requested by the Veteran through the VA Pharmacy. Now that the rule change has gone into effect, limitations in the VA electronic health record means Veterans must contact their providers, either in person or by telephone, to have a new prescription written when their supply is running low before the VA Pharmacy can dispense the hydrocodone combination prescriptions. Although refills for hydrocodone-containing products are not permitted, under the DEA rule change, Veterans do not necessarily always need to physically see their provider at a clinic visit. VHA policy requires patients on chronic opioid therapy to be evaluated once every 1 to 6 months, based on provider assessments. Each Veteran's case is different and providers may issue a new prescription for Veterans based on telephone contact, if that is clinically appropriate.

VA'S OPIOID EDUCATION AND NALOXONE DISTRIBUTION PROGRAM

In certain situations, opioids are the best choice for pain. Naloxone is an antidote to respiratory depression which can cause fatal overdose. With opioid use, risks are involved, and VA is taking precautionary steps to mitigate these risks. In May 2014, a VHA team developed and implemented VA's Overdose Education and Naloxone Distribution (OEND) program. Although VA's national OEND program is less than 1 year old, as of March 8, 2015, over 2,400 naloxone kit prescriptions have been dispensed to at-risk Veterans throughout the United States. As a result of these efforts, 33 individuals' life-threatening opioid overdoses were reversed as a direct result of the OEND program.

CONCLUSION

In conclusion, we are continuing to investigate the situation at the Tomah VAMC and will keep you up-to-date on our findings. If employee misconduct is identified, VA will take the appropriate action and hold those responsible accountable. These investigations are an opportunity to get to the bottom of any issues so that moving forward, these actions are not repeated elsewhere.

While we know our work to improve pain management programs and the use of medications will never truly be finished, VA has been at the forefront in dealing with pain management, and we will continue to do so to better serve the needs of Veterans.

Mr. Chairman, we appreciate this Committee's support and encouragement in identifying and resolving challenges as we find new ways to care for Veterans.

Chairman ISAKSON. Thank you, Dr. Clancy.
Dr. Daigh.

STATEMENT OF JOHN D. DAIGH, JR., M.D., C.P.A., ASSISTANT INSPECTOR GENERAL FOR HEALTHCARE INSPECTIONS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF VETERANS AFFAIRS

Dr. DAIGH. Thank you. Good morning, Chairman Isakson, Ranking Member Blumenthal, and Members of the Committee. Thank you for the opportunity to appear before you today on this important topic of opioid prescription policies of the Department of Veterans Affairs and efforts in combating over-medication. My written statement references several OIG reports and a national review on the dispensing of take-home opioids that contain national data from fiscal year 2012.

In 2010, VA and DOD published an excellent clinical practice guideline, The Management of Opioid Therapy for Chronic Pain. Our national review demonstrates that in 2012, VA providers were, in general, non-compliant with guideline requirements.

Whether it be the use of urine drug screens and follow-up visits where they were 37 percent compliant with the guideline, whether it be the practice of refilling prescriptions at least 7 days early 23 percent non-compliance with the guideline, the concomitant use of benzodiazepines and narcotic medications which occurred in the chronic use population 92 percent of the time. Or ensuring that veterans with substance use disorder and chronic pain receive concurrent treatment for their substance use disorder and urinary drug testing, there was 10.5 percent compliance.

The data and the report make clear that the VA as a system of care in fiscal year 2012 that was managing this patient population very poorly. Who were these patients? One in 16 served in Operation Enduring Freedom or Operation Iraqi Freedom. One in three was diagnosed with a mood disorder, one in five with PTSD, one in seven with substance use disorder.

Since the publication of this report, I believe the VA has made serious efforts and dramatic improvement in the way they deliver pain care.

On another topic, some have claimed that the Office of Healthcare Inspections has hidden secret, unpublished reports. I dispute this claim. I have always had a policy, upon accepting a hotline, of either publishing the report to the Web in an unredacted format or administratively closing the report.

The semiannual has a list, including the number of admin closures each 6 months, it is common practice to brief Members of Congress on the results of accepted hotlines, whether they are admin-closed or published. Going forward, all hotlines will be published to the Web and admin closures going back to 2006 are in the process of being published to the Web. I hope to revisit this policy going forward with both the House and Senate Committees.

The admin closure of the Tomah hotline is drawing particular attention. On August 31, 2011, my office opened a hotline at Tomah that was based upon the receipt of a request from Congressman Kind, data from an employee survey that we did as part of our routine cap, and allegations that were received from out hotline.

In summary, it was alleged that narcotic medication was being used as the primary treatment for PTSD, that specific patients were receiving poor quality of medical care, that numerous patients were dying of narcotic overdose, that Tomah providers were contemplating the amputation of a veteran's leg as treatment for his pain syndrome, and that there was inappropriate interference with the administration of the pharmacy service by Tomah management.

In the administrative closure on this matter, the first four pages, detail the steps that OIG staff took to determine if these allegations had factual support. We reviewed numerous medical charts and peer reviews. We interviewed many current and former employees. We contacted the local Tomah police, the Milwaukee police, the Drug Enforcement Agency. We pulled the email from 17 employees.

The Office of Investigations, which is another element of the IG, investigated aspects of these allegations. We found that the allegations that led us to Tomah could not be substantiated. We did find examples of failure to comply with the DOD/VA chronic pain guidelines, consistent with the national data that I just discussed with you today from fiscal year 2012.

Given that the data we collected did not support the allegations that led us to Tomah, and knowing that our national report would highlight the many deficiencies in VA providers' compliance with these guidelines, and that other projects in my office had great demand for OIG psychiatry time, I chose to administratively close this report.

To ensure that the deficiencies we identified were corrected by Veterans Health Administration (VHA), my staff met with the Director of the Tomah VAMC and with the Veterans Integrated Service Network (VISN) Director for Tomah. Both gentlemen were familiar with the individuals and issues we described at Tomah. These leaders discussed the changes that had been instituted and future planned actions to address the deficiencies we identified.

I did not brief Congressman Kind on the admin closure. That was a deviation from our practice and I apologized to him for this failure. I will be pleased to answer your questions.

[The prepared statement of Dr. Daigh follows:]

PREPARED STATEMENT OF JOHN D. DAIGH, JR., M.D., CPA, ASSISTANT INSPECTOR
GENERAL FOR HEALTHCARE INSPECTIONS, OFFICE OF INSPECTOR GENERAL, U.S.
DEPARTMENT OF VETERANS AFFAIRS

Mr. Chairman and Members of the Committee, Thank you for the opportunity to discuss the Office of Inspector General's (OIG) work concerning VA's opioid prescription policies and practices. My statement will focus on a national review issued on May 14, 2014, *Healthcare Inspection—VA Patterns of Dispensing Take-Home Opioids and Monitoring Patients on Opioid Therapy*, as well as other reviews that we have conducted since 2011. A listing of those reports is included in Appendix A.

BACKGROUND

Adequate management of pain has become a tenant of the compassionate delivery of health care. Subjective pain levels are now considered to be the fifth vital sign in medicine in addition to body temperature, pulse rate, respiration rate, and blood pressure. It has been estimated that pain affects 100 million adults in the United States. More than 50 percent of veterans enrolled and receiving VA care are affected by chronic pain. Servicemembers come to VA with a combination of health care conditions: pain resulting from injuries during military service, mental health disorders including Post Traumatic Stress Disorder (PTSD), and substance use disorders that involve alcohol and/or narcotic medications.

In 1998, the Veterans Health Administration (VHA) initiated a National Pain Management Strategy to establish pain management as a national priority. In 2009, VHA issued a directive for the improvement of pain management consistent with VHA's National Pain Management Strategy.¹

In 2003, VA and the Department of Defense (DOD) published the first Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (Clinical Practice Guideline) to improve management, quality of life, and quality of care for veterans and servicemembers. It was last updated in 2010.²

Opioid therapy is intended for patients who suffer from moderate to severe chronic pain and who have been previously assessed and treated with non-opioid or non-pharmacological therapy with no response or limited success or response, and who may benefit from opioid therapy for pain control. Opioids are powerful medications that can help manage pain when prescribed for the right condition and when used

¹ VHA Directive 2009-053, *Pain Management*, October 28, 2009.

² *Clinical Practice Guideline—Management of Opioid Therapy for Chronic Pain*, May 2010, http://www.healthquality.va.gov/guidelines/Pain/cot/COT_312_Full-er.pdf.

properly. However, if prescribed inappropriately or if used improperly, they can cause serious harm, including overdose and death. Patient adherence with the proper use of opioids is crucial in the delivery of appropriate opioid therapy. Patient assessments, follow-up evaluations, and urine drug tests (UDTs) are recommended monitoring tools for safe and effective use of opioids.

VA PATTERNS OF DISPENSING TAKE-HOME OPIOIDS AND MONITORING PATIENTS ON OPIOID THERAPY

As requested by the U.S. Senate Committee on Veterans' Affairs, the OIG conducted a study to assess the provision of VA outpatient (take-home) opioids and monitoring of patients on opioid therapy (hereinafter referred to as opioid patients). The objectives of the study were to:

- Describe both the prevalence of VA patients who filled any take-home opioid prescriptions at VA in fiscal year (FY) 2012 and their baseline characteristics.
- Evaluate VA dispensing patterns of take-home opioids, including concurrent (filled) benzodiazepines, filled acetaminophen, and early refills of opioids.
- Assess the extent to which VA screens and monitors opioid patients in alignment with measures adapted from selected recommendations in the Clinical Practice Guideline.
- Define VA patterns of providing psychosocial treatment for pain, pain clinic service, and medication management/pharmacy reconciliation for take-home opioid patients.
- Determine the prevalence of six selected serious clinical adverse effects among VA take-home opioid patients that may reasonably be expected to relate to opioid therapy.

In our May 14, 2014, report, we made six recommendations, and the Under Secretary of Health agreed to the findings and recommendations and provided an improvement plan. As of March 20, 2015, four recommendations are closed:

- We recommended that the Under Secretary for Health ensure that the practice of prescribing acetaminophen is in compliance with acceptable standards.
- We recommended that the Under Secretary for Health ensure that follow-up evaluations of patients on take-home opioids are performed timely.
- We recommended that the Under Secretary for Health ensure that opioid patients with active (not in remission) substance use receive treatment for substance use concurrently with urine drug tests.
- We recommended that the Under Secretary for Health ensure that VA's practice of prescribing and dispensing benzodiazepines concurrently with opioids is in alignment with acceptable standards.

As of March 20, 2015, only two recommendations remain open:

- *Recommendation 2:* We recommended that the Under Secretary for Health ensure that VA's practice of routine and random urine drug tests prior to initiating and during take-home opioid therapy to confirm the appropriate use of opioids is in alignment with acceptable standards.

VA management provided an estimated implementation date of February 28, 2015. In its most recent status update dated December 30, 2014, VA indicated that actions to implement this recommendation remain in progress. VA is scheduled to provide another status update to the OIG by March 31, 2015.

- *Recommendation 6:* We recommended that the Under Secretary for Health ensure that medication reconciliation is performed to prevent adverse drug interactions.

VA management provided an estimated implementation date of December 31, 2014. However, VA indicated in its most recent status update dated December 30, 2014, that actions to implement the recommendation remain in progress. VA did not provide an updated implementation date estimate. VA is scheduled to provide another status update to the OIG by March 31, 2015.

Findings

We integrated and analyzed VA administrative files, as well as the Death Master Files of the Social Security Administration, for the population of nearly half a million VA patients who filled at least one oral or transdermal opioid prescription from VA for self-administration at home in FY 2012. We followed retrospectively the 442,544 patients in the population who did not receive any hospice or palliative care during the fiscal year or within 1 year prior to their first take-home opioid prescription for their experience with the provision of VA opioid therapy.

Population

We found that 7.7 percent of VA patients were on take-home opioids. A majority (92.5 percent) of the opioid patients were male, which mirrored the gender composition of VA patients. The average and the median patient age at their first opioid prescription in FY 2012 was 59.4 and 61, respectively. Approximately 1 in every 16 patients had served in Operation Enduring Freedom/Operation Iraqi Freedom. Approximately 87 percent of the opioid patients were diagnosed with a primary pain site of non-cancer origin that could result in pain serious enough to warrant an opioid medication. Six out of 10 patients had been diagnosed with mental health issues, 1 in 3 with mood disorders, 1 of 5 with PTSD, and 1 of 7 with substance use. Nearly 94 percent of the study population had been diagnosed with either pain or mental health issues and 58.4 percent with both. About one third of the opioid patients were on take-home opioids for more than 90 days (chronic users) in FY 2012. Approximately half of the study population were new patients in the sense that they were initiated on take-home opioid therapy during FY 2012 after not having been on take-home opioids for at least more than 1 year. Seven out of 10 of the non-chronic users were new patients in contrast to 1 in 5 of the chronic users. Nearly 41 percent of the study population had been dispensed with one prescription. This 41 percent was composed entirely of the 61.4 percent of non-chronic users because none of the opioids were allowed to be prescribed for more than 90 days in one prescription. Patients with six or more prescriptions were mainly chronic users, which amounted to 69.3 percent of that group.

Dispensing Patterns and Drug Interactions

Almost all (98.4 percent) patients received their prescriptions from a single VAMC, and three quarters of the patient population had all their (filled) prescriptions issued from a single prescriber. Most (95.0 percent) of the patients were dispensed with a single type of opioid. More than 6 percent of patients received at least one long-acting opioid product, with the percentage of chronic users being four times that of non-chronic users. Opioid dosages with a morphine equivalent of at least 200 milligrams (mg)/day were dispensed to 1.2 percent of the study population. We found that refills of opioids at least 7 days early occurred in 23 percent of the population, with refills of at least 11 days early in 14 percent of the population.

The concurrent use of benzodiazepines and opioids can be dangerous because opioids and benzodiazepines can depress the central nervous system and thereby affect heart rhythm, slow respiration, and even lead to death. We found that take-home benzodiazepines were dispensed to 7.4 percent of the study population, with the percentage of chronic opioid users being 1.6 times that of non-chronic users. We determined that 71 percent of the opioid patients who also received take-home benzodiazepines were dispensed benzodiazepines concurrently with opioids. The percentage of chronic opioid users with concurrent benzodiazepines was 92.6, and the percentage of non-chronic users was 53.6.

Acetaminophen poisoning is a leading cause of liver toxicity. We determined that take-home acetaminophens were given to 92.3 percent of the study patients and that 2.0 percent of them were given an average daily dose of 4 g/day or more. The Clinical Practice Guideline calls for a urine drug test (UDT) prior to initiating opioid therapy and a follow-up contact at least every 2–4 weeks after any change in medication regimen. We determined that 6.4 percent of the new patients who were initiated take-home opioids in FY 2012 after not having been on take-home opioids for at least more than 1 year received both a UDT prior to and a follow-up UDT within 30 days.

Screening and Monitoring

The Clinical Practice Guideline requires routine and random UDTs to confirm the appropriate use of opioids by patients and a follow-up contact either in-person or a telephone encounter at least once every 1–6 months for the duration of opioid therapy. We determined that 37 percent of the existing opioid patients who were on take-home opioids at least from FY 2011 received both an annual UDT and a follow-up contact within 6 months of each filled opioid prescription. We found that VA conducted an annual UDT for 37.9 percent of the existing opioid patients which accounted for 40.9 percent of the chronic opioid users and 33.7 percent of the non-chronic users. We observed wide variation of VA medical centers' practice on an annual UDT, ranging from 4.4 percent to 87.6 percent.

We found that 13.1 percent of the study population was diagnosed with active substance use. The Clinical Practice Guideline specifies that chronic (for more than 1 month) opioid therapy is absolutely contraindicated in patients with active (not in remission) substance use disorders (SUD) who are not in treatment. It recommends that active substance use patients receive SUD treatment concurrently

with urine drug testing as an adjunctive tool at regular intervals. For the active substance use patients who had at least 90 days available for follow-up in FY 2012, we determined that 10.5 percent received both a treatment for substance use and a UDT within 90 days of each filled opioid prescription.

Pain Management Requires Multiple Specialties

Psychotherapy, including cognitive behavioral therapy, is recommended to reduce pain and improve function in chronic pain patients. We found that 45.2 percent of the opioid patients received at least one psychosocial treatment for pain and that 35.1 percent of these patients received this treatment after their first filled opioid prescription in FY 2012. We determined that 8.7 percent of the opioid patients received care from a Pain Clinic. A review of medications by a pharmacist or other health care professional can prevent harmful interactions between these medications. We found that 38.8 percent of the opioid patients received medication management or pharmacy reconciliation during the fiscal year.

Opioid Side Effects

We determined percentages of opioid patients with evidence of a serious adverse effect that may reasonably be expected to be related to opioid therapy for the following six serious adverse effects: (1) opioid overdose, (2) sedative overdose, (3) drug delirium, (4) drug detoxification, (5) acetaminophen overdose, and (6) possible and confirmed suicide attempts. We found that less than 1 percent of the population experienced any one of these adverse effects during the fiscal year, except for the adverse effect of possible and confirmed suicide attempts that was evident in 2 percent of the opioid patients.

OTHER OIG REPORTS

The OIG has published a number of reports that address aspects of the issues when patients are prescribed large doses of opioids. These reports have certain themes:

- The use of high dose opioids in patients with a substance use disorder and mental illness is a common clinical situation.
- Compliance with clinical guidelines is not routine.
- Primary care providers bear the responsibility for managing these complex patients, often with limited support from pain management experts and related specialists.
- The use of high dose opioids causes friction within provider groups, where opinions on the proper use of these medications varies.
- Non-traditional therapies that may offer the benefit of less narcotic use are not fully utilized.

I would like to discuss four reports that highlight these themes.

In our report, *Healthcare Inspection—Medication Management Issues in a High Risk Patient, Tuscaloosa VA Medical Center, Tuscaloosa, Alabama*, we substantiated that facility providers collectively prescribed oxycodone, methadone, and benzodiazepines to a high-risk patient who died of an accidental multi-drug overdose. Three factors contributed to this outcome:

- Providers did not consistently comply with VHA and local policies for the management of chronic pain in this high-risk patient. Additionally, the patient's primary care provider did not conduct key portions of the pain assessment program. These include the requirement to address previous pain treatments and their effectiveness, suicide risk status, and drug overdose history. The primary care provider did not initiate an opioid pain care agreement with the patient or ensure adequate patient monitoring and follow-up after prescribing methadone. Required patient education regarding the specific dangers of methadone was not documented.
- The facility did not ensure access to an interdisciplinary pain management team or a pain clinic to provide needed expert services to this patient.
- Providers did not ensure communication and coordination of care. The primary care provider did not read other providers' progress notes reflecting concerns about prescribing opioids and benzodiazepines, the primary care and mental health providers did not communicate directly about this high-risk patient, and the suicide prevention staff did not assist in coordinating this patient's care although the patient was on the High Risk for Suicide list.

We made seven recommendations and as of March 20, 2015, only Recommendation 7 that the Facility Director ensure access to interdisciplinary pain management care for chronic pain patients who do not respond to standard medical treatment remains open. We will continue to follow-up until VHA provides documentation that planned corrective actions have been implemented.

In our report, *Healthcare Inspection—Alleged Improper Opioid Prescription Renewal Practices, San Francisco VA Medical Center, San Francisco, California*, we addressed several issues related to the group practice of primary care, where opinions vary on the use of high dose narcotic medications. The OIG substantiated the allegation that physicians are tasked with evaluating numerous opioid renewal requests for patients with whom they are unfamiliar. VHA policy requires that certain opioid prescriptions are restricted to a 30-day supply with no refills, which means patients must obtain a new or renewal prescription every month. During the course of our inspection, we found that all clinic physicians were part-time; therefore, patients requiring opioid prescription renewals every 30 days could be subjected to extended periods without their opioid medication, if required to see one provider. Senior leaders reported that in an effort to avoid such situations, a prescription renewal process was implemented for those instances when a patient requires a medication renewal but is unable to schedule a timely encounter with his or her primary care provider. The renewal process, established in 2006, assigned the attending on duty the responsibility for evaluating all medication renewal requests, including opioids for a period of time. The facility also hired clinical pharmacists who were designated to screen all renewal requests prior to provider evaluation for refills. The physicians we interviewed validated the complainant's allegation that within their on-duty half-day clinics they evaluated multiple opioid renewal requests for patients unknown to them. VHA policy, however, does not prohibit a provider from renewing an opioid prescription for a patient he or she has not evaluated in person.

We partially substantiated that providers do not routinely document patients' opioid prescription renewal problems in the electronic health record. The providers did not consistently document an assessment for adherence with appropriate use of opioids and monitor patients for misuse. The primary care providers did not consistently complete the "narcotic instructions note" in the health record template.

We substantiated that there have been patient hospitalizations related to opioid misuse. Seven clinic patients were hospitalized for opioid overdose; however, the primary care provider, Psychiatry Service, and/or the facility's Substance Abuse Program appropriately assessed and monitored the patients. There were no deaths related to opioid overdose.

The report made two recommendations with which the Veteran Integrated Service Network (VISN) and facility directors concurred. We closed our report on April 17, 2014, after receiving documentation from VA that corrective actions were sufficiently implemented.

In an August 21, 2012, report, *Healthcare Inspection—Management of Chronic Opioid Therapy at a VA Maine Healthcare System Community Based Outpatient Clinic*, we substantiated the allegation that providers did not adequately assess patients who were prescribed opioids for chronic pain. Although providers performed initial pain assessments of patients, reassessments were not consistently documented at the minimum required frequency.

We also substantiated the allegation that providers did not adequately monitor patients who were prescribed opioids for misuse or diversion of the medications. One provider did not properly follow-up on a patient's positive urine drug test, and due to staffing constraints at the clinic, patients often obtained prescriptions from multiple providers.

We substantiated the allegation that facility managers asked providers to write opioid prescriptions for patients whom the providers had not assessed.

We made one recommendation with which the VISN and facility directors concurred. Based on documentation from VA that corrective actions were sufficiently implemented, we closed our report on February 22, 2013.

In a June 15, 2011, report, *Healthcare Inspection—Prescribing Practices in the Pain Management Clinic at John D. Dingell VA Medical Center, Detroit, Michigan*, we substantiated that providers prescribed controlled substances without adequate evaluation of patients and the facility did not have a policy outlining requirements for the ongoing assessment of patients treated with opioid medications. The Clinical Practice Guideline recommends that patients be evaluated every 1–6 months. We reviewed 20 patients' electronic medical records, including those named by the complainant and those with the largest aggregate opioid doses identified from among the 4,445 patients who received these medications during December 2010. We found that during 2010, five patients on chronic opioid therapy had no evaluation and six patients had evaluations more than 7 months apart. For 10 of these patients, prescriptions were written by one physician.

We did not substantiate the allegation that clinic supervisors coerced providers to prescribe controlled substances to patients not under their care. A provider had numerous patients who would require medication renewals. Physician coverage for

these patients was arranged, after some discussion regarding the proper provision of care, to this population of controlled substance Users.

We made two recommendations with which the VISN and facility directors concurred. Based on documentation from VA that corrective actions were sufficiently implemented, we closed our report on November 25, 2011.

CONCLUSION

The use of high dose opioids for the primary treatment of pain conditions is all too common within the veteran population. Patients with mental health or substance use disorders comprise a particularly complex subgroup of patients whose chronic mental health disorders may exceed the competence expected of primary care providers. As the findings in our national report demonstrate, VA was not following its own policies and procedures in six key areas: acetaminophen prescription practices; follow-up evaluations of patients on take-home opioids; concurrent substance use treatment with urine drug tests; prescribing and dispensing of benzodiazepines concurrently with opioids; routine and random urine drug tests prior to and during take-home opioid therapy; and medication reconciliation. We note that VA has taken actions to implement a number of the recommendations in this report, but VA must be vigilant in monitoring facility compliance with opioid prescription policies and in completing outstanding recommendations.

Mr. Chairman, this concludes my statement. I would be pleased to answer any questions you or other Members of the Committee may have.

APPENDIX A

VA OFFICE OF INSPECTOR GENERAL REPORTING ON OPIOID PRESCRIPTION PRACTICES

December 9, 2014	Alleged Inappropriate Opioid Prescribing Practices, Chillicothe VA Medical Center, Chillicothe, Ohio http://www.va.gov/oig/pubs/VAOIG-14-00351-53.pdf
July 17, 2014	Quality of Care and Staff Safety Concerns at the Huntsville Community Based Outpatient Clinic, Huntsville, Alabama http://www.va.gov/oig/pubs/VAOIG-14-01322-215.pdf
June 25, 2014	Medication Management Issues in a High Risk Patient, Tuscaloosa VA Medical Center, Tuscaloosa, Alabama http://www.va.gov/oig/pubs/VAOIG-13-02665-197.pdf
June 9, 2014	Quality of Care Concerns Hospice/Palliative Care Program, Western New York Health care System, Buffalo, New York www.va.gov/oig/pubs/VAOIG-13-04195-180.pdf
May 14, 2014	VA Patterns of Dispensing Take-Home Opioids and Monitoring Patients on Opioid Therapy http://www.va.gov/oig/pubs/VAOIG-14-00895-163.pdf
November 7, 2013	Alleged Improper Opioid Prescription Renewal Practices, San Francisco VA Medical Center, San Francisco, California http://www.va.gov/oig/pubs/VAOIG-13-00133-12.pdf
August 21, 2012	Management of Chronic Opioid Therapy at a VA Maine Health care System Community Based Outpatient Clinic http://www.va.gov/oig/pubs/VAOIG-12-01872-258.pdf
August 10, 2012	Patient's Medication Management, Lincoln Community Based Outpatient Clinic, Lincoln, Nebraska http://www.va.gov/oig/pubs/VAOIG-12-02274-244.pdf
August 19, 2011	Alleged Improper Care and Prescribing Practices for a Veteran, Tyler VA Primary Care Clinic Tyler, Texas http://www.va.gov/oig/54/reports/VAOIG-11-01996-253.pdf
June 15, 2011	Prescribing Practices in the Pain Management Clinic at John D. Dingell VA Medical Center, Detroit, Michigan http://www.va.gov/oig/54/reports/VAOIG-11-00057-195.pdf

Chairman ISAKSON. Thank you, Dr. Daigh. Dr. Clancy, you made an interesting statement in your remarks I have to seize on for just a second. You were talking about violations of policy at VA in terms of over-prescription of opiates, and you made the statement

that wherever we find that taking place we will take the appropriate action, talking about discipline, I presume.

To what extent can you terminate somebody for a continual violation in terms of over-prescribing opiates and pain relief at the VA?

Dr. CLANCY. In general, there are multiple steps to this process and I know that some of your staff have been briefed on some recent investigations. If it came up about a single patient, the first step would be a peer review where their practice is reviewed by their peers. If this came up—and this goes on across our system for any kind of clinical deviation, if you will.

We have about 15 to 20 percent of those peer reviews across our system routinely re-reviewed by an organization in California that works with us under contract for just that purpose, mostly to make sure that our clinicians are calibrated, because in general, they are rated as one of three levels. One is, the vast majority of clinicians would have done it exactly this way; three is, almost no one on the planet would have done it this way; two is sort of intermediate.

For repeated deviations from practice, whether that is level two or three, or other concerns that come up, we do have procedures in place to actually work very closely with that clinician to see if the deviations can be corrected. If they cannot, then they can be removed from their practice.

Chairman ISAKSON. If in that first initial peer review there is evidence that the over-prescription was taking place and there was a violation of policy, how many hoops do you still have to go through to terminate that individual?

Dr. CLANCY. There are a number of steps. The first is to discuss that with the individual and counsel them about what is the right kind of practice, and so forth, and that is why we have all this expertise, to be able to bring to the attention of—I mean, this is a part of routine practice across all areas.

Chairman ISAKSON. And it takes a long time?

Dr. CLANCY. It does, it does.

Chairman ISAKSON. The reason I asked the question is, it was announced this morning, I believe, at the VA that the director of the project in Denver, the construction of that hospital, is no longer with the VA and took retirement. Is that correct?

Dr. CLANCY. Yes.

Chairman ISAKSON. Is it easier to try and induce someone who has violated policy to retire or transfer to go somewhere else than it is to actually fire them?

Dr. CLANCY. I think that is sometimes the case, yes.

Chairman ISAKSON. I appreciate your great service and the great information you provided us with. One thing you could do for me and the Committee, I think, any counsel you could give us on what we could do as legislators to give you statutory ability to run your department in a responsive way, not an abusive way, but a responsive way, would be greatly appreciated.

I think the VA is being blamed for an action that really was not fair because the policies and procedures are so great to go from the violation to termination that it is easier to try and induce somebody to transfer or somebody to just retire. If you have statutory impediments that we could deal with, I would love to make your

job easier and the justice more swift for our veterans in terms of those. If you would do that, I would appreciate it.

Dr. CLANCY. Well, I appreciate that, Mr. Chairman. I would just call to your attention and those of your colleagues that there are really two big issues on the clinical side. One is, although it is true for other areas. One is having enough evidence that it will stick and not be overturned.

In the example of strong concerns about a clinician's practice, a good lawyer can sometimes actually help us. A settlement ends up being that we end up having that person do something non-clinical because we have so many concerns we would not want to have them seeing patients. That is costing the taxpayers. We definitely want to avoid that if we can. For other kinds of behaviors, having enough evidence to withstand an appeal is a big part of our issue as well.

The other issue clinically is just always trying to make sure that for some reason, in the case of opioids, for example, there is not a good reason to think that perhaps a clinician selectively saw unusually complex or unusual patients. That is really why our clinician investigations have been very, very thorough in that regard.

Chairman ISAKSON. Thank you for that response. In the interest of time, I will not ask another question, but I will make a comment. In Dr. Daigh's testimony, he talks about the March 14th recommendations of the IG's report and the six recommendations of the VA. I want to congratulate you on closing four of the six—that is a record—in a short period of time, and the two that are open deal with a subject you and I talked about yesterday which is urine testing and making sure you have the proper testing on these prescription of opiates. So, congratulations on your responsiveness to that.

Dr. CLANCY. Thank you.

Chairman ISAKSON. I will turn to the Ranking Member for his questions.

Senator BLUMENTHAL. Thank you, Senator Isakson. First of all, thank you, Dr. Clancy, for acknowledging the value of a good lawyer. Rarely are good and lawyer combined in the same phrase in these halls, but I do appreciate your comments. I want to say that I appreciate your service to our Nation. You are a relatively recent appointee to your current position and you have been very cooperative and helpful to the Committee and to members individually, and I want to thank Dr. Daigh as well for your work in the Inspector General's Office as well as members of your team.

None of the criticisms that we are aiming at you, the panel, are meant to be personal to you. As you understand, they are institutional. You mentioned that the systemwide or network wide reporting will be instituted, I think you said, as of June. What will that system then encompass?

Dr. CLANCY. So, that system—and in the interest of time I was trying to be succinct in terms of details. This consists of every single clinician getting a customized consultation, and it is not optional, combined with a review of their prescribing practices. And we have seen that this works very well in three networks.

It is called academic detailing because it takes a page from a practice that the pharmaceutical industry has used to market their

products, where they go out and they kind of customize their pitch, if you will, to the needs of an individual clinician. In their case, they are selling a product. This is selling knowledge and skills or marketing, communicating.

Senator BLUMENTHAL. This is a new system that will be going nationwide as of June?

Dr. CLANCY. It is not brand new, but what will be new is actually that it is going to be nationwide and not optional.

Senator BLUMENTHAL. That is distinct from the opioid therapy prescribing report that was in use earlier or is that the same system?

Dr. CLANCY. It builds on it. The Opioid Safety Initiative, if you will, is maybe 500 or 1,000 feet off the ground. It is all about the knowledge and so forth. This is getting it right down to you, the individual clinician personally, and your patients.

Senator BLUMENTHAL. Even under this new system, will the prescribing providers in the VA system be compelled to provide information to the State prescription monitoring programs, that is the State registries?

Dr. CLANCY. Because I have been paying a great deal of attention to Wisconsin in response to concerns from Senator Baldwin and other members of the delegation, and we have been reporting to the Wisconsin State program for some time, I made the blithe assumption that we were reporting to all the State programs.

Senator BLUMENTHAL. But that is not true.

Dr. CLANCY. Correct. We are reporting to 20 of them. We have identified that we have an internal disagreement among some of our IT folks around privacy and security issues, which we will be resolving very promptly.

Senator BLUMENTHAL. In some States, 20 of them——

Dr. CLANCY. Yes.

Senator BLUMENTHAL [continuing]. Out of the 49 that have prescription monitoring programs——

Dr. CLANCY. Yes.

Senator BLUMENTHAL [continuing]. You are providing this information to State systems, but in some 29 of them you are not doing so. Connecticut happens to be one where it is not occurring.

Dr. CLANCY. That is correct. Now, obviously, resolving the difference of opinion here could lead to one of two outcomes. One, we immediately report to 49. The other is that we have to come up with an alternative solution that fits our standards for security and privacy. Either way, this will happen.

Senator BLUMENTHAL. I understand there are privacy concerns. Just to be very clear, if I am a VA patient right now in Connecticut, or those 29 other States, I can go to a private provider and that private provider has no way of knowing the doses of opioids that I am receiving through the VA system?

Dr. CLANCY. Correct.

Senator BLUMENTHAL. It is a blind one-way source of information where it is working now, and if I am reading your testimony correctly, where you use the word—and I am quoting—VA providers can now access the State Prescription Drug Monitoring Program (PDMP), it is not compulsory that they do so?

Dr. CLANCY. Is it compulsory?

[Discussion off the record with Mr. Valentino.]

Dr. CLANCY. Not yet, but it will be.

Senator BLUMENTHAL. When?

Dr. CLANCY. We are saying in the next 3 months.

Senator BLUMENTHAL. I would like a definite timeline.

Dr. CLANCY. Alright. We will get back to you with a very specific date. I will tell you that I am very worried about this, particularly since I learned extremely recently that we are not reporting to all the State programs, because in the context of our buying more care out of network, either through our usual non-VA care program or through the Choice program, this becomes an even bigger risk for us and for veterans, most importantly.

Senator BLUMENTHAL. My time has expired. I have a raft of additional questions relating, for example, to the lack of revised guidelines. You and I spoke about this issue yesterday. The last guidelines were done in 2010. Even the most, I think, permissive of recommendations would say they are well due for revision in 2015, 5 years later.

My questions also relate to the lack of implementation of two of the recommendations—Dr. Daigh mentioned them—from his report relating to urine tests and medicine reconciliation. I am going to be submitting questions for the record because in the interest of my colleagues, I do not want to impinge on their time.

I think there are some very urgent inquiries that need to be pursued here. Thank you very much.

Dr. CLANCY. Well, let me just assure you we will get you responses expeditiously. The other two things I would just note is, I had briefly forgotten yesterday that we are participating in a broad HHS series of guidelines on pain management and adverse reactions to medications and so forth, and we have three or four of our experts who are part of that work going on.

I do think we need to close the loop with our own guideline that we developed with the Department of Defense and we will be reaching out to those folks.

Senator BLUMENTHAL. The relationship and the coordination with the Department of Defense is an entirely other area that I was going to pursue, and I hope I will through the written questions. I might just close by saying, since you referred to a good lawyer, if you need a good lawyer to reconcile privacy concerns with access to VA data by State registries, I am volunteering, at least as a lawyer, not necessarily a good lawyer. If we need legislation to do it, you will have it.

Dr. CLANCY. Thank you.

Senator BLUMENTHAL. At least you will have my commitment to pursue it and I hope it will be a bipartisan initiative because this kind of coordination of information is really essential to protecting veterans. You make the point, and I think it may be one of the most important points in this hearing, that 30 percent of people in America suffer from chronic pain.

But more than 50 percent of our veterans, for obvious reasons, they have endured the wounds and scars of battle and they suffer with them for a lifetime. Providing them with responsible pain treatment is one of our obligations and it ought to be responsible. Thank you, Mr. Chairman.

Chairman ISAKSON. I think Senator Blumenthal's willingness to volunteer proves that old adage that if there is a billable hour out there somewhere, there is always an attorney. [Laughter.]

Senator BLUMENTHAL. I guarantee that whether I am good or not, my rates are very affordable, namely zero.

Chairman ISAKSON. We will follow the early bird rule and our next questions will be Sen. Cassidy followed by Sen. Baldwin, followed by Sen. Tillis.

Senator Cassidy.

HON. BILL CASSIDY, U.S. SENATOR FROM LOUISIANA

Senator CASSIDY. Yes, sir. Dr. Clancy, I am not so much concerned about the physician or the osteopathic physician (DO) having access to the State database, but does your pharmacist have access to it? When someone goes out to a private provider, sees that provider and gets a prescription, is that prescription filled at the VA pharmacy or in a private pharmacy? I do not know. I am asking.

Dr. CLANCY. Sorry?

Senator CASSIDY. If someone goes to a private provider and gets a prescription for an opioid, would that prescription be filled in a VA pharmacy or would it be filled in a community pharmacy?

Dr. CLANCY. It would most likely be filled in a community pharmacy, in part because these medications are pretty inexpensive. So they could get it filled at VA if they were enrolled in our system, but they would have to come in and actually be seen by someone first, because we are not legally authorized to be dispensary.

Senator CASSIDY. I will just echo my friend, the attorney. Clearly having physicians involved in that database would be important because I, as a physician, have learned that many patients who are addicted doctor shop. We all know this. They are getting a reasonable prescription here and a reasonable prescription there, but in aggregate, it is an unreasonable prescription.

Let me ask second, in your testimony, you mentioned that you have decreased the percent of people receiving chronic opioid therapy, and I have your review paper from the American Academy of Neurology, and I will quote from it. Although there is evidence for significant short-term relief with opioid therapy, there is no substantial evidence for maintenance of pain relief or improved function over long periods of time without incurring serious risk of overdose, dependence, or addiction.

Why would anybody be on long-term maintenance for non-cancer pain? I say that as a doctor. I used to give somebody with chronic pancreatitis, I may give them something for break-through pain, but if you will, that was acute relaxing pain. It was not chronic pain. I know that this is not the position paper that would state this. Why would anybody be, much less 370,000 people, on chronic opioids for non-cancer pain? You with me?

Dr. CLANCY. Largely because we do not have easy alternatives. It is very easy to see the safety and adverse affects associated with narcotics, particularly in some case for veterans, especially combined with other medications, but we do not have a good answer to chronic pain that fits everyone.

Senator CASSIDY. I accept that. So, two things about that. One, if there is no evidence for long-term benefit, then clearly this is not an answer even though it is being used for 370,000 people. Do you follow what I am saying? Knowing that as a doc, believe me, I used to love to refer to pain doctors because these are such tough patients.

The Academy of Neurology says there is no evidence that we should use it, which means it is not even a non-answer, it is a negative answer. It violates first do no harm. It seems like there should be stricter prescriptions, proscriptions against doctors providing it. For example, you only get it after 90 days if you get a waiver from the local pain doctor, sort of thing. You follow what I am saying?

Dr. CLANCY. Yes. First, let me just say, starting with your last point, that having even more pain expertise into these decisions, I think, is only a good thing and I think the academic detailing approach will actually accomplish quite a bit of that.

Many of the servicemembers who are transitioning into VA, particularly from our most recent conflicts, have substantial amounts of morbidity. I mean, it is a great tribute to battlefield medicine that the mortality for—

Senator CASSIDY. I accept that.

Dr. CLANCY [continuing]. People who served in Iraq and Afghanistan is much, much lower.

Senator CASSIDY. But again, the point is, is that there is no evidence that for non-cancer pain longer than 90 days, that risk appears to outweigh benefit.

Dr. CLANCY. That is correct. But understand that when they come to VA, they have often been treated with narcotics and many other—

Senator CASSIDY. I accept that. It seems as if they would be immediately entered into a program which would begin to wean them from this, because again, American Academy of Neurology long-term—and I know you know this. Believe me, people come and you want to please them. We both know as physicians sometimes the best answer is no. Otherwise, it is addiction, dependence, suicide.

Knowing that it is not efficacious for those with long—long-term therapy is not efficacious for those with non-cancer pain, it does seem like it should not be 370,000. It should be closer to 5,000 or something like that.

Dr. CLANCY. I think ultimately, that is probably the right answer. The trick is, how do we actually help veterans live in a way where they have a quality-of-life that they can maintain. I certainly have had patients who, after, are trying many, many different things. Together we ended up with a pain contract for them to get chronic narcotics because nothing else quite seemed to work and they seemed remarkably functional.

Senator CASSIDY. Real quickly, your testimony mentioned Cleveland having a good pain clinic, and Dr. West was helping me with my back problems even as we started.

Dr. CLANCY. And no narcotics either.

Senator CASSIDY. No narcotics. So I guess the question is, how successful have you been in broadening access to pain clinic doctors among all your different facilities?

Dr. CLANCY. What happened in Cleveland that was particularly exciting, and then I will ask Dr. West to comment, is that they formally implemented and tested an approach that leverages the expertise of pain management clinicians in a multi-disciplinary group working together and used telehealth to reach out to doctors practicing in rural areas.

Many of our facilities have that kind of multi-disciplinary approach. This would be the major facilities, but if you live a couple of hours away from that, coming in periodically may not be all that practical.

Senator CASSIDY. What percent of your facilities would have access to expertise such as this?

Dr. WEST. I do not have that number right off-hand, but we—

Senator CASSIDY. 50 percent, 20 percent, 80 percent? Ballpark? Because telemedicine obviously allows you to extend this reach to everyone, should you make the decision.

Dr. WEST. I would say—the vast majority of our facilities have access to telehealth. We are rapidly expanding our access to pain medicine programs. It is relatively new. It has been rolled out very successfully in Cleveland. It will be a published peer reviewed article very shortly.

You brought up all the very critical points here. We need better access to pain physicians through our system of technology, through telehealth, which we do a very nice job with. We can expand access through our existing networks.

The problem is, just as you also alluded to, there is not a whole lot of pain doctors out there to tap into. So we can use technology and leverage the advantages. We have in already forming these networks to network those people in and take those messages out to the other clinics, rural clinics—we have a huge rural population and a rural base—and bring that education system.

The education system, at the end of the day, is so important because providers for so long, and mentioned in previous testimony, were—the training of the use of opiates was, you use opiates. Now we are seeing this horrible epidemic.

Senator CASSIDY. Dr. West, I am way over, so let me just finish by summing up. It does seem, instead of 370,000 people, we should have 5,000 people because there is always the exception, and it does seem like telemedicine has that ability to take that reach, knowing your number of doctors is limited. Since I have done telemedicine in the past, you can bring it across the country. Cleveland can be in Baton Rouge or Lafayette or Shreveport, LA.

Hopefully, 2 years from now, it will be 5,000 because that seems to be most consistent with modern medicine. I yield back and I apologize for going over.

Chairman ISAKSON. Thank you, Sen. Cassidy.

Senator Baldwin.

HON. TAMMY BALDWIN, U.S. SENATOR FROM WISCONSIN

Senator BALDWIN. Thank you, Mr. Chairman, and Ranking Member Blumenthal. I very much appreciate you and the Members of the Committee agreeing to my request to hold this hearing and for inviting me to participate as a non-Member of the Committee today.

As you have heard, in my home State of Wisconsin, the Tomah VA medical center is currently the subject of multiple investigations that I have called for, including the one that Dr. Clancy mentioned earlier today being conducted by the Department of Veterans Affairs Under Secretary for Health, the VA Office of Inspector General, and the Drug Enforcement Agency.

Among other issues, these investigations are looking at disturbing allegations of improper opioid-prescribing practices, the subject of today's hearing. I am going to have a chance next week at a field hearing in Tomah to give a longer opening statement, but I briefly wanted to state today that the problem of over-prescribing of opioids at the VA has led to tragic and real consequences for veterans, their families, and entire communities across our Nation.

We should never lose sight of the central human dimension of these issues, which we in Wisconsin have been learning so much about. Dr. Clancy, it is my understanding as part of the opioid safety initiative that VHA has set up a central database that tracks all opioid prescriptions across the network.

I would like to know if the system also tracks the prescribing of dangerous drug combinations, for example, opioids concurrently prescribed with benzodiazepines? As we saw at the Tomah VA, a former Marine, Jason Simcakoski tragically died last August as an inpatient from mixed drug toxicity. At the time of his death, he was reportedly on 15 different prescription drugs, including antipsychotics, tranquilizers, muscle relaxants, and opioid pain killers. Does the VA's new system recognize when these dangerous combinations are being prescribed?

Dr. CLANCY. Yes. In fact, the report that we released several weeks ago actually makes that available to individual clinicians so they can look at one screen and see this for all the patients under their care.

Senator BALDWIN. So, can this system alert the providers in real time to stop the prescriptions?

Dr. CLANCY. Real time here, I think, is defined as we pull the data. I think it is every couple of weeks right now. We are trying to see if we can do it daily without blowing up the rest of the network. It is pretty close to real time.

Senator BALDWIN. So right now a couple of weeks?

Dr. CLANCY. Yes.

Senator BALDWIN. Who at the VA is tracking this data and who has use of it today?

Dr. CLANCY. Our pharmacy benefit management service tracks this very carefully, and I know that we had a discussion yesterday about would there be some value in making this public, and I said, Yes, I just think it would be a little bit hard to do that in a way that is comprehensible, which is not in any way saying no. It is simply saying that we would have to do so thoughtfully, because the quality measures that tend to be easiest to understand are those where the right answer is 100 percent or zero, this is more nuanced.

Senator BALDWIN. Among the allegations that are being looked into at the Tomah VA are early refills of prescriptions for opioids. Also, refills when a urine analysis indicates that a patient is nega-

tive for use of the prescribed drugs. Can you tell me whether this is easily tracked with the system that you are describing?

Dr. CLANCY. The system I am describing is actually focused on prescribers, but the system also does tell prescribers which of their patients have had a urine drug screen and when, because we will be monitoring that much more closely than we have been in the past.

Senator BALDWIN. I am reading between the lines that it is not an effective tool in real time to help—

Dr. CLANCY. It does not slap your wrist in real time, no. It does tell you which of your patients, because some patients take these medications intermittently. Part of the idea is to get random urine tests as opposed to on a regular prescribed—

Senator BALDWIN. It would track the negative urine test, but it would not necessarily—I did not get the answer on early refills.

Dr. CLANCY. Early refills should not be happening, period. I think one of the issues that has been surfaced at Tomah, and we are going to be dealing with, just still in the investigation phase, is the pharmacist who felt uncomfortable about that because their State boards generally make it very, very clear to them that this should not be happening, either left or they first tried to protest and then left the employ of that facility.

Senator BALDWIN. In terms of the opioid safety initiative and the tracking system, I have two other questions on this topic. Is it acceptable practice to send a prescription to a patient at home while they are in inpatient at a VA facility, and would you be able to track that with this system?

Mr. VALENTINO. Normally no, but a large percentage of our prescriptions go through the mail. So I could envision a system where a patient requested a refill and it was in the queue, and it was sent to them automatically, and perhaps after they ordered it and it was in the queue that they were admitted, and if the timing was close, there just would not be enough time to stop that.

Senator BALDWIN. Maybe on an incidental basis, but if it was happening over a long period of time, that prescriptions were being sent to a home when somebody was a long-term inpatient, that would be—

Mr. VALENTINO. That would indicate there is a problem.

Senator BALDWIN. Would the tracking system capture that?

Mr. VALENTINO. Not the opioid safety tracking system.

Senator BALDWIN. OK. Last, on this tracking system, does this link the prescriptions to the underlying diagnosis of the patient? So would it flag, for example, where a patient who is being seen for conditions other than chronic pain is receiving an opioid prescription?

Dr. WEST. Yes, that is a wonderful question. The new tool that we have been talking about, the Opiate Therapy Risk Report, actually does. OK. So we are making it more easily accessible to front line providers. I mean, I am still a front line provider. I have a quarter-day clinic a week. And the important thing is to be able to get easy access to that information.

With the new Opiate Therapy Risk Report, you can see the last primary care visit, last time they may have been in a substance abuse clinic visit, last time that they saw mental health. It also

looks at—you know, you brought it up earlier—co-morbid illnesses that may be a counter-indicator to contra-indicated with opiates such as sleep apnea. We kind of are covering the whole bases there with our new risk report.

Senator BALDWIN. Mr. Chairman, I have additional questions, but I went way beyond my time, so either for the record or if you have a second round.

Chairman ISAKSON. You owe Senator Cassidy a debt of gratitude. I let you go as long as he went.

Senator BALDWIN. I will thank him on the floor.

Chairman ISAKSON. We will leave the record open for any questions you want to submit, and for the record to reflect, I appreciate Senator Baldwin's thanks for calling this hearing. Both Senators from the State of Wisconsin requested a hearing and both were invited to be here, and I understand Senator Johnson is going to come as well. We appreciate your being part of the meeting today.

I am going to have to go to the floor in just a minute, so as I recognize Senator Tillis to come forward and ask his questions, I am going to also ask him to conduct the rest of the hearing until I get back, if that is OK. After Senator Tillis, Senator Manchin, and Senator Boozman will be the next to question.

Senator Tillis.

HON. THOM TILLIS, U.S. SENATOR FROM NORTH CAROLINA

Senator Tillis [Presiding.]. Thank you, Mr. Chair. I am neither a doctor nor a lawyer. I am a management consultant, which I am sure is a great baseline for a joke, they walk into a bar. My question really relates to trying to reconcile some of the numbers. Senator Cassidy, said there are some 350,000 people on medications today and that realistically that should be 5,000. I like getting numbers right.

If that is even within the realm of possibilities, what are we doing? Assuming that the people who are on these prescription medications, they are on it for one of two or three reasons: they are on it and they should not be; they are using it, but it is not the most effective treatment they can get, which is there a question about, is there some mis-prescribed treatment or are there other options that we should be providing available; and then some of them are doctor shopping and probably not taking the medication and putting it out on the market.

Can you just give me some sense of that challenge we have now with this more than 300,000 people? Has there been any research done on what a realistic number is for the long-term use of opioids?

Dr. CLANCY. To the best of my knowledge, there is not a number that comes out of all these efforts. What we know is we can continue to make progress and that is exactly what we are planning to do. In terms of your breakdown, Senator Cassidy is completely correct that there is no evidence that they are effective. Unfortunately, there is not any evidence that anything else is more effective.

So, you have got a choice between drugs that do not—or other modalities that do not work terribly well. What we do in VA is make access to other alternatives more available as much as we can. That can be different types of rehabilitation services, particu-

larly for musculoskeletal pain, physical therapy, sometimes chiropractic. For some types of pain, acupuncture and massage treatments like that.

To be quite honest, to get off opioids, I think people should be able to try anything. The trick is whether that works or not. Acupuncture tends to be better on more peripheral types of pain than it does on more centralized visceral types of pain.

That is the path that we are going down. What is likely? It feels like the kinds of models you might have used as a management consultant, but I bet—I would like to actually ask some of our experts to try to figure out how low could we go. 5,000 feels possibly a little too ambitious, but I do not think we should make it up. I think we ought to figure that out.

Senator TILLIS. I think it is very important because to me, unless you have that sort of baseline target, I do not know how you develop strategies around achieving the target. It seems to me it would be helpful. Dr. West, you looked like you were about to say something. Do you have something to add?

Dr. WEST. I always look like that.

Senator TILLIS. OK.

Dr. WEST. I always have something to add. I am an internist, so if you give me a chance, I will talk your ears off.

Senator TILLIS. Dr. Daigh, you went back in your opening comments and you were talking about compliance numbers. It just seemed to be very, very low, and that was a 2012 report?

Dr. DAIGH. It was data from fiscal year 2012.

Senator TILLIS. OK.

Dr. DAIGH. The report is from May 2014.

Senator TILLIS. What does it look like in fiscal year 2014?

Dr. DAIGH. I do not know. We would have to ask VA the data. That was a one-time look and we have not gone back to regenerate that data.

Senator TILLIS. Is there any, based on the analysis of the fiscal year 2012 data, has there been any way to map what seemed to be unacceptable compliance numbers to individual people who need to be held accountable for achieving higher compliance numbers? To the extent the compliance numbers were so low in 2012, have there been any consequences or was it appropriate to have any consequences for those who were responsible at the time?

Dr. DAIGH. For the first question, the methodology of the study, was a snapshot in time. It was not a longitudinal study.

Senator TILLIS. OK.

Dr. DAIGH. You cannot get to where you would like to go and where we would like to go, too.

Senator TILLIS. Great. That is where you really need to get to?

Dr. DAIGH. Absolutely. That study will not take you there, unfortunately.

Senator TILLIS. OK. The last question I have is about as far off topic as possible, but there is probably not a day or a week, at least, that goes by that I do not hear from certain veterans organizations I did as Speaker of the House with respect to opioids not necessarily being the only source that we should look to for palliative care, for pain care, and cannabinoids come up and, in fact, we are having the discussion here.

To what extent have you all looked at this as a—of the 300,000 who are currently depending on opioids, there may be some efficacy in consideration of cannabinoids or certain extracts for this sort of pain? Because I tend to agree. I do not think you get to 5,000 from 350,000. Are there other things that you tier into there and to what extent do you all think that merits our consideration? Thank you.

Dr. CLANCY. So, our clinicians cannot prescribe that by law. As far as I know, there is no federally-funded research—I am putting a small caveat on that—that looks at the effectiveness of medical marijuana. It has been more of a compassionate use sort of approach to make that available in some States. Frankly, putting that specific issue aside, which has a number of sensitivities, I think we should be willing to try anything.

The other thing I would say that offers some hope for the future is actually not starting opioids to begin with. Most of the time we are not starting them, and, in fact, Defense has some very compelling studies in process right now of actually testing acupuncture in the field. I would guess it will not be 100 percent effective, but if you can delay or actually prevent the initiation of opioids, you have completely changed the ball game.

I know that when they launched the studies, they were sufficiently optimistic before making a big investment in a large study that they went to the researcher and said, Wait a minute. Before we cut the check here, you need to include the component that talks about the training program. How would we train medics, and so forth, in the field to actually administer this?

Senator TILLIS. OK. Thank you. I am going to tell myself my time has expired.

Senator Manchin.

HON. JOE MANCHIN, U.S. SENATOR FROM WEST VIRGINIA

Senator MANCHIN. Thank you, Mr. Chairman. Last year the VA found that more than half a million VA patients are abusing opioids. I think we have gone through all this. I am so sorry I am coming in late from another Armed Services meeting. VA patient overdose on prescription medication is double the national average, from what our statistics have shown.

I have seen the tragedy first hand in West Virginia. Sadly, we have the highest mortality rate in the country, and the 605 percent increase in deaths since 1999, 605 percent. I have worked to re-schedule Hydrocodone, combination drugs like Vicodin, Lortab, trying to get them from three to two. It makes the drugs a little bit harder to get.

I have heard some alarming stories from my constituents, and often they are prescribed one drug after another. I have had people stop me on the street coming out of the military. When I first got here as a Senator, I started looking at the highest unemployment categories we have and it is our veterans.

I started looking into why that might be. It is drug use. Cannot pass a drug test. It is an epidemic all through this country, in my State, and I am sure in Wisconsin, everywhere else. How well are your doctors trained and how well are they basically able to detect these types of dependencies?

I just had a person stop me on the street Saturday and say their husband was given certain drugs, he was complaining; he is schizophrenic, he was almost suicidal. They would not change them. They kept doubling down. We had to fight to get to another clinic that truly specializes in this away from the VA to find someone who could cure our problem. Now, thank God, they are living more of a normal life.

So, I can tell you that some of the veterans in the State of West Virginia do not believe that the veterans portion of medical care is really expertise enough to be able to handle this. Do you find that to be—I am not being derogatory at all. I am just saying, what can we do to help? Or can we just get them to someone who has the expertise?

Dr. CLANCY. What came up before you arrived, Senator—and I am sorry we did not get a chance to meet briefly yesterday and I know that you all were pulled into many votes—is, I did bring some data from West Virginia which I did not bring today, but I will make sure that your staff get a copy.

Senator MANCHIN. It is quite high, is it not?

Dr. CLANCY. It is, although there has been progress in terms of reducing the rates and the doses. One of the biggest challenges for veterans is both the severe injuries that many have had, musculoskeletal nerve injuries and so forth, as well as the associated Post Traumatic Stress and Traumatic Brain Injury.

There are many veterans who get off opioids or down to an extremely low dose only needing it sometime who are profoundly grateful and appreciative and will say that their lives are transformed. There are far, far more who are very hesitant, absolutely resistant to even starting that journey. That is the sort of broad spectrum of challenges that we are dealing with.

Senator MANCHIN. Let me ask you, as a non-medical person, it just makes common sense to me that if you gave me one, prescribed one, and I come back and I tell you it is not working, would you not take the prescription away before you gave me another? Does that make sense? It is so common sense to me that something did not work so I am going to try something else—they are telling me nothing ever gets taken away.

Dr. CLANCY. That may actually be true, and I think an issue that we struggle with, as the rest of the country does, is that we have a pretty important shortage of pain management specialists and we are—

Senator MANCHIN. I mean, common sense, remove and replace.

Dr. CLANCY. Well, you would be surprised how many times in medicine, actually the reason the drug is not working is they got the wrong dose. Giving an ineffective dose is sometimes referred to as homeopathic.

Senator MANCHIN. You all recognize, I mean, it is a serious problem.

Dr. CLANCY. Yes, without question.

Senator MANCHIN. Especially, let me tell you, if you go down into the age groups, our highest unemployed age group is veterans 18 to 24.

Dr. CLANCY. Right.

Senator MANCHIN. I can assure you that is where most of addiction comes right out, and then it changes as the ages change a little bit more. Every indication is that's where the problem is. Again, it goes back. Do you require patients receive mandatory counseling when being prescribed opiates?

Dr. CLANCY. Yes. They now have to—and this is one of the features of the risk report that we were discussing earlier. They actually have to sign an informed consent and that is part of their record which walks through benefits and potential harms of these treatments.

Senator MANCHIN. You are saying you are still practicing, correct, Dr. West?

Dr. WEST. Correct.

Senator MANCHIN. Dr. Daigh, are you still practicing?

Dr. DAIGH. No, I am not.

Senator MANCHIN. OK. Dr. West, how much training did you have in dispensing as far as pain medication?

Dr. WEST. It is a wonderful question. When I first came out of residency, which was not all that long ago, none. We just were not trained in residency. I went to a strong academic program here.

Senator MANCHIN. Sure.

Dr. WEST. Now, it has significantly increased. One of the things I talked about earlier as well was getting this education to the primary care providers. So now primary care providers are getting the information.

Senator MANCHIN. What would you say that in the VA—I am so sorry, my time, I will just be a second—that basically in the VA medical delivery system the doctors that come in, how they come, where they come from, would they have that expertise?

Dr. WEST. Doctors coming into the system really are not being trained on pain management the way they should be. That is why they need to be trained. That is why VA has a responsibility to train those physicians and get that expertise out directly to them.

Senator MANCHIN. Do you not think we should get advice from those who specialize in—

Dr. WEST. Absolutely.

Senator MANCHIN [continuing]. Before you start prescribing?

Dr. WEST. Absolutely. Getting that information out there is critical.

Senator MANCHIN. No, I am saying, if I am just deploying out, I am 19, 20, 21, 22, and I have chronic pain or whatever other ailments I may have, would you not think I should be evaluated by someone who specializes in it before you give me a prescription?

Dr. WEST. It is definitely a reasonable thing to say and again, the issue is we do not have a whole lot of pain providers out there. We are working through that and we are getting the appropriate education programs there.

Senator MANCHIN. Thank you.

Dr. CLANCY. One other thing, Senator, two things. One is, I do have the information so I will leave that with you, and one of your facilities is actually making substantial progress, particularly in the proportion of veterans who are on both a narcotic and another drug that have a particularly high risk of adverse affects. That is modestly good news.

Senator MANCHIN. Can you—

Dr. CLANCY. Absolutely, yes. We will get it to you right afterwards. Part of the challenge is that oftentimes these veterans come to us having been treated for many, many different conditions acutely. We are not starting them on those drugs to begin with. Many are arriving having been treated with them for a few weeks, months, or whatever their period is.

Senator MANCHIN. I am not here to blame, I am really not. I am just looking for answers to serious problems and we want to work together to try to cure these problems.

Senator TILLIS. In the interest of time, we have got another panel after this and I know we all have got a place to be at noon.

Senator Boozman.

HON. JOHN BOOZMAN, U.S. SENATOR FROM ARKANSAS

Senator BOOZMAN. Thank you, Mr. Chairman. Thank you, all of you all, for being here today. I agree with you, Dr. Clancy. You mentioned that one of the most important things to prevent these problems from happening is to not prescribe them in the first place when they are not needed.

The other thing, though, is that when they are prescribed—when they are needed—is having adequate follow up, and I think in medicine in general these days are getting better at that. Sometimes those safeguards have not been in place. That is where you get the mail order. My county sheriffs tell me that it has become a cottage industry, not only with veterans, but others selling pills to get a little extra income.

So it is a huge problem. One of the things that appears to be promising, perhaps, is—is it Vivitrol? There is a drug. Am I pronouncing it correctly?

Mr. VALENTINO. Yes.

Senator BOOZMAN. That again blocks, from what I understand, blocks the receptors from getting the whatever. It is certainly not habit forming. The other drugs that are used, Methadone and various other things are all controlled substances and you have to worry about them. Can you talk a little bit about that, if we are using that, or the effectiveness of that? I know it is an expensive drug.

Mr. VALENTINO. Yes. We are using that drug. We are also using other alternatives to Methadone, Suboxone and Subutex. We are using those. They are—

Senator BOOZMAN. Suboxone, again, you have to worry about becoming addicted to that, also.

Mr. VALENTINO. Yes. Not quite as much. It has an antagonist along with the agonist, so it is—

Senator BOOZMAN. And again, correct me if I am wrong, the preliminary stories seem to be very, very positive about the other. Is cost the reason that we are not, perhaps, jumping in with both feet?

Mr. VALENTINO. Regarding Vivitrol?

Senator BOOZMAN. Yes.

Mr. VALENTINO. It is expensive, but it is not horribly expensive. I think it is about \$500 per month. So it is not like a Hepatitis C drug or other drugs. So no, I do not think cost is the issue. When

new therapies are introduced in medicine, there is a lag. People have to get comfortable with how to prescribe, how to monitor.

We do have guidance out for the drug. It is on our formulary. We have seen a pretty dramatic up tick in its utilization over the last 6 months.

Senator BOOZMAN. Good. again, perhaps we can get some evidence based on what are the most effective of these. I am concerned about the transition. You know, you will have individuals in the military, active duty transitioning to the VA and these individuals are having problems over a period of a great deal of time. Sometimes you finally get them on a formulary that works and then you come to the VA and they are told we do not have the particular drugs they need.

Dr. Tuchschildt was in on Tuesday and said there is the opportunity to override that. I guess my question is, how long does it take? Are we actually using the ability to override or are these individuals basically saying come back in a few weeks, we cannot do this?

Dr. CLANCY. We are just arguing about who gets to say yes first, but yes.

Mr. VALENTINO. Yes.

Senator BOOZMAN. But that has been a no in the past or a difficult yes.

Mr. VALENTINO. We have not had a policy in the past, but we have actually had a practice in the past of continuing pain medication—

Senator BOOZMAN. I do not mean to interrupt, but the practice is such that when we have these families come in, that is kind of the common thread in the sense that many times they cannot get the medicines that they need and are frustrated.

Mr. VALENTINO. Yes, I understand that concern. When somebody comes in from DOD, we have to take a look at their medications that they are on. For example, in particular with what we are talking about here, if somebody comes in on an opiate and a benzodiazepine, the VA physician is really compelled to take a close look at that and probably stop one or the other or both.

A lot of these drugs in mental health have changed—

Senator BOOZMAN. Is that because the DOD physician is not doing a good job?

Mr. VALENTINO. I am not saying that. Patients' conditions change over time, and perhaps what was initiated at one point is no longer the best therapy because patients' conditions have changed, other things have changed.

Dr. CLANCY. Their focus is acute in its short term. Right? So opioids usually work great for people in the short term.

Senator BOOZMAN. No, I understand.

Dr. CLANCY. It is the longer term.

Senator BOOZMAN. Yes and no. Some of these, they have been kind of fiddling with and getting them fine-tuned where they can live with whatever they are doing. Would it not make sense, with some of these drugs for specific things like that—and I do not know what the expense is. Would it not make sense to mesh the formulary?

Dr. CLANCY. We have a very clear agreement and commitment before transitioning servicemembers, particularly focused on those who are on mental health medications, that there will be no change until they have had an opportunity to be evaluated.

We continue those medications, depending on the clinical circumstances of the individual, a former servicemember now veteran. Some of those drugs may be continued and we can do that in our formulary. I think that we prescribe or have the opportunity to prescribe about 96 percent of what is in the DOD formulary.

What we are really focusing on is a veteran-centered approach at that time of transition, because with all the other things you have to deal with, to be told that, Oh, no, thank you, we think we will give you different medications now, is not actually helpful.

Senator BOOZMAN. Thank you, Dr. Clancy. Thank you, Mr. Chairman.

Senator TILLIS. Thank you.

Senator Johnson.

HON. RON JOHNSON, U.S. SENATOR FROM WISCONSIN

Senator JOHNSON. Thank you, Mr. Chairman. I would like to thank you and the Committee for allowing Senator Baldwin and I to come and participate in this because this is, obviously, an issue that is striking dear to our hearts here in Wisconsin. I would like to thank you, Dr. Clancy, for responding to my letter, and certainly starting your own investigation in terms of the problems at Tomah.

Senator Manchin would say, and we all recognize this is a serious problem, I guess I just want to ask, how long has the VA recognized the potential of opiate overdosing or over-prescription to be a problem?

Dr. CLANCY. We have recognized it since at least 2012 and launched a very serious initiative starting in 2013, and we are now upping that. Upping it is probably the wrong way to say it. We are renewing the focus on it to get it right down to ground level for each individual prescriber and their patient panel.

Senator JOHNSON. How long have you been at the VA?

Dr. CLANCY. I have been there for a year and a half.

Senator JOHNSON. OK. Dr. Daigh, how long have you been in the Inspector General's Office?

Dr. DAIGH. About 12 years.

Senator JOHNSON. About 12 years. How long have you been aware, or the Inspector General's Office, how long have they been aware that opiate over-prescription may be a problem?

Dr. DAIGH. I think if you look through our hotlines for as long as I have been at the VA, it has been a problem. And the reason that we did the national review in 2012 was that it has been my experience that in order to get VA to respond and make change, I need national data. We put a tremendous amount of effort into providing a national report to demonstrate at least what we think the level of the problem is and then encourage VHA to move forward.

Senator JOHNSON. How long have you been aware, or the Office of Inspector General, and/or, been aware of the problems at the Tomah facility? When were you first hearing of these problems?

Dr. DAIGH. In recent time, that would be the first time Tomah has come up to me. We got a hotline allegation in roughly 2011, and I can give you a timeline, and that allegation of improper care to providers at Tomah was sent to the VISN director to respond to.

Historically, I have produced about 60 hotlines a year. I write about one hotline a week, is about what I can publish for manpower. The OIG gets roughly 50,000 contacts and that distills down to, in 2014, 2,400 health care issues. So, in the triage process, I sent that to the VISN director and the VISN director responded to those allegations, essentially saying they found no problems at Tomah.

About a month or two later, we got another hotline. Again, I can provide the data.

Senator JOHNSON. OK. Now, I do not want to get into the whole thing right now.

Dr. DAIGH. OK.

Senator JOHNSON. The Office of Inspector General first became aware of problems at Tomah in terms of potential opiate over-prescription in 2011? Are you looking in a more robust fashion in terms of possibly knowing before that? This is when you were first aware of it. Are you checking either the Inspector General's Office or within the VA in terms of previous reports of problems with Tomah?

It may be even beyond opiate over-prescription. Allegations of intimidation? How long has that been known? Are you inspecting that right now? Are you launching an investigation in terms of how long this has been known?

Dr. DAIGH. I would say in recent time, roughly 2011 timeframe, is when we became of those issues.

Senator JOHNSON. Are you going to launch an investigation to see if this was known sooner to hold people accountable?

Dr. DAIGH. So in order—

Senator JOHNSON. Just simply yes or no. Are you going to?

Dr. DAIGH. I am not planning to go back further.

Senator JOHNSON. Dr. Clancy, are you going to look into how long this has been known?

Dr. CLANCY. Yes. Right now we have got two rigorous investigations going on. One is being done by an entity that Secretary McDonald and the Deputy set up called the Office of Accountability and Review. Historically, VA has 150 facilities and many clinics and so forth, so highly decentralized and for many policies, including HR, was pretty decentralized or federated, if you will.

The whole purpose of this Office of Accountability and Review, fondly known as OAR, is to hold senior leaders in particular accountable. Part of that investigation will also include any previous allegations or issues that have surfaced.

Senator JOHNSON. OK. My time is up. Dr. Daigh, one of the things we have been trying to work with the Office of Inspector General. Certainly sensitive to the privacy issues, that type of thing. We also are conducting our own investigation as part of my Committee. That is my responsibility.

We are going to require some of these files so we can do our own investigation to find out how far this went back, when it was known, who knew it so we can, first and foremost, the number 1

goal here is to make sure these tragedies never happen to another veteran or their families, but also to find out who knew what when and hold those individuals accountable.

I am hoping that the Office of Inspector General actually cooperates with the Committee as we undertake our responsibility to do our own investigation as well. Thank you, Mr. Chairman.

Senator BLUMENTHAL [presiding]. I think that concludes the questioning. Just to let you know, both Senator Isakson and Senator Tillis are on the floor where they have to be right now. So, I have been asked to take over as Chairman.

In the interest of time since we only have about half an hour left, I am going to invite Senator Baldwin to submit any additional questions she may have for the record. I want to thank her for being here today, as well as Senator Johnson, and ask the second panel to please come forward.

RESPONSE TO POSTHEARING QUESTIONS SUBMITTED BY HON. BERNARD SANDERS TO CAROLYN CLANCY, M.D., INTERIM UNDER SECRETARY FOR HEALTH, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS

In Vermont, naturopathic doctors are licensed as primary care physicians by the state of Vermont. Only physicians licensed by the state may call themselves naturopaths, naturopathic physicians, naturopathic doctors, or use the initials "ND" after their name. In order to be licensed by the state of Vermont, naturopathic physicians must graduate from an approved naturopathic medical school, pass medical board exams, and fulfill continuing medical education requirements.

Other states that license naturopathic physicians include Maine, New Hampshire, Connecticut, California, Arizona, Montana, Oregon, Hawaii, Washington, Utah, Alaska, Idaho, Kansas, Minnesota and the District of Columbia.

Question 1. Since naturopathic physicians are trained in a variety of diagnostic and therapeutic modalities, is the VHA considering hiring certified naturopathic physicians to augment VA medical facilities' pain management clinics?

Response. VA has no legal authority under 38 U.S.C. 7402(b) to appoint certified naturopathic physicians unless they otherwise meet the degree and licensure requirements of that section. For those that do, the problem remains that no mechanism currently exists by which VA can credential them to practice within VHA as naturopathic physicians. However, alternative medicine strategies are currently being actively incorporated into VHA's inventory of treatments for chronic, refractory pain syndromes. These emphasize non-pharmacologic approaches and include modalities such as acupuncture, massage therapy, and yoga.

RESPONSE TO POSTHEARING QUESTIONS SUBMITTED BY HON. MAZIE K. HIRONO TO CAROLYN CLANCY, M.D., INTERIM UNDER SECRETARY FOR HEALTH, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS

VA OPIOID SAFETY INITIATIVE

Question 2. You mention in your testimony that the Opioid Safety Initiative has been in place since 2013. What failed with the program in Wisconsin? How can you be sure it is effective across the country?

Response. The Opioid Safety Initiative (OSI) was not fully functional during the time the Tomah events occurred. VA's initial focus for the Opioid Safety Initiative (OSI) was to identify and take corrective action for Veterans Integrated Service Networks (VISNs) that were outliers on the OSI metrics. VA then shifted its focus to identify and take corrective action for individual facilities that were outliers on the OSI metrics. VA is now focusing on identifying and taking corrective action on individual providers who appear to be outliers on the OSI metrics. This current focus is complex because administrative databases do not lend themselves well to conducting the type of analysis that is necessary to accurately identify inappropriate prescribing. For example, a pain management specialist, a hospice care provider or an oncologist may "appear" to be an outlier, when in actuality their prescribing may indeed be clinically appropriate. VA is working through these issues now to develop a reliable way to identify potential cases of inappropriate prescribing practices so that local review, validation and intervention, if necessary, can occur.

Going forward, VA will ensure enhancements to the OSI enable identification at the national level of individual provider prescribing patterns. The OSI will also become a more useful tool when augmented by VA's mandated deployment of the Academic Detailing Program. The Academic Detailing program is designed to provide the infrastructure and processes needed for VISNs, facilities, and individual providers to achieve safe and appropriate opioid prescribing practices and consumption. Each VISN will submit its first Academic Detailing Program progress report to the Under Secretary for Health by September 30, 2015.

Nationally, the Opioid Safety Initiative (OSI) has been effective. From Quarter 4, Fiscal Year 2012 (beginning in July 2012) to Quarter 2, Fiscal Year 2015 (ending in March 2015) there are: 109,862 fewer patients receiving opioids; 33,871 fewer patients receiving opioids and benzodiazepines together; 74,995 more patients on opioids that have had a urine drug screen to help guide treatment decisions; and 91,760 fewer patients on long-term opioid therapy. The overall dosage of opioids is decreasing in the VA system as 12,278 fewer patients are receiving greater than or equal to 100 Morphine Equivalent Daily Dosing (MEDD). The desired results of the OSI have been achieved during a time that VA has seen an overall growth of 90,488 patients that have utilized VA outpatient pharmacy services.

We are confident that individual provider-level enhancements to the OSI, coupled with the Academic Detailing Program will foster safer and more appropriate opioid treatments.

VA'S COORDINATION WITH STATES

Question 3. While you tout coordination with states that have monitoring programs, testimony provided here seems to indicate a lack of actual coordination—what reassurances can you offer that the VA is actually following through on all of these protocols and efforts and not just paying lip service to the very real issue of opioid abuse?

Response. VA's State PDMP is a new capability to share prescription drug information, including opiate prescription data, with the PDMP of each state in the country that has a drug monitoring program in place. VA is participating with all states with which it is able to. PDMP deployment is now complete at 29 states; deployment of the system to 6 additional states is currently underway; Missouri is the only state without a PDMP; and 1 state is not yet ready to accept data from VA (New Mexico). Thirteen states have data, communication, or format issues that need to be resolved before VA prescription drug information can be shared with them (New York, Massachusetts, Illinois, California, Indiana, Rhode Island, Iowa, Nebraska, Michigan, West, Virginia, Nevada, Texas, and Montana). VA is conducting a state-by-state assessment of these 13 states to determine the specific requirements for data transfers of VA prescription drug information, and VA is working to secure funding and contracts to support the changes needed.

Additionally, VHA is currently drafting a new directive titled, which will establish policy requiring VHA health care provider participation in State Prescription Drug Monitoring Programs, consistent with applicable state laws.

VA'S POLICY ON PRESCRIBING SUBOXONE

Question 4. Are you monitoring the Suboxone so it's not being misused or untracked?

Response. Yes. Monitoring of adherence at a minimum involves routine urine drug screens for metabolites of buprenorphine/naloxone (Suboxone) to confirm recent ingestion of the medication. When clinically indicated based on patient symptoms and function, providers also use pill counts to determine if patients have possession of doses prescribed for future use. Some clinics institute random calls for patients to present within 24 hours for medication counts and alert patients to this procedure as a standard part of the treatment consent process. Patients without the appropriate doses in their possession have adjustments to their treatment plan such as more frequent monitoring or enrollment in an Opioid Treatment Program with dispensing of medication observed daily.

RESPONSE TO POSTHEARING QUESTIONS SUBMITTED BY HON. TAMMY BALDWIN TO CAROLYN CLANCY, M.D., INTERIM UNDER SECRETARY FOR HEALTH, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS

Question 5. VA Prescribing Standards

Your clinical review findings for Phase 1 of your investigation into the Tomah medical facility found that Tomah patients were 2.5 times more likely than the na-

tional average to be prescribed opioids greater than 400 morphine equivalents per day and were more likely than the national average to be prescribed opioid doses between 200–300 morphine equivalents per day. With respect to the use of benzodiazepines and opioids concurrently, which is discouraged due to risks of complications, your team found that Tomah was almost double the national average.

a. In your opinion, are these prescribing practices at Tomah appropriate?

Response. Since the prescribing practices at Tomah are at the core of VA's ongoing investigation, we are unable to offer a formal opinion on the matter at this time. However, the clinical review findings for Phase 1 of the VA investigation found mixed results in the use of opioids at the Tomah VAMC. From the fiscal quarter beginning in July 2012 to the fiscal quarter ending in December 2014 the percent of pharmacy users receiving an opioid decreased 6% (2,124 to 1,994 Veterans), while the national percentage decreased 13% (679,376 to 587,762 Veterans). The percent change for this metric must be considered within the context that Tomah has a lower percentage of Veterans receiving an opioid compared to the rest of the VA. The percent of pharmacy users receiving an opioid or tramadol who are also receiving a benzodiazepine decreased 9% (611 to 554 Veterans), while the national percentage decreased 24% (122,633 to 93,352 Veterans). The percent of pharmacy users receiving opioids for longer than 90 days who also received a urine drug screen to monitor treatment increased 36% (453 to 712 Veterans), while the national percentage increased 31% (160,601 to 231,856 Veterans). The percent of pharmacy users who are receiving doses of opioids greater than or equal to 100 MEDD has not changed (274 Veterans), while the national percentage decreased 17% (59,499 to 49,356 Veterans).

b. Are these prescribing practices at Tomah consistent with VHA's clinical practice guidelines for prescribing opioids; for prescribing benzodiazepines; and for prescribing both drugs concurrently?

Response. VA is deeply concerned with and is actively addressing the overuse and dependence on opioid medications by Veterans. After many years of promoting the aggressive treatment of pain with powerful opioid analgesics, the United States is in the midst of an epidemic of misuse and abuse of opioid analgesics. The extent and complexity of our Nation's Veterans multiple chronic pain conditions, including many severe battlefield injuries associated with blasts and co-morbid Traumatic Brain Injury and/or psychological conditions such as depression and Post Traumatic Stress Disorder, often make effective pain management clinically challenging and increase the risks for complications due to both over- and under-treatment with opioids and other therapies.

Per VHA clinical practice guidelines, the use of benzodiazepines and opioids concomitantly is discouraged due to risks of complications, including apnea and death. The clinical review findings for Phase 1 of our investigation suggest that Clinical Practice Guidelines (CPGs) for chronic opioid therapy may have not been correctly followed. However, as previously stated, our investigation is ongoing and we are unable to offer a formal opinion on the matter at this time.

In the months following the clinical review findings for Phase 1 of the VA investigation at Tomah VAMC, the medical center has been vigorously pursuing implementation of the Opioid Safety Initiative (OSI) similar to other VA facilities to ensure optimal pain management and to safeguard Veterans from harm inherent in high-risk medications such as opioids and benzodiazepines. The objective of OSI is to make the totality of opioid use visible at all levels in the organization with a particular emphasis on identifying and remediating prescribing practices that place Veterans at increased risk for adverse outcomes. To assist Veterans, providers and clinical teams in achieving OSI goals for safer opioid prescribing practices, an interdisciplinary VHA Task Force assembled a 15 module, peer-reviewed OSI Toolkit that is continually updated as new information becomes available, including new evidence-based practices. The OSI Toolkit is accessible to all VHA clinicians and disseminated widely and repeatedly through multiple communication channels and educational formats to facilitate safe opioid prescribing practices.

– If yes, do you believe the relevant VHA clinical practice guidelines should be revised?

Response. We agree that it would be useful to update the guidelines with the latest evidence; a Chronic/Long Term Opioid Therapy Clinical Practice Guideline Panel is scheduled to begin this work in September/October 2015. However, considerable work has already been completed in developing specific guidance for safe opioid prescribing in the Opioid Safety Initiative Toolkit, which has been widely disseminated to VHA clinicians. These documents can be found on the VA Pain Management Intranet Site, <http://vaww.va.gov/PAINMANAGEMENT/index.asp>.

- If no, what actions do you recommend to bring facilities like Tomah into compliance?

Response. Suggested actions would include a clinical consultation by an expert team followed by action plans to establish competent stepped clinical care for pain in primary care and in specialty care, as articulated in VHA Directive 2009-053.

The Tomah VAMC and VISN 12 leadership are committed to providing the best pain management to Veterans, who need such care. Specific steps taken at Tomah in past three months include:

- Implementation of pain resource folder in computerized medical record that is easily accessible to providers;
- Provider training on how to better leverage VHA's on-line opiate safety tools;
- Hiring a tracking nurse to help monitor and track Urine Drug Screen results and actions as part of a continuous monitoring/maintenance plan; and
- Provider education: in addition to academic detailing, VISN 12 has sponsored a pain management workshop on June 3, 2015.

- c. When was the last time the VHA updated the relevant clinical practice guidelines?

Response. The current VA/DOD Management of Opioid Therapy Clinical Practice Guideline (CPG) was updated in 2010. A CPG update kick-off meeting is scheduled for August 2015. Dr. Jack Rosenberg (VHA National Pain Management Strategy Coordinating Committee) has agreed to be the VA's champion for this update. As part of the CPG development/update process a thorough evidence review and synthesis will be conducted. Inclusion or exclusion of the CDC's updated prescribing guideline will be dependent on the evidence synthesis and the work groups recommendations at that time.

- d. The Center for Disease Control and Prevention plans to update its guidelines for opioid prescribing practices in the near future. Does the VHA currently use the CDC's prescribing guidelines and does the VHA plan to incorporate CDC's updated prescribing guidelines when they are complete?

Response. The current VA/DOD Management of Opioid Therapy Clinical Practice Guideline (CPG) was updated in 2010. A CPG update kick-off meeting is scheduled for August 2015. Dr. Jack Rosenberg (VHA National Pain Management Strategy Coordinating Committee) has agreed to be the VA's champion for this update. As part of the CPG development/update process a thorough evidence review and synthesis will be conducted. Inclusion or exclusion of the CDC's updated prescribing guideline will be dependent on the evidence synthesis and the work groups recommendations at that time.

Question 6. VA Prescribing Guidance and Continuing Medical Education for Providers

In Dr. Forster's testimony, she notes how Kaiser Permanente distributes "clear and concise protocols" to providers so they can identify and take action to stop inappropriate prescription narcotic use, including drug diversion or drug seeking behaviors. Dr. Forster also notes that Kaiser offers continuing education to providers on this issue. Based on what I've learned from prescribing practices at Tomah and from multiple GAO reports on the VHA system, it appears that VHA lacks similar "clear and concise protocols," or what it does have is not implemented effectively or consistently followed.

- What protocols does VHA distribute to doctors, nurses and pharmacists so they can spot and prevent opioid abuse?
- Does VHA have continuing education programs so providers can stay up on the latest trends and tools?

Response. VHA has multiple projects, coordinated under the National Pain Program (NPP) Office, to support and educate clinicians and Veterans about safe and effective pain management, including use of opioids, such as: the Opioid Safety Initiative (OSI), the Joint Pain Education and Training Project (JPEP) with the Department of Defense (DOD), the Pain Mini-Residency, Pain SCAN-ECHO, asynchronous web-based training, and Community of Practice calls which providers may elect to take but which are not required. These programs have presentations on universal precautions and risk management, including clinical evaluation, written informed consent, screening such as urine drug monitoring, use of state monitoring programs, and safe tapering.

In recognition of the clinical challenges to successfully manage pain and prescribe medication safely for our Veterans while implementing the Opioid Safety Initiative (OSI) Directive and the Informed Consent Directive, the NPP Office convened a national task force to create an OSI Toolkit (evidence-based to the extent possible) to help guide the field. The OSI Toolkit Task Force (Task Force) is comprised of experienced experts from pain management, pharmacy, primary care, and mental health

and is charged to systematically peer-review and standardize clinical education and patient education materials for distribution throughout the VHA in support of OSI goals. In developing the OSI Toolkit, completed October 2014, the Task Force met in weekly conferences over several months to create content which was then merged with Pharmacy Benefits Management Academic Detailing Program Office product development. The resulting Toolkit contains documents, some in presentation form, that can aid in clinical decisions about starting, continuing or tapering opioid therapy and other challenges related to safe opioid prescribing. These documents can be found on the VA Pain Management Intranet Site, <http://vawww.va.gov/PAINMANAGEMENT/index.asp>, or on the Adobe SharePoint Site, <https://va-eerc-es.adobeconnect.com/osi/>

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 12. Pain management opioid safety guide 91314—Power Point
 13. Patient Information Guide on Long-term Opioid Therapy for Chronic Pain—Power Point

Senator BLUMENTHAL [presiding]. Let me dispense with lengthy introductions in the interest of time. We have votes scheduled for noon. Thank you to our staff for so quickly arranging for you to come forward.

We are very pleased and grateful to welcome G. Caleb Alexander, who is not only an M.D., but Co-Director of the Center for Drug Safety and Effectiveness at Johns Hopkins Bloomberg School of Public Health; Carol Forster, also a doctor, M.D., Physician Director of Pharmacy and Therapeutics/Medication Safety at the Mid-Atlantic Permanente Medical Group of Kaiser Permanente; and John Gadea, Director of the Drug Control Division at the Connecticut Department of Consumer Protection.

We are thankful to all of you. Let us proceed with your opening statements. Thank you.

**STATEMENT OF G. CALEB ALEXANDER, M.D., CO-DIRECTOR,
CENTER FOR DRUG SAFETY AND EFFECTIVENESS, JOHNS
HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH**

Dr. ALEXANDER. Good morning, Ranking Member Blumenthal and Senator Baldwin. The opinions expressed here are my own and do not necessarily reflect the views of Johns Hopkins University, and I thank you for inviting me.

Doctors of my generation were taught not to worry about the addictive potential of opioids if a patient had true pain. Although well-intentioned, doctors have contributed to soaring opioid use. We have heard some of the statistics. Another one is that enough opioids were prescribed last year in the United States to provide every adult a 4-week, round-the-clock, continuous supply of Vicodin.

Abuse of opioids has become an epidemic that devastates America's families, and we have lost far too many lives from this epidemic, more than twice the number of Americans as have died in the Vietnam, Iraq, and Afghanistan wars combined. A core contributor to this epidemic is that doctors and patients continue to over-estimate the benefits and under-estimate the risks of these products.

In my testimony I would like to mention three important steps to address this problem, and I also discuss several popular ideas that I am concerned may distract us from the primary cause of this epidemic.

First, we need to improve prescribing practices. Best practices for opioid use have been described. Doctors need to be more cautious with opioid initiation as well as use over longer durations and with higher doses. They need to limit the use of fentanyl and methadone for pain. They need to use multi-disciplinary teams that incorporate non-pharmacologic pain treatments.

They need to avoid combining opioids with medicines such as benzodiazepines and barbiturates. These approaches are especially vital among individuals with mood disorders such as depression, Post Traumatic Stress Disorder, Traumatic Brain Injury, or substance abuse since we know that high risk use and adverse outcomes are both more common among these patients.

To improve practice, it is also vital to improve the measurement and accessibility of data about opioid utilization and prescribing at a patient, provider, clinic, and health system level. Such measurements allow for bench marking and enhance our understanding of practices contributing to opioid misuse and overdose deaths.

Second, we need to help people who are addicted to opioids access effective treatment. Treatment with the medicines buprenorphine and methadone is the most effective means of helping individuals regain control of their lives and avoid overdose.

Yet, despite over five million Americans with opioid dependence, fewer than one in five are currently receiving available treatments. There is too little provider interest. There are too many regulatory and payment barriers to access the most effective remedies.

Third, we need to help people get rid of opiates that they do not need. It is stunning that these drugs are so easy to get, and yet, so difficult to get rid of. There are millions of pounds of unwanted and unused medicines sitting in bathroom cabinets and bedroom night stands all over America.

The DEA recently finalized its rules regarding the disposal of controlled substances, and properly implemented, I believe that these take-back programs can serve an important role in reducing opioid-related injuries and deaths.

Other tools may be valuable, but I am cautious because the scientific evidence to support them is limited. Urine testing, for example, may be reasonable to routinely apply in practice, but urine tests do not reduce the addictive potential of opioids and they do not change the overall unfavorable risk/benefit balance for many, many current users.

The FDA and manufacturers are also pursuing so-called abuse deterrent formulations to re-engineer medicines to reduce their abuse potential. I would also approach this strategy with substantial caution. While these re-engineered medicines are designed to thwart abuse, their active chemical ingredients are no less addictive and most people that are abusing or addictive to these medicines swallow them whole.

Moreover, our research suggests that prescribers may over-estimate the safety of abuse deterrent formulations. I am not convinced that we can engineer our way out of this problem. Some have framed efforts to rein in runaway prescribing as a threat to quality of care for those with chronic pain. As a practicing physician, I can assure you nothing could be farther from the truth.

An overwhelming amount of evidence supports that compatibility of effective pain treatment with reducing opioid prescribing. High quality care for patients in pain is not jeopardized by such efforts. High quality care demands it. Thank you for the opportunity to testify today. I look forward to your questions.

[Opioid Prescribing: A Systematic Review and Critical Appraisal of Guidelines for Chronic Pain from the Annals of Internal Medicine appears in the Appendix.]

[The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction appears in the Appendix.]

[The prepared statement of Dr. Alexander follows:]

PREPARED STATEMENT OF G. CALEB ALEXANDER, MD, MS, CO-DIRECTOR, JOHNS HOPKINS CENTER FOR DRUG SAFETY AND EFFECTIVENESS

Good morning Chairman Isakson, Ranking Member Blumenthal and Members of the Committee. Thank you for the opportunity to speak today.

I am a practicing internist and prescription drug expert at the Johns Hopkins Bloomberg School of Public Health, where I co-direct the Johns Hopkins Center for Drug Safety and Effectiveness. The opinions expressed herein are my own and do not necessarily reflect the views of Johns Hopkins University.

Doctors of my generation were taught not to worry about the addictive potential of opioids if a patient had true pain. Although well intentioned, many doctors have unwittingly contributed to soaring opioid use * * * so much so that enough opioids are prescribed each year to provide every adult in the United States a 4-week round the clock supply of Vicodin.

I know that you are well aware of the devastating consequences of this epidemic on America's families. We have lost far too many lives—more than twice the number of Americans as have died in the Vietnam, Iraq and Afghanistan wars combined—and these deaths are the tip of the iceberg. Although there are many contributors

to this epidemic, a core problem is that doctors and patients continue to overestimate the benefits of opioids and underestimate their risks.

In my testimony, I would like to mention three important steps to address this problem. I will also discuss several popular ideas that I am concerned may take our eyes off the ball.

First, we need to continue to improve prescribing practices. Best practices for opioid use have been described—including cautious use with longer durations or higher doses, limiting the use of fentanyl patches and methadone for pain, incorporating multidisciplinary pain management teams, and avoiding the combination of opioids with medicines such as benzodiazepines. These approaches are especially vital among patients with comorbid conditions such as mood disorders, Post Traumatic Stress Disorder (PTSD), Traumatic Brain Injury (TBI) or substance use, since high-risk opioid use and adverse outcomes are both more common among these patients.

To improve practices, it is also vital that we continue to improve the measurement and accessibility of data about opioid utilization and prescribing at a patient, provider, clinic and health system level. Such measurements allow for benchmarking and enhance our understanding of practices contributing to opioid misuse and overdose deaths.

Second, we need to help people who are addicted to opiates access effective treatment. Treatment with the medicines buprenorphine and methadone is the most effective means of helping individuals regain control of their lives and avoid death by overdose, yet despite over 5 million Americans with opioid dependence, fewer than 1 in 5 are receiving available treatments due to low provider interest and a variety of regulatory and payment barriers.

Third, we need to vastly expand opportunities for people to get rid of opiates that they do not need. It is stunning that these drugs are so easy to get, yet so difficult to get rid of. There are literally millions of pounds of unwanted and unused medicines sitting in kitchen drawers, bathroom cabinets and bedroom nightstands all over America. The DEA recently finalized its rules regarding the disposal of controlled substances, and properly implemented, I believe that these “take back” programs can serve an important role in reducing opioid-related injuries and deaths.

Other risk mitigation methods such as patient contracts, risk assessment tools and urine testing are increasingly common. Despite their appeal, the scientific evidence to support them is limited. Although some of these approaches, such as urine testing, may be reasonable to routinely implement in clinical practice, such measures do not reduce the addictive potential of these products, nor do they change the overall unfavorable risk/benefit balance of them for many current opioid recipients.

The FDA and manufacturers are also pursuing so-called “abuse deterrent formulations” to reduce the chance a particular product will be misused. These formulations should also be regarded with caution. While these re-engineered medicines are designed to thwart abuse, their active products are no less addictive, and most individuals who abuse or are addicted to opioids swallow them whole. Moreover, our research suggests that prescribers may have important misconceptions regarding their safety. In short, I am not convinced that we can engineer our way out of this problem.

Some have framed efforts to reign in runaway prescribing as a threat to quality of care for those with chronic pain. As a practicing physician, I can assure you, nothing could be further from the truth. An overwhelming amount of evidence supports the compatibility of effective pain treatment with reducing opioid prescribing. High quality care for patients in pain isn’t jeopardized by such efforts, it demands it.

Thank you for the opportunity to testify today. I look forward to your questions.

Senator BLUMENTHAL. Thank you, Doctor.
Dr. Forster.

**STATEMENT OF CAROL FORSTER, M.D., PHYSICIAN DIRECTOR,
PHARMACY & THERAPEUTICS/MEDICATION SAFETY, MID-
ATLANTIC PERMANENTE MEDICAL GROUP, KAISER
PERMANENTE**

Dr. FORSTER. Good morning, Mr. Chairman. I should say Ranking Member Blumenthal and the Committee Members. Thank you for the invitation to be here today. I am Dr. Carol Forster, Physician Director of Pharmacy and Therapeutics and Medication Safety

for the Mid-Atlantic Permanente Medical Group, one of the regions of Kaiser Permanente which is a national health program.

It is the largest private integrated health care program in the United States, a private integrated health care program, I should say, providing comprehensive care to over 9.5 million members in eight States and the District of Columbia. We have over 500 pharmacies, 38 hospitals, and more than 170,000 employees, and we partner with over 17,000 physicians.

Our health care organization has been focusing on improving overall pain management services and appropriate prescribing for several years. The impact of narcotic abuse and over-use is felt by every sector of health care in every community. Our integrated electronic medical record and targeted prescribing reports have allowed us to identify potential non-medical use of prescription narcotics, even in those with a history of a chronic pain condition.

I would like to tell a story of a patient named Robert. Robert was diagnosed with a spinal injury after a motor vehicle accident in 2012. Since that time, he has been referred to several specialists and has received treatment, including surgery on his spine.

During the post-op period, Robert was soon identified as possibly depressed and drug-seeking. He had requested more medication and in higher doses from his surgeon as well as several other emergency room physicians. Subsequent involvement of his primary care physician and pain management team, as well as review of pharmacy reports, led to identifying that Robert was actually visiting ERs and multiple providers every week, many outside of Kaiser Permanente, and was not being truthful about his reasons for requested medications.

He was quickly referred to our specialist in behavioral health and addictionology and weaned off of all narcotics safely and received counseling and continued treatment for his depression and his chronic pain conditions.

National statistics showing the direct relationship between increasing deaths from narcotic overdose and increasing sales of narcotics in the U.S. have helped to motivate Kaiser Permanente to develop a national narcotic drug use initiative and aggressive monitoring program.

First, we have supported, developed, and communicated comprehensive continuing education programs for our physicians on the subjects of pain management, appropriate opioid prescribing, narcotic abuse, and diversion. As our physicians develop a comprehensive treatment plan for patients with chronic pain, they focus initially on alternatives to opioid therapy.

If they do prescribe opioids, it is recommended that a narcotic agreement between patient and doctor is used which clearly defines goals and conditions of therapy. They will then reassess the patient periodically for effectiveness, adverse affects, and other risk behaviors. If there is evidence of narcotic ineffectiveness or any concerns of misuse, an exit strategy is developed to effectively and safely wean the patient from the drug. Clear and understandable patient education from the beginning as far as expectations of treatment is essential.

Second, using our integrated delivery approach and electronic medical record system that provides clinical decision support, we

generate reports on individual physician prescribers patterns and compare them to others in the same specialty.

When physicians and pharmacists understand the bigger picture that good data can provide, prescribing behavior often does change. We also have started to look at groups of datasets known as drug-seeking behavior reports that we believe have potential to identify patients at risk using various datasets such as those filling prescriptions at multiple pharmacies, those having multiple prescribers, those using high doses, and those having infrequent in-person visits with their physician.

Third, we avail ourselves of outside resources, especially those of the State prescription drug monitoring programs, that allow us to share data and know when Kaiser Permanente patients seek prescriptions outside of our system. Our involvement also allows us to be part of the larger community in response to problems of over-use and abuse.

Fourth, our entire 75-year history at Kaiser Permanente is one of physician leadership and group problem-solving. Our regions have developed multi-specialty chronic pain boards to review difficult and complex cases and offer recommendations to individual physicians. Local Kaiser Permanente physicians and pharmacists have also organized interdisciplinary work groups to address systematic problems of opioid use and to improve care.

Thank you for inviting me to testify before the Committee today. I hope this information will be helpful as you understand and address narcotic use and over-use in VA hospitals and the communities they serve.

[The prepared statement of Dr. Forster follows:]

PREPARED STATEMENT OF CAROL A. FORSTER, M.D., PHYSICIAN DIRECTOR, PHARMACY & THERAPEUTICS/MEDICATION SAFETY, MID-ATLANTIC PERMANENTE MEDICAL GROUP, KAISER PERMANENTE MEDICAL CARE PROGRAM

Thank you for the invitation to be here today; it is an honor to be able to share our experiences with you. I am Dr. Carol Forster, Physician Director of Pharmacy and Therapeutics and Medication Safety for the Mid-Atlantic Permanente Medical Group at Kaiser Permanente. I received a pharmacy degree from Saint John's University College of Pharmacy in New York and a medical degree from the State University of New York School of Medicine at Buffalo. I also have received training as a Patient Safety Officer at the Institute for Healthcare Improvement. I have used my background in pharmacy and medication safety to develop and augment several programs within Kaiser Permanente related to improving the appropriate prescribing of narcotics.

I am testifying today from my perspective as a clinician and expert on medication safety and also on behalf of the national Kaiser Permanente Medical Care Program, the largest integrated healthcare delivery system in the United States, which provides comprehensive healthcare services to over 9.5 million members in eight states (California, Colorado, Georgia, Hawaii, Maryland, Oregon, Virginia and Washington) and the District of Columbia.

We hope the information we share today about the programs Kaiser Permanente has established will provide additional resources to help the Committee further understand and address narcotic overuse and/or abuse in VA hospitals and the communities they serve.

BACKGROUND: THE PROBLEM OF NARCOTIC OVERUSE/ABUSE

Controlled substance use has been subject to significant scrutiny in recent years, as the mortality from narcotic overdoses has increased proportionally to the sales

of prescription narcotics.¹ These types of statistics along with the disproportionately high volume of narcotic prescriptions in the United States,² and other data showing worldwide increases in fraud, addiction, and abuse of narcotics motivated our organization to develop aggressive monitoring programs and mechanisms to assure that 1) we are providing the most appropriate care to our patients with chronic pain; and 2) we are doing whatever we can to reduce the likelihood of inappropriate narcotic use in our Program and in our communities.

Narcotic medications are most often prescribed to treat chronic pain. According to a 2011 Institute of Medicine study, this condition is widespread, affecting 100 million Americans.³ Forty-two percent have pain lasting over 1 year; 33% report their pain as disabling. Pain also drives utilization nationally, accounting for up to 20% of outpatient visits and representing a \$600 billion annual cost.⁴

KAISER PERMANENTE: OVERVIEW

Standard and established principles for appropriate opioid prescribing are used in all Kaiser Permanente regions. These include: appropriate patient selection, initial patient assessment, and development of a comprehensive treatment plan focusing initially on alternatives to opioid therapy when indicated. When opioid medication is prescribed, it is important to establish and document effectiveness upon reassessment, as well as identifying an exit strategy if therapy does not achieve pain reduction within a desired/expected period of time. Patient education during this process is critical to success. Physicians are encouraged to regularly assess the “Four A’s”: analgesia, activity, adverse reactions, and aberrant behavior.

Program-wide efforts to reduce the volume of patients taking high-dose narcotics for chronic non-cancer pain and to combat fraud, waste, and abuse of controlled substances have been instituted for the past several years. These efforts evolve appropriately to incorporate state and national laws and clinical guidelines and reflect our own best practices. Complex patients who are difficult to manage can usually be recognized early in the course of treatment, by exhibiting patterns that alert physicians to risks. When there are indications of drug-seeking behaviors, physicians can also seek additional consultation from internal Fraud, Waste, and Abuse Special Investigations Units if needed.

Using our integrated health system we have been able to establish baseline data to understand our opportunities for improving narcotic use and set specific goals. One region set a goal to decrease the percentage of patients receiving chronic high-dose chronic narcotic therapy (120mg or more morphine equivalent doses per day or MEDD) by 25%. Most recent data show a 29% reduction, mostly through providing improved feedback to physicians, using other non-pharmacologic pain therapies, and establishing a team of regional pain management experts.

We set more overarching goals: to improve overall management of patients with chronic pain, to augment resources internally, and to refer chronic high utilizers to appropriate therapy in an effort to wean or discontinue narcotics due to lack of effect.

We also widely communicated clear and concise protocols and established multiple education programs to ensure physicians and pharmacists were aware of the specific actions they should take when they suspect inappropriate prescription narcotic use. These protocols are consistent with existing pharmacy policies regarding controlled substance dispensing. Requests to refill too soon, multiple requests for more medication, missed appointments, multiple prescribers (internal and external to Kaiser Permanente), and multiple pharmacy locations are patterns and behaviors that alert our staff and physicians to investigate further before any drug orders are sent. Multiple continuing education programs are offered in all regions to refine and reinforce these actions expected of healthcare providers.

As we work to address medication issues, we have been able to take advantage of our integrated delivery system to provide data and feedback to prescribers and to understand how patients with chronic pain are managed. Most pharmacy, diagnostic, and laboratory services delivered to Kaiser Permanente members are performed within Kaiser Permanente. We have also made a significant investment in developing a secure Electronic Health Record (EHR) system. The system includes functionality that helps to improve medication safety and reduce errors, such as automated clinical decision support for adverse drug event prevention, drug-allergy

¹ <http://www.cdc.gov/homeandrecreationalsafety/rxbrief/>

² 80% of the world’s narcotic use for 5% of the world’s population

³ Compared to 26 million individuals with diabetes, 16 million with coronary heart disease, and 12 million with cancer

⁴ Includes direct healthcare expenses and indirect costs, such as lost income and lost productivity

checking, and medication adherence monitoring. The EHR enables coordination across the care delivery spectrum, including primary care, inpatient and specialty care, pharmacy, laboratories, etc., providing opportunities to manage drug utilization, including being able to closely monitor narcotic use.

Kaiser Permanente recognizes that several states have also established improved monitoring and methods to detect inappropriate prescribing. Arizona, Massachusetts, New York, New Jersey, Kentucky, and Tennessee are among states that have instituted detailed mechanisms to provide feedback to prescribers, and on occasion law enforcement and/or licensing boards when state prescription drug monitoring program (PDMP) data reveal suspicious prescribing patterns.⁵ For example, prescribing large quantities/large volumes of opioids, prescribing unsafe combinations, and prescribing more frequently than expected by that medical specialty will prompt an investigation in states employing this type of monitoring.

CLINICAL LEADERSHIP AND PHYSICIAN EDUCATION

Physician leaders and other clinicians in various Kaiser Permanente regions have formed local workgroups to address the complex problems related to narcotic prescribing for chronic pain. In the Mid-Atlantic region, a Chronic Pain Workgroup was convened in May 2012 as part of our overall strategy to address narcotic overuse in our local communities. This workgroup focused on developing a strategy to further enhance our efforts to assure appropriate prescribing and dispensing of controlled substances. Interdisciplinary experts came from Pharmacy Operations, Clinical Pharmacy, Pain Management, Adult Primary Care, Behavioral Health, the Regional Spine Service Behavioral Health, Surgical subspecialties, and Addictionology.

The workgroup met frequently over a period of about six months to revise existing protocols and policies, create tools in our EHR related to appropriate care of chronic pain, and agree upon appropriate reporting to monitor use. The workgroup also revised goals for our continuing education programs for physicians and pharmacists.

Many of our efforts focus on prescriber education and on supporting improved management of chronic pain treatment and non-pharmacologic pain therapies. We offer continuing medical education (CME) courses that cover pain management clinical guidelines as well as detection and prevention of abuse, diversion, and fraud. We have developed a comprehensive chronic pain order set with clinical references, appropriate doses for various medication orders, lab orders including urine drug testing, patient instruction sheets, narcotic agreements, and multi-specialty referral resources to improve narcotic prescribing and management at the point of care.

CHRONIC PAIN BOARD

A number of Kaiser Permanente regions have established regional Chronic Pain Boards to review difficult and complex cases by referral as well as cases that meet criteria for review. Such Boards typically will have physicians from a number of related specialties, such as Pain Medicine, Interventional Pain, Anesthesia, Addictionology, Psychiatry, Clinical Pharmacy, Medication Safety, and potentially others including primary care providers (PCPs) and any specialists involved in cases under review. The Board review process includes discussion of each case, developing customized therapy goals, providing recommendations to the primary care provider, and documenting a plan for treatment.

THE IMPORTANCE OF DATA

Reliable information is also critical to understand and manage narcotic pain medication and chronic pain treatment. Our Pharmacy Analytics Department is able to generate reports based on specific data elements and patient populations. For the last several years, our regions have established national and local prescribing reports to monitor appropriate use of opioids and controlled substances. Prescriber feedback reports give specific information regarding individual physician prescribing patterns, including quantities prescribed, average MEDD and how one physician's prescribing might compare to another in the same specialty.

We can sort by patient, provider, specialty, facility, and can see all filled prescriptions, including external pharmacies if paid for using the Kaiser Permanente drug benefit. There are also reports that focus on unsafe combinations of drugs used, for example, a "triad report" was created to detect when carisoprodol (a muscle relaxant), oxycodone or hydrocodone (a narcotic), and a benzodiazepine such as lorazepam (an anti-anxiety drug) have been prescribed concurrently for the same patient.

⁵ www.pdmpeexcellence.org/sites/all/pdfs/Brandeis_PDMP_Report.pdf

More recently, our Program has developed a “drug-seeking behavior” report for all regions. By using a group of selected data sets, we can calculate a score for patients that meet several criteria associated with such behaviors. Multiple pharmacies, multiple prescribers, high doses, infrequent in-person visits with their doctor, etc., are examples of some of the data elements used in scoring. We are also able to separately identify and report any patients who meet a set of specific criteria, for example: 4 or more prescriptions, 4 or more pharmacies, AND greater than 120mg MEDD in a 90-day period. We can also look at subgroups, such as Medicare patients.

In most regions, we have required our prescribing physicians to register with their state prescription drug monitoring program (PDMP). Kaiser Permanente pharmacies provide the required controlled substance dispensing data to the state prescription monitoring programs. The PDMPs are invaluable as they allow us to see which patients fill external prescriptions even if they are not using their Kaiser Permanente drug benefit. These state programs along with our own internal reporting have enabled us to review in a comprehensive way all the controlled substances the patient may be receiving both inside and outside of the Kaiser Permanente facilities.

Providing actionable data is the key to uncovering and addressing suspicious patterns of narcotic use. Feedback is given to physician leadership when indicated, with individual messaging to prescribers if their patients have been identified as high-utilizers or suspected of drug seeking.

CENTRALIZED INFORMATION RESOURCES

Making information available in one place is also important. We have established an online secure site to post important references for the Chronic Pain Workgroup as a single site resource, where documents and presentations, including those from other Kaiser Permanente regions and external sources are posted. These resources can be accessed by members of group and other interested parties. We are also developing a KP Program-wide Chronic Non-Cancer Pain web page, accessed through our National online Clinical Library, to contain resources for all healthcare providers.

CONCLUSION

In summary, we continue to take specific steps, as we have described here today, to combat the increased problem of narcotic overuse and abuse in our communities.

We are committed to aligning ourselves with other institutions that face problems of narcotic overuse and abuse. Our efforts to date that have helped us achieve reductions in use include:

- Implementing recognized, well-established national, state and local principles and clinical guidelines throughout our program;
- Engaging our prescribers in PDMP registration in their states;
- Maintaining a continued focus on education and awareness for pharmacists and physicians;
- Supporting clinical leadership and community engagement in addressing problems of narcotic overuse;
- Monitoring targeted prescribing and drug-seeking behavior reports, based on pharmacy analytic data and our EHR system; and,
- Establishing expert consultative Chronic Pain Boards for review of difficult cases and making referrals to recommended subspecialists when necessary to improve the care of the patient.

Through these internal programs, we have achieved improvements in managing narcotic prescribing and limiting the use of unsafe combinations of medications. We will continue to work closely with our local, state, and national organizations as we strive to decrease the morbidity and mortality associated with narcotic overuse and abuse in the U.S.

Thank you to the Committee for the opportunity to provide this testimony. I would be happy to respond to questions.

Senator BLUMENTHAL. Thanks, Dr. Forster.
Mr. Gadea.

STATEMENT OF JOHN GADEA, DIRECTOR, DRUG CONTROL DIVISION, CONNECTICUT DEPARTMENT OF CONSUMER PROTECTION

Mr. GADEA. Good morning, Ranking Member Blumenthal, Senator Baldwin. My name is John Gadea. I am the Director of State Drug Control. I am also a pharmacist. For you who do not know what we do, we monitor the entire pharmaceutical industry from manufacturer to the patient. We do that through various compliance inspections, and when something goes away from that route, we also investigate it.

We have been doing that for over 40 years. I personally have been involved in it for over 30. In addition to that responsibility, the Division is also home to the Connecticut Prescription Monitoring program, the Connecticut Medical Marijuana program, and we are also home to the board administrator for the Commission of Pharmacy.

We are going to primarily focus in on the Prescription Monitoring program. With the backing and help of, at the time, Attorney General Blumenthal, and the Commissioner at the time, we went live in July 2008 with our Prescription Monitoring program and we require all pharmacies and hospital outpatient pharmacies to be uploading data into the system.

We gave them between 3 and 4 months to have their system in order to be able to upload that data. We followed a sequence of access. The access was primarily, and first, given to physicians to access the system, followed by pharmacists and eventually followed by law enforcement. This was in keeping with the program's goal of having the actual Prescription Monitoring program be, first and foremost, a health care tool, and we wanted them to have that access.

The third major group is law enforcement as well as the folks in my unit and they came on board substantially sometime further down the road.

I would like to underscore that fact, that physicians and prescribers are key to it, and that is that the system is there to provide better health care, and in order to provide that better health care, you have patients that, unfortunately, as part of their treatment, have to receive certain regimens that include controlled substances.

What happens is, what we started learning is that various groups on both sides of the issue identify that because you have a large quantity of drugs, you are a drug abuser. What we found is that you are not really a drug abuser, most of the time. You are a drug misuser and you have been placed in a situation that, either between your own actions as a patient or because of problems in drug management or health care management, you now have this problem.

I would also point out that working with addictionologists in the course of our investigations that many times that is the symptom of the problem and not so much the problem in and of itself. After hearing this issue discussed today and in other times where this issue has come up, not just with the VA, but with any health care system we must ask of the problem we are talking about is the addiction of the patient or is the prescribing of those products the

symptom of a greater issue that is not really going to be addressed? If it is not addressed, all the efforts you put into correcting what you are going to try and correct may not really give us a solution that we want.

We find that the program works best when it is tied to a robust educational program and we have done several things to increase that usage of the program through education. We recently included morphine milli-equivalents on our program reports that give a good benchmark to physicians based on Substance Abuse and Mental Health Services Administration (SAMHSA) data, whether they are approaching the high end of prescribing.

The problem in Connecticut is that we have a VA that does not upload data into our system. It provides relatively a Swiss cheese approach to data. It does not help anybody. We have tried having these discussions at the request of physicians in the VA system, and at one point, we went down to speak to those physicians and were told by the privacy officer, who is no longer there, to never discuss that with their physicians, leave the premises immediately and do not return.

Since then, physicians have been given access to the system, which is very, very, good. But currently, we do not have their data being uploaded and that presents a problem because we are a small State and sometimes patients from the VA wind up in emergency rooms or getting health care outside of there and it is not beneficial to, at that point, look up a patient that you are trying to take care of and you do not know the complete picture.

I have submitted written testimony. I would like to thank you for the time to present this information and I look forward to answering any of your questions or comments. Thank you.

[The prepared statement of Mr. Gadea follows:]

PREPARED STATEMENT OF JOHN GADEA, JR., DIRECTOR OF STATE DRUG CONTROL
DIVISION, DEPARTMENT OF CONSUMER PROTECTION, STATE OF CONNECTICUT

I am John Gadea, Jr., RPh, Director of State Drug Control Division, Department of Consumer Protection for the State of Connecticut. I am honored to appear before this Committee.

The Drug Control Division oversees the entire pharmaceutical industry from manufacturer to patient and includes wholesalers, pharmacies, prescribers, dispensers and any location where drugs may be purchased, dispensed or stored. This involves performing compliance inspections. The Division also investigates the loss and diversion of all drugs, including controlled substances from the state's registrants and healthcare professionals. This is all accomplished with 12 agents, all of whom are pharmacists, and two of whom are supervisors.

In addition to the described responsibilities, the Division also is home to the Connecticut Prescription Monitoring Program, the Connecticut Medical Marijuana Program, and the Board Administrator to the Commission of Pharmacy.

The Connecticut Prescription Monitoring Program, also known as the Connecticut Prescription Monitoring and Reporting System (CPMRS), went live on July 1, 2008. Shortly after going live, pharmacies and hospital outpatient pharmacies began uploading data into the system. All these entities were afforded three months to modify their systems to be able to upload their controlled substance data into the CPMRS.

Soon after the upload process was completed by the pharmacies, access was afforded to prescribers, pharmacists and law enforcement under certain conditions. We followed the sequence of authorized access to the system by allowing prescribers access to the system first, followed by pharmacists. This was in keeping with the program's goal of providing better care to patients by enabling health care professionals to have access to their patients' controlled substance history. Law enforcement was the last of the major user groups to be given access to the system.

I would like to underscore that first and foremost this system can attain the most by encouraging the prescribers and pharmacists to use the system to provide better healthcare to their patients. Many patients being treated for a condition may, as part of the treatment, use controlled substances. Some patient profiles may display large quantities of medications or the use of several different prescribers or pharmacies; that alone may appear to be indicative of some type of fraudulent activity. Often, we find that these patients are categorized as drug abusers when, in reality they are misusers of the medications. Their misuse is either a result of their own actions or that of the prescribers, through lack of proper medication management or lack of total healthcare management.

The end result of this increase in the pool of 'drug abusers' is that it creates an increased workload on law enforcement and strains the criminal justice system, when in fact, many of these cases could have been handled as a healthcare event. Law enforcement should not have to use their valuable resources to manage the result of poor healthcare.

We believe the Connecticut Prescription Monitoring Program is at its best when combined with a robust education program. The education is directed at prescribers and pharmacists on the use of the system; and on prescribers, pharmacists and the public on prescription drug abuse. Collaborations with associations such as the Connecticut Medical Society and the Connecticut Pharmacists Association are critical to the program's educational completeness.

Knowing the type of disastrous situations that can arise from prescription drug abuse and misuse we believe that it is critical for the prescribers and pharmacists to have accurate, timely and complete information at their disposal that allows them to make those needed decisions affecting their patients' well-being. This is what we try to achieve with the CPMRS. There are times though, when we are not able to provide this program in the form that we believe it should be.

The problem of not providing a complete data set to both prescribers and pharmacists on their patients can be illustrated by the lack of data being uploaded into the CPMRS by the U.S. Veterans Administration ("VA"). The VA out-patient pharmacies and the VA mail-order pharmacies perform a valuable function in the care of our veterans. While a number of veterans receive the bulk of their healthcare from within the VA, many of these same veterans have physicians both in the VA system and in their communities. They also have some prescriptions dispensed from their local pharmacies. Only recently have the prescribers in the VA been allowed to access the CPMRS and, while this is a desirable situation, it is incomplete because it does not contain the uploaded controlled substance information from within the VA Healthcare system. That VA system prescription information would be extremely beneficial to the community prescribers and pharmacists. It should be further noted that any admittance to a non-VA hospital or emergency room without this information being included in the patient's controlled substance history could be detrimental to the health of the veteran.

In the past, physicians in the VA Healthcare system have resorted to gaining access to the CPMRS by using their own computers or performing the patient reviews from an off campus location. Being invited on to the VA campus to explain the CPMRS resulted in the program manager and me being instructed to leave the campus, not to discuss our system with VA practitioners and not to return. Although Federal law was eventually changed allowing VA Healthcare system prescribers to access the system, it was not until in 2013 that we received a call from the VA in Connecticut indicating that practitioners were allowed to register in the CPMRS and the VA Central Office in Washington, DC, would perform the uploading of data. As of today, no uploads into the CPMRS have occurred. It is of great concern that the state of Connecticut can access the data from 17 other states in addition to the 684 in-state and 872 out-of-state pharmacies but it cannot access the data from two campuses located within the boundaries of the state.

To this point in this testimony I have described the system as a healthcare tool for both prescribers and pharmacists, but there are those individuals who go beyond what healthcare care providers can correct or control and it becomes a law enforcement matter. The CPMRS is a valuable tool for certain members of local, state and Federal law enforcement that have been specifically authorized by my agency to use the system. Many of the comments regarding prescription-monitoring programs revolve around the detection of "doctor shopping." While this is a major problem, doctor shopping is only one form of diversion. Forgeries and false call-ins of controlled substance prescriptions can only be detected by the prescriber who supposedly prescribed the drugs; therefore we encourage prescribers to review their own prescribing history using this system. Prescription monitoring programs also offer an invaluable tool in the detection of economic fraud committed by prescribers, pharmacist, pharmacies and patients. As a result, agencies such as the Connecticut

Department of Social Services and the U.S. Department of Health and Human Services have recouped fraudulent claims. Additionally, my agency along with the Connecticut Department of Public Health and the U.S. Drug Enforcement Administration have just completed a case against a midlevel practitioner that has resulted in the surrender of Federal and state controlled substance registrations. The same practitioner was recently identified as one of the top ten prescribers of controlled substances in the country. Other agencies utilizing the system include the FBI, the Office of the Connecticut Chief State's Attorney, the Connecticut State Police, and numerous local police departments.

Thank you for providing me this opportunity to present this information to you. I would be happy to respond to any questions you have today.

Following that, please feel free to contact me or Commissioner Jonathan Harris if you have any additional questions or comments.

Senator BLUMENTHAL. Thanks, Mr. Gadea. Before I turn the gavel back to Senator Isakson, let me just say all of your written testimony, if you wish, will be made a part of the record without objection. Senator Isakson.

Chairman ISAKSON. In order for Senator Isakson to get re-organized, I am going to leave the gavel with you for just a minute, sir, for your questions first.

Senator BLUMENTHAL. Thank you. Mr. Gadea, let me begin by asking you about the real life consequences of the Swiss cheese, as you have aptly described it, and I described it in the same way earlier, in terms of the gaps between the State Prescription Monitoring program and the Federal VA system for tracking and monitoring prescriptions.

You mentioned the potential emergency room visit where the emergency room doctor would have no knowledge about what the prescriptions were from VA doctors. There are also law enforcement consequences, are there not?

Mr. GADEA. Yes. Law enforcement has access to our system for specific cases. They have to have an open case number. Because we are a small State and there are a lot of patients that are outpatients in the VA system, they are in the community and they are receiving products, medications from both inside the VA and outside the VA.

They are filling those prescriptions in pharmacies. Pharmacies are the first trip wire to identify that something is not right. It becomes extremely difficult if that trip wire has been cut, in this case, and that dovetails into the first thing that the pharmacy will do is contact local narcotics division, Statewide narcotics, and they are at a loss because you then have to go and search manually.

We have 684 pharmacies in the State. It becomes very difficult, even by phone call, to do that search. It is not very efficient to have a system which is only being fed partially.

Senator BLUMENTHAL. As I know because I was Attorney General and did a number of these cases. There have been both civil and criminal prosecutions resulting from the excellent work done by your program.

Mr. GADEA. The Department of Social Services combined with the U.S. Health and Human Services, use the system to recoup fraudulent claims. We work closely with the U.S. Drug Enforcement Administration and the compliance folks. And we recently had a case where we used this system to identify someone, conduct a case, and we have just received the surrender of their controlled substance registration, both at the State and Federal level.

That case was rather important because they were also identified on Centers for Medicare and Medicaid Services (CMS) listing as one of the top ten prescribers in the country.

Senator BLUMENTHAL. Uploading this information from the VA to the State system, in other words, complete connectivity would aid not only better treatment, but also law enforcement that would save taxpayer dollars?

Mr. GADEA. Oh, absolutely. Even at the health care level, we can currently share data with 17 other States. We have uploads of data from approximately 800 out of State pharmacy providers and over 600 in-state pharmacy providers. We do not have the Newington VA and we do not have the West Haven VA able to complete the picture.

Senator BLUMENTHAL. Dr. Alexander, there was a question earlier, and I think you were here, about possible alternative ways of treating pain. Could you comment on the potential alternatives for treating Post Traumatic Stress and pain associated with it or other means of alternative treatments for pain that might be as effective or more so and far less dangerous in terms of the potential side effects of addiction and dependence?

Dr. ALEXANDER. Thank you for the question. There are lots of different treatments for both post-traumatic stress disorder as well as pain, and these treatments include both pharmacologic and non-pharmacologic approaches. Unfortunately, at times prescribers over rely on prescription drugs and underutilize non-pharmacologic approaches that, in the case of pain, may include physical therapy, massage, biofeedback and acupuncture.

To some degree the optimal approach depends upon the type of pain, since different treatments work variously well for different types of pain. There was a comment earlier regarding, for example, the difference between visceral and non-visceral pain. I think that these are important to keep in mind and these alternative approaches tend to be under-used.

It is also important to note that we have less information than we would like about the long-term safety and effectiveness of some of the pharmacologic treatments and alternatives to opioids. But given the well-demonstrated serious adverse events associated with opioids, I think that overall, their risk/benefit balance is unfavorable for many, many current users.

Senator BLUMENTHAL. Thank you. Unfortunately, my time has expired and since Senator Isakson is here and since he is the Chairman, I am going to yield to him and just say I have many more questions. I am going to submit them. I apologize, Dr. Forster, that I did not get to my questions for you. I have other questions for the additional witnesses.

This panel is extraordinarily useful and expert and I really want to thank you for being here today. We are just kind of denting the surface of the immense resource in terms of knowledge that you have to help us, and I really am very grateful to you for being here and your continuing help to the Committee. Mr. Chairman.

Chairman ISAKSON. Thank you, Senator Blumenthal, and I appreciate very much the panelists being here and apologize that I had to go to the floor to present an amendment. That was part of the process I could not avoid today.

Maybe I will cover Dr. Forster's question that you had anyway, because in reading the testimony, one of your regions at Kaiser-Permanente realized a 29 percent reduction in the prescription of opioids, and in your remarks, you pay credit to that. You say this was primarily a result of improved feedback to physicians. What does your feedback system entail and how are providers kept accountable, held accountable should they be over-prescribing opiates at a much higher rate than normal?

Dr. FORSTER. Thank you for the question. I actually will correct that. We just got our newest report yesterday and it is now 33 percent.

Chairman ISAKSON. It is the right direction.

Dr. FORSTER. Thank you for asking. This region specifically is actually the Mid-Atlantic region, which is my region. What we do have is, I think, a really amazing level of reporting regarding narcotic use. We have been using it since the end of 2011.

I helped work on getting it to the right level of reporting that would be useful to a physician and actionable to a physician so we are able to see, you have already mentioned, the morphine equivalent doses per day which is very important as far as severity or risk severity as well as the amount of drug they are taking across all different types of drugs.

We have MEDs on our report. We also have the days supply that is being given. We have, of course, the physician, the prescriber, and who the primary physician is. We have also done combination reports. We call it a "triad report." We look at the combinations of benzodiazepines, narcotics, and Carisoprodol which is a muscle relaxant that on the street is actually part of the "trinity" or "holy trinity," as it is called, used to achieve the best "high."

These kinds of combinations are very important for us to know about and our physicians may not be aware that there is concurrent prescribing. Of course, now more physicians are using the Prescription Monitoring Program (PMP) as another aspect of the report that is tied into the prescriber feedback.

We also have a new report which is almost a year old now, and that is a drug-seeking behavior report. It is not meant to put any blame on the patient, but it is meant to identify behaviors that seem to be or have a potential to be drug seeking.

It shows us that, for instance, a patient may not have had a visit with their provider for many months, as well as have had multiple providers prescribe a narcotic or have had visited multiple pharmacies, both inside and outside of Kaiser, to get that prescription. Those are hallmarks or red flags to us that there is a problem.

These types of reports are—I mean, I can go into much more detail about it, but it would take a long time. I have presentations on these types of reports. We really feel that they really have helped all of us, the pharmacists, the physicians, and even our patients understand that appropriate monitoring is the best way to really take care of the patient.

I think it has already been mentioned before, our physicians are also receiving a lot of education as well. In addition to receiving those reports, they are receiving much education on appropriate prescribing. You cannot give just a report. You need to educate as well.

From the very beginning, we have been adding education along with giving that report and have initiated mandatory training, and mandatory registration for the state PMPs. I think all States except one, I believe, now have PMPs in place. I think D.C. is about to start theirs at the end of this year. So pretty soon we will be able, in all of our regions, we will be able to have PMP access for everyone.

Chairman ISAKSON. If, by virtue of the information you are collecting, you find one of your providers prescribing at a much higher rate than others, what do you do to hold them accountable?

Dr. FORSTER. Well, that is one of my roles. I work with that physician and their chief of service or their leader in their local facility and give them the data they need to show that there has been variant prescribing and we try to take action along with them, help them identify resources for the patient.

Part of the electronic medical record we use has what they call "smartsets" which provide decision support at the point of care. We encourage the physicians to understand all the resources that are available for treating pain, and that includes the many referrals that we have already mentioned on the panel, the various lab tests, and other resources that we can use other than drug treatment to take care of that patient.

We make sure that that physician understands the concerns so that he can start the weaning process. One of those referrals, of course, is also to pain management. We have pain management specialists.

Chairman ISAKSON. Let me ask you a question. Is hydrocodone an opiate?

Dr. FORSTER. Yes.

Chairman ISAKSON. The reason I ask that question is, more information—information is power and that is what you are really talking about and the better the information you have, the better tracking. I had back surgery in October and was prescribed hydrocodone for, I guess for pain or whatever, and it worked.

Dr. FORSTER. They can work.

Chairman ISAKSON. I did not work after taking it. My point I want to get to and I do not want to take any more time is, the pharmacy that I filled that prescription at, when my prescription time had run out, I got a letter from them telling me that my prescription could not be renewed and that if I had any leftover hydrocodone pills, they would be happy to destroy them for me, which I was very impressed with, because I think a lot of that stuff is getting into the secondary market or the black market or the kid market.

Dr. FORSTER. Yes.

Chairman ISAKSON. I think the more information you have and the more awareness you have, the better results you are going to have.

Dr. FORSTER. I totally support that.

Chairman ISAKSON. Thank you for what you are doing.

Dr. FORSTER. Thank you.

Chairman ISAKSON. Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman. Dr. Alexander and Dr. Forster, in your testimony, you both highlight a focus on avoid-

ing the unsafe combination of opioids with medicines such as benzodiazepines, and also focus on, Dr. Alexander in particular, when you are treating patients with co-morbid conditions such as mood disorders, Post Traumatic Stress Disorder, Traumatic Brain Injury, and substance abuse, these are both issues that were very apparent when we started learning of problems at the Tomah VA facility. That sort of dangerous combination had tragic results at that facility.

It also motivated me to work with this Committee to ensure strong report language with regard to a bill, and I do want to give the Chairman and Ranking Member a big shout out and thank you for all of your work on the Clay Hunt SAV Act, a suicide prevention act that was passed by Congress and signed into law last month.

I thank the Chairman and Ranking Member for working with me to include report language that requires that the third party evaluation of VA mental health and suicide prevention programs that are required by the Clay Hunt SAV Act includes a review of opioid use by patients in those programs.

I do, Mr. Chairman, want to submit for the record a letter from the National Alliance on Mental Illness, also known as NAMI, in support of including opioid prescribing practices in the Clay Hunt third party evaluation.

[The letter referred to is in the Appendix.]

Senator BALDWIN. Dr. Alexander, please talk a little bit more about why these combinations of opioids and benzodiazepines and other strong prescription drugs are so dangerous, and also, with regard to the treatment of patients not with, necessarily, chronic pain, but with mental illness or PTSD.

Dr. ALEXANDER. Sure. Thank you for the question. As you have identified, these are particularly high risk patients and I think it is really important that they are prospectively identified and carefully managed throughout the continuum of their care. Multi-disciplinary teams, which ideally would be involved in the management of virtually every patient that is on opioid therapy for chronic pain, are particularly important for these types of patients, as are especially vigilant efforts to decrease opioid use among them.

Some of the medicines that we are talking about are considered psychotropic drugs. They have specific targeted effects on the central nervous system. Benzodiazepines, for example, have effects not dissimilar from alcohol within the brain, and they can compound or act synergistically with opioids and increase the magnitude of adverse effects from opioids, ranging from sedation and impaired cognition to respiratory depression and death.

So, although many risk factors for high risk prescribing have been identified, the presence of these co-morbid conditions, I think, is of particular concern and warrants particular focus.

Senator BALDWIN. Dr. Forster, the same question.

Dr. FORSTER. Yes. The combination is definitely unsafe and, as I mentioned, there is also a combination using Carisoprodol which is a muscle relaxant and that actually adds to this euphoria that a person who is misusing narcotics may seek. We are trying our best to not use narcotics in patients with co-morbid conditions

knowing the potential is there, and there is a concern that they are a relatively high risk population.

In cases where a short-term narcotic is needed, they have to be watched very closely. Again, as I mentioned, we have addiction medicine specialists, behavioral health specialists, and pain management specialists that are there for us. As a primary care physician myself, I would probably, if I had a patient that was a difficult or more complex patient with multiple co-morbidities, I probably would seek their advice and recommendation much earlier than later, in fact, almost at the outset.

Senator BALDWIN. Thank you.

Chairman ISAKSON. Thank you, Senator Baldwin.

Senator BLUMENTHAL has one additional question.

Senator BLUMENTHAL. Yes. I want to ask Mr. Gadea about sources of funding for the Prescription Monitoring program. Can you tell us how Connecticut system is funded and whether that same system or source of funding is used for other PMPs in the 49 States that have them around the country, if you know?

Mr. GADEA. It is a little haphazard around the country. I can tell you what we have done. We initially had implementation grants and execution grants from the Bureau of Justice Assistance. Those grants eventually, as more States came on, became more difficult to obtain. We were very fortunate in having your office as part of restitution to the State would provide us with funding to keep us afloat.

We have been able to do that since the onset and have never used, to this date, any funding from the State, general funds.

Senator BLUMENTHAL. Just for the record, your reference to my office was to the Office—

Mr. GADEA. The Attorney General.

Senator BLUMENTHAL [continuing]. Of Attorney General in the settlement that was done with Perdue Farmer in the case that we did jointly with the U.S. Department of Justice.

Mr. GADEA. Yes.

Senator BLUMENTHAL. Just so that is clear in the record. To state it succinctly, you receive no Federal or State funds for the operation of your office?

Mr. GADEA. No. At this point we do have in the proposed budget that one more position—we currently operate the entire system with just one person and we are hopeful that if the budget passes in the format that we like, that we do get funding for that, for the program, the maintenance, as well as one more individual. Around the country, it is some grants, some funding, partial funding. It is kind of all over the place.

Senator BLUMENTHAL. To again try to state it succinctly, for systems that are critically and profoundly important to law enforcement, for effective treatment for addition abuse prevention, the system right now is, at best, haphazard—

Mr. GADEA. Yes.

Senator BLUMENTHAL [continuing]. Funding?

Mr. GADEA. Yes.

Senator BLUMENTHAL. My view is that fact ought to be changed. So thank you for your testimony—

Mr. GADEA. Thank you.

Senator BLUMENTHAL [continuing]. Mr. Gadea, Dr. Forster, Dr. Alexander.

Chairman ISAKSON. I want to thank our witnesses for their participation today and their leadership. Thanks, Senator Baldwin, for being here, Senator Johnson for making time. The record will be left open for 5 days for additional questions to be submitted or opening statements or closing statements to be made. If there is no other business to come before the Committee, we stand adjourned.

RESPONSE TO POSTHEARING QUESTIONS SUBMITTED BY HON. TAMMY BALDWIN TO CAROL FORSTER, M.D., PHYSICIAN DIRECTOR, PHARMACY & THERAPEUTICS/MEDICATION SAFETY, MID-ATLANTIC PERMANENTE MEDICAL GROUP, KAISER PERMANENTE

ALTERNATIVE TREATMENTS FOR CHRONIC PAIN

VHA is trying to expand the use of complementary and alternative medicine to treat patients with chronic pain, recognizing that there's growing evidence of the effectiveness of these approaches. Furthermore, when I speak with veterans, I consistently hear a desire for more acupuncture, massage, yoga, aqua-therapy, and other techniques. I would like to see VA more rapidly expand the use of these techniques.

- What types of alternative and complementary approaches are used by Kaiser specifically, and private health providers generally?

Response. Recent research findings indicate growth in Americans' use of complementary and alternative practices for a variety of health conditions, including pain.¹ The goal of integrating these practices is to improve functioning and reduce the need for pain medicines that can have serious side effects.²

KP offers its members certain complementary and alternative medicine (CAM) therapies. The most consistently available, program-wide, is mindfulness training (e.g., biofeedback, meditation, guided imagery). We also offer some movement-based CAM interventions (e.g., Feldenkrais, Tai Chi) through Health Education departments as health promotion activities at a cost for members outside of the traditional healthcare benefit. Other treatments, like acupuncture, may be available to some patients as a covered service, depending on an individual's plan benefits.

Kaiser Permanente employs CAM specialists to manage various conditions, including pain. CAM can encompass a very broad spectrum of different therapies and techniques, from health education resources to alternative treatments, such as acupuncture, chiropractic or osteopathic treatment. Some CAM approaches fall outside the typical services offered or covered by health care systems, for instance, herbal remedies, exercise or movement therapies (e.g., yoga) or massage; some approaches, like lifestyle changes, depend primarily on self-motivation and individual action, rather than external interventions.

The uptake for CAM therapies across the overall population of chronic pain patients may vary. There can be several barriers to CAM adoption for pain management, including the timing of CAM (i.e. whether CAM is offered as initial therapy) and the investment and commitment required of patients and providers. For the right patients, CAM may be a beneficial component of pain management.

The ability to aggregate and analyze electronic clinical data can allow providers to flag certain prescribing/utilization patterns. Applying these analytics successfully is enhanced within integrated care delivery systems, like KP and the VA, where it is possible to coordinate care across care settings (both in- and out-patient primary and specialty care and pharmacy).

Within KP, we have used this approach for managing members who are receiving long-term opioids, applying population care strategies. While we have tried to target these members to the CAM modalities, the pharmacy analytics approach was more successful: in promoting "universal precautions" such as: tracking early refills, emergency room/urgent care dispensed medications, annual urine toxicology screenings, documented medication agreements, etc.

- How would you rate their effectiveness?

¹ <https://nccih.nih.gov/news/press/02102015mb>

² Chronic pain is a common problem among active-duty military personnel and veterans. NCCIH, the U.S. Department of Veterans Affairs, and other agencies are sponsoring research to see whether integrative approaches can help. For example, NCCIH-funded studies are testing the effects of adding mindfulness meditation, self-hypnosis, or other complementary approaches to pain management programs for veterans. <https://nccih.nih.gov/health/integrative-health>

Response. While the evidence of CAM's safety and effectiveness in chronic pain management is not overwhelming, certain modalities may help patients motivated to integrate CAM into their treatment plan. One of the challenges to determining clinical effectiveness is that the goals of CAM therapies focus on feelings of well-being and mastery of the illness, outcomes that are harder to define and measure than objective primary endpoints typical to research involving traditional medicine.³

[Whereupon, at 12:04 p.m., the hearing was adjourned.]

³See <http://www.ncbi.nlm.nih.gov/pubmed/23126534>; see also <http://www.ncbi.nlm.nih.gov/books/NBK83795/>; see also www.va.gov/RAC-GWVI/docs/Minutes_and_Agendas/Presentations_Feb2011

A P P E N D I X

PREPARED STATEMENT OF LOUISE R. VAN DIEPEN, MS, CGP, FASHP

Mr. Chairman and Members of the Committee: Thank you for this opportunity to testify today on United States (US) data and strategies on opioid overprescribing to put into context VA opioid prescription policy, practice and procedures. I am a retired Veterans Health Administration (VHA) executive and clinical pharmacist who served in a number of Federal and private sector health care executive and clinical roles, most in direct support of high quality health care for Veterans (e.g., VHA National Chief of Clinical Pharmacy/Quality Management; Director of Clinical [Pharmacy] Services, PharmMark Corporation; Vice President for Clinical [Pharmacy] Services for AARP Pharmacy Services; VHA Chief of Staff).

I will frame my testimony around six questions to ensure that Committee has adequate context for its discussions today:

1. What is the magnitude of the opioid abuse problem in the United States?
2. Which are the higher-risk opioids and where are they being prescribed?
3. What are the major recommendations to address overprescribing of opioids?
4. What major actions actually have been taken nationally to address opioid overprescribing?
5. Are VHA's actions, as a system, adequate and consistent with the national momentum on this issue?
6. What more could VHA do to improve opioid prescribing?

THE FIRST QUESTION TO ASK IS

"WHAT IS THE MAGNITUDE OF THE OPIOID ABUSE PROBLEM IN THE UNITED STATES?"

According to the CDC:¹

- From 1999 through 2012, the age-adjusted drug-poisoning death rate nationwide more than doubled, from 6.1 per 100,000 population in 1999 to 13.1 in 2012 (Table 1).
- During the same period, the age-adjusted rates for drug-poisoning deaths involving opioid analgesics more than tripled, from 1.4 per 100,000 in 1999 to 5.1 in 2012 (Figure 1). Opioid-analgesic death rates increased at a fast pace from 1999 through 2006, with an average increase of about 18% each year, and then at a slower pace from 2006 forward. The 5% decline in opioid-analgesic death rates from 2011 through 2012, is the first decrease seen in more than a decade.
- Also from 1999 through 2012, the age-adjusted rates for drug-poisoning deaths involving heroin nearly tripled, from 0.7 deaths per 100,000 in 1999 to 1.9 in 2012. The rates increased substantially beginning in 2006. Between 2011 and 2012, the rate of drug-poisoning deaths involving heroin increased 35%, from 1.4 per 100,000 to 1.9.
- In 2012, 14 states had age-adjusted drug-poisoning death rates that were significantly higher than the overall U.S. rate of 13.1 per 100,000 population (Figure 2). The states with the highest rates per 100,000 population were West Virginia (32.0), Kentucky (25.0), New Mexico (24.7), Utah (23.1), and Nevada (21.0).
- In 2012, there were 41,502 deaths due to drug poisoning (often referred to as drug-overdose deaths) in the United States (Table 1), of which 16,007 [38.6%] involved opioid analgesics and 5,925 involved heroin.

¹ CDC: NCHS Health E-Stat: Trends in Drug-poisoning Deaths Involving Opioid Analgesics and Heroin: United States, 1999–2012. Margaret Warner, Ph.D., Division of Vital Statistics; and Holly Hedegaard, M.D., M.S.P.H., and Li-Hui Chen, M.S., Ph.D., Office of Analysis and Epidemiology

THE SECOND QUESTION RELATES TO THE PRESCRIBING PATTERNS. “WHICH ARE THE HIGHER-RISK OPIOIDS AND WHERE ARE THEY BEING PRESCRIBED?”

CDC recently studied 2012 prescribing patterns of 57,000 pharmacies, which dispense nearly 80% of the retail prescriptions in the United States. Prescriptions included in the study were dispensed at retail pharmacies and paid for by commercial insurance, Medicaid, Medicare, or cash. The study examined prescribing patterns for opioid pain relievers (OPRs), long acting/extended release (LA/ER) OPRs, high dose OPRs, and benzodiazepines.² According to CDC, LA/ER OPRs are more prone to abuse, and high-dose formulations were more likely to result in overdoses, so they deserved special focus; Benzodiazepines were often prescribed in combination with OPR, even though this combination increases the risk for overdose.³

The updated labeling further clarifies that, because of the risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death, these drugs should be reserved for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain; ER/LA opioid analgesics are not indicated for as-needed pain relief.

CDC found that State prescribing rates varied for all drug types (See Table 2) with rates that were 2.7fold for OPR and 22fold for one type of OPR, oxymorphone. Overall, prescribing rates varied widely by state for all drug types (See table 2). When looking for patterns by Region, the southern US had the highest rate of prescribing OPR and benzodiazepines. The Northeast had the highest rate for high-dose OPR and long acting and extended release OPR, although high rates also were observed in individual states in the South and West. In the Northeast, 17.8% of OPR prescribed were LA/ER OPR. States in the South ranked highest for all individual opioids except for hydromorphone, fentanyl, and methadone, for which the highest rates were in Vermont, North Dakota, and Oregon, respectively.⁴

THE THIRD QUESTION IS “WHAT ARE THE MAJOR RECOMMENDATIONS TO ADDRESS OVERPRESCRIBING OF OPIOIDS?”

In the general US population, Center for Disease Control recommends:

- Use of prescription data combined with insurance restrictions to prevent “doctor shopping” and reduce inappropriate use of opioids.
 - Users of multiple providers for the same drug, people routinely obtaining early refills, and persons engaged in other inappropriate behaviors can be tracked with state prescription drug monitoring programs or insurance claim information.
 - Public and private insurers can limit the reimbursement of claims for opioid prescriptions to a designated doctor and a designated pharmacy. This action is especially important for public insurers because Medicaid recipients and other low-income populations are at high risk for prescription drug overdose. Insurers also can identify inappropriate use of certain opioids for certain diagnoses (e.g., the use of extended-release or long-acting opioids like transdermal fentanyl or methadone for short-term pain).
- Improving legislation and enforcement of existing laws.
 - Most states now have laws against doctor shopping, but they are not enforced uniformly. In contrast, only a few states have laws regulating for-profit clinics that distribute controlled prescription drugs with minimal medical evaluation. Laws against such “pill mills” as well as laws that require physical examinations before prescribing might help reduce the diversion of these drugs for non-medical use.
 - In addition, a variety of other state controls on prescription fraud are being employed. For example, according to the National Alliance for Model State Drug Laws, 15 states required or permitted pharmacists to request identification from persons obtaining controlled substances as of March 2009.
- Improve medical practice in prescribing opioids.

² Benzodiazepines are antianxiety drugs like alprazolam (Versed), diazepam (Valium), and chlordiazepoxide (Librium). The class includes approximately 39 unique agents.

³ In September 2013, FDA announced labeling changes for these products. The updated labeling states that ER/LA opioids are indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

⁴ CDC Vital Signs (Weekly): Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines—United States, 2012. MMWR July 4, 2014/63(26);563–568

– Care for patients with complex chronic pain problems is challenging, and many prescribers receive little education on this topic. As a result, prescribers too often start patients on opioids and expect unreasonable benefits from the treatment. In a prospective, population-based study of injured workers with compensable low back pain, 38% of the workers received an opioid early in their care, most at the first doctor visit. Among the 6% who went on to receive opioids for chronic pain for 1 year, most did not report clinically meaningful improvement in pain and function, even though their opioid dose rose significantly over the year.

– Evidence-based guidelines can educate prescribers regarding the under-appreciated risks and frequently exaggerated benefits of high-dose opioid therapy. Such guidelines especially are needed for emergency departments because persons at greater risk for overdose frequently visit emergency departments seeking drugs. Guidelines will be more effective if health system or payer reviews hold prescribers accountable for their behaviors.

- Develop a public health approach of secondary and tertiary prevention measures to improve emergency and long term treatment.

– Overdose “harm reduction” programs emphasize broader distribution (to non-medical users) of an opioid antidote, naloxone, that can be used in an emergency by anyone witnessing an overdose. Efforts also are under way to increase the ability of professionals responding to emergencies to administer optimum treatment for overdoses.

– Substance abuse treatment programs also reduce the risk for overdose death. Continued efforts are needed to remove barriers to shifting such programs from methadone clinics to office-based care using buprenorphine. Office-based care can be less stigmatizing and more accessible to all patients, especially those residing in rural areas.⁵

The National Association of Boards of Pharmacy recommends:

- Recognizing “red flag” warnings. These warnings are based on how the patient presents, how the medication has been taken, how the patient is communicating, and how the patient does (or does not) participate in the treatment plan.
- Based on patient populations and behaviors, physicians and pharmacists should identify situations that indicate whether a patient may be more likely to be abusing or diverting prescription drugs.
- When warning signs are present, health care practitioners should immediately assess the situation and/or the patient’s medical and psychological condition and determine the appropriate action (e.g., continuation of treatment, intensify monitoring, refer for substance use/addiction treatment, refuse to issue/dispense a prescription).

The Behavioral Health Coordinating Committee of the Prescription Drug Abuse Subcommittee of Health and Human Services recommends (in addition to activities underway; See Appendix I for details):

- Strengthen surveillance systems and capacity
- Build the evidence-base for prescription drug abuse prevention programs
- Enhance coordination of patient, public, and provider education programs among Federal agencies
- Further develop targeted patient, public, and provider education programs
- Support efforts to increase provider use of Prescription Drug Monitoring Programs (PDMPs)
- Leverage health information technology to improve clinical care and reduce abuse
- Synthesize pain management guideline recommendations and incorporate them into clinical decision support tools
- Collaborate with insurers and pharmacy benefit managers to implement robust claims review programs
- Collaborate with insurers and pharmacy benefit managers to identify and implement robust programs that improve oversight of high-risk prescribing.
- Improve analytic tools for regulatory and oversight purposes
- Continue efforts to integrate drug abuse treatment and primary care
- Expand efforts to increase access to medication-assisted treatment
- Expand Screening, Brief Intervention, and Referral to Treatment services
- Prevent opioid overdose through new formulations of naloxone

⁵ CDC Grand Rounds (Weekly): Prescription Drug Overdoses—a U.S. Epidemic; January 13, 2012/61(01);10–13.

THE FOURTH QUESTION IS “WHAT MAJOR ACTIONS ACTUALLY HAVE BEEN TAKEN
NATIONALLY TO ADDRESS OPIOID OVERPRESCRIBING?”

The States have taken various actions to control opioid prescribing. As automation has improved, States have introduced electronic prescription monitoring systems to aggregate data, for use by health care providers and enforcement agencies.

- In one example, New York established the Prescription Monitoring Program (PMP) on August 27, 2013. Most prescribers are required to consult the PMP Registry when writing prescriptions for Schedule II, III, and IV controlled substances. The PMP Registry provides practitioners with direct, secure access to view dispensed controlled substance prescription histories for their patients. The PMP is available 24 hours a day/7 days a week. Patient reports include all controlled substances that were dispensed in New York State and reported by the pharmacy/dispenser for the past six months. This information will allow practitioners to better evaluate their patients’ treatment with controlled substances and determine whether there may be abuse or non-medical use.

Many States and professional associations have published pain treatment guidelines to better inform prescribers of evidence-based treatment guidelines for pain.

- For example, the Medical Board of California published Guidelines for Prescribing Controlled Substances for Pain in 2014 (http://www.mbc.ca.gov/licensees/prescribing/pain_guidelines.pdf) This comprehensive, 90 page document includes information for providers on the various types of pain, considerations of treating pain in different populations, patient treatment options and risks, and patient contracts (which include agreement to urine screening). Similarly, the state of Washington has published comprehensive guidelines (<http://www.agencymeddirectors.wa.gov/files/opioidgdline.pdf>)

- As an example of a professional association guideline, the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine published updated practice guidelines for chronic pain management.

Regulators have taken action to better educate providers and improve labeling.

- The Food and Drug Administration (FDA) required manufacturers to make educational materials available for prescribers and patients based on FDA-approved materials for continuing education for prescribers.

- FDA established a Web site to assist providers in quickly identifying and accessing educational programs (<https://search.er-la-opioidrems.com/Guest/GuestPageExternal.aspx>)

- FDA changed labeling on long acting opioid drugs. Older labeling stated that “[Name of drug] is indicated for the relief of moderate to severe pain in patients requiring continuous around the clock opioid treatment for an extended period of time.” Newer labeling states that “[Name of drug] is indicated for the management of pain severe enough to require continuous around the clock opioid treatment and for which alternative treatment options are inadequate.”

- FDA required a new boxed warning on long acting opioid drugs that increased emphasis on risks, including abuse, overdose, death, and Neonatal Opioid Withdrawal Syndrome

- FDA’s newer labeling urges prescribers to “assess each patient’s risk” for abuse before prescribing and to “monitor all patients regularly for the development of abuse.”

- FDA has recently approved several “abuse deterrent” opioids to minimize the risk for prescription diversion or abuse.

- FDA approved a naloxone auto-injectable product for the emergency treatment of known or suspected opioid overdose outside of a healthcare setting. Naloxone is a medication that rapidly reverses the effects of opioid overdose.

National enforcement agencies have taken action to require more frequent prescribing by providers. Previously, opioid combination products could be prescribed for up to a 30 day supply with 5 refills (e.g., up to a 6 month period between physician visits). That changed under new DEA rules:

- Hydrocodone combination products are now in a more restrictive category of controlled substances, along with other opioid drugs for pain like morphine and oxycodone. After a scientific review, FDA made the recommendation that DEA take this step.

- If a patient needs additional medication, the prescriber must issue a new prescription. Phone-in refills for these products are no longer allowed.
- In emergencies, small supplies can be authorized until a new prescription can be provided for the patient.

- Patients will still have access to reasonable quantities of medication, generally up to a 30-day supply.
- In addition, DEA continues its community “Take Back” programs to assist consumers in the proper disposal of unused medication, including opioid prescriptions.

THE FIFTH QUESTION IS: “ARE VHA’S ACTIONS, AS A SYSTEM, ADEQUATE AND CONSISTENT WITH THE NATIONAL MOMENTUM ON THIS ISSUE?”

- In August 2013, VHA implemented a national opioid surveillance program (Opioid Safety Initiative) to monitor utilization. The program analyzes data to identify outliers in terms of opioid (and benzodiazepine) prescribing and refers that information to VA medical centers for more critical evaluation and action, as appropriate. Recent VHA prescription dispensing data shows improvement since the implementation of the program. For example, VHA has advised that:
 - In Q4 FY 2012, 59,499 patients were dispensed greater than 100 MEDD.⁶ By Q1 FY 2015, only 49,356 patients were dispensed greater than 100 MEDD—a **17% reduction**.
 - From Q4 FY 2012 through Q1 FY 2015, 91,614 **fewer patients received an opioid prescription**. This reduction was seen despite an overall increase (1.8% -from 3,966,139 to 4,035,695) in the number of pharmacy patients during the same period.
 - From Q4 FY 2012 through Q1 FY 2015, there were **67,466 fewer pharmacy patients on long term opioids**. During this same period, urine drug screening (screening essential to detecting potential drug diversion) increased by 71,255 patients.
- In 2014, outside research experts assessed VHA’s opioid utilization and testified before the U.S. Senate Committee on Veterans’ Affairs that VHA was exercising appropriate vigilance. “The research, funded by the National Institute on Drug Abuse, showed that the percentage of VHA patients with chronic pain who receive higher doses of opioids is relatively small and lower than those in other health care systems. The amount of days in which chronic pain patients receive opioids is typically higher within the VHA; however, the median dose of opioids is lower than other health care systems, according to Edlund * * * Edlund reported that the VHA, overall, screens out substance abuse patients from high use of opioids better than other health care systems.”⁷
- VHA has published opioid treatment guidelines (with education and decision support tools and pocket guides) in 2010, updated in 2013 (<http://www.healthquality.va.gov/guidelines/Pain/cot/>) In addition, VHA’s treatment guidelines for substance use disorder (<http://www.healthquality.va.gov/guidelines/MH/sud/>) are directly linked to and complement the opioid guidelines. These guidelines are equally comprehensive to the State and professional guidelines cited previously.
- Academic detailing is a model of peer based education intended to improve prescribing performance (<http://www.narcad.org/>) where there is a gap between best practice and current treatment patterns. VHA conducted a 3 year pilot of academic detailing program to change prescribing habits in a variety of practice settings. Based on the extraordinary success of VHA’s initial pilot, the program will be expanded nationwide and include opioid prescribing as one of the focus areas.
- VHA has developed software to interact with State Prescription Drug Monitoring Programs (PDMPs). This will ensure that opioid prescriptions for Veterans receiving purchased care and/or VHA care are monitored consistently. (But deployment of the software has been problematic. See recommendation below.)
- VHA has expanded its health care model to include treatment modalities (e.g., chiropractic care, yoga, acupuncture, etc.) that can provide attractive alternatives to opioid treatment.
- In 2014, VHA has instituted a naloxone distribution program ([http://www.pbm.va.gov/PBM/clinicalguidance/clinicalrecommendations/Naloxone Kits Recommendations for Use Rev Sep 2014.pdf](http://www.pbm.va.gov/PBM/clinicalguidance/clinicalrecommendations/Naloxone%20Kits%20Recommendations%20for%20Use%20Rev%20Sep%202014.pdf)) to reverse life-threatening opioid overdoses. The program has already literally saved lives.
- VHA has increased its use of injectable naltrexone, a drug used to prevent relapse after opioid detoxification.
- VHA has a robust substance use disorder program that can support provider and patient efforts to discontinue opioid use when addiction and abuse is apparent.

⁶VHA defines higher-risk patients as those receiving prescriptions of greater than (or equal to) 100 morphine sulfate equivalent doses dispensed (100 MEDD).

⁷<http://www.rti.org/newsroom/news.cfm?obj=01E25DFA-9549-3A9E-0A638C19F38BDD1E>

- VHA has a national Pain Management Office that coordinates information and programs to ensure that providers have the most current information at their fingertips (http://www.va.gov/PAINMANAGEMENT/Clinical_Resources.asp)

THE FINAL QUESTION IS
“WHAT MORE COULD VHA DO TO IMPROVE OPIOID PRESCRIBING?”

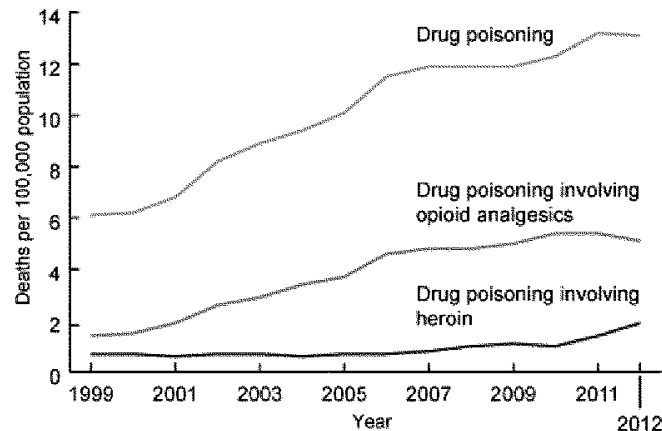
While overprescribing patterns are improving, there is always more that can be done to ensure continued progress. VHA should:

- Resource the national opioid surveillance and academic detailing initiatives appropriately to ensure success. Many of the initiatives are currently minimally staffed and sustainment is at risk if staffing is not adequate.
- Expedite VA's deployment of software to interact with State Prescription Drug Monitoring Programs (PDMP). The deployment is at risk due to an assessment by the Office of Information Technology of a security risk. The Department should be encouraged to report its progress on a quarterly basis to drive this to successful resolution.

In conclusion, I find that the actions of VHA, as a system, are consistent with the national momentum on this issue. I reached this conclusion based on the review of outside studies, VHA's internal surveillance data, and my own evaluation relative to other national and State program benchmarks. I believe that this momentum can be sustained and improved given adequate resources.

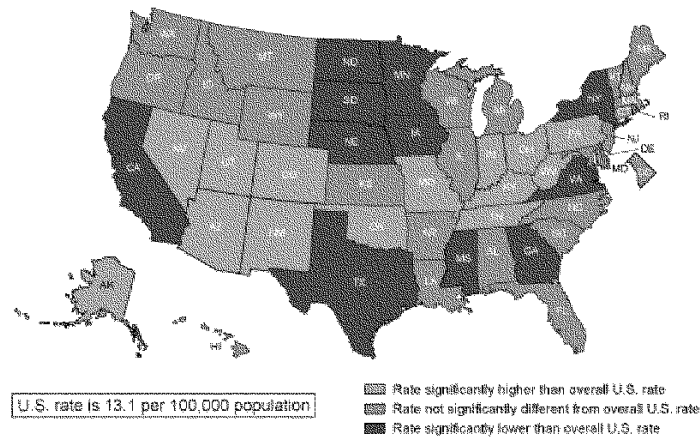
Mr. Chairman and Members of the Committee, I wish to thank you for this opportunity to present this perspective today.

Figure 1. Age-adjusted drug-poisoning death rates: United States 1999–2012



NOTE: Drug-poisoning deaths may involve both opioid analgesics and heroin.
SOURCE: CDC/NCHS, National Vital Statistics System, Mortality File.

Figure 2. Age-adjusted drug-poisoning death rates, by state: United States, 2012



SOURCE: CDC/NCHS, National Vital Statistics System, Mortality File.

Table 1. Number and age-adjusted rate of drug-poisoning deaths involving opioid analgesics and heroin: United States, 1999-2012

bYear	All		Opioid analgesics		Heroin	
	Number	Rate	Number	Rate	Number	Rate
1999	16,849	6.1	4,030	1.4	1,960	0.7
2000	17,415	6.2	4,400	1.5	1,842	0.7
2001	19,394	6.8	5,528	1.9	1,779	0.6
2002	23,518	8.2	7,456	2.6	2,089	0.7
2003	25,785	8.9	8,517	2.9	2,080	0.7
2004	27,424	9.4	9,857	3.4	1,878	0.6
2005	29,813	10.1	10,928	3.7	2,009	0.7
2006	34,425	11.5	13,723	4.6	2,088	0.7
2007	36,010	11.9	14,408	4.8	2,399	0.8
2008	36,450	11.9	14,800	4.8	3,041	1.0
2009	37,004	11.9	15,597	5.0	3,278	1.1
2010	38,329	12.3	16,651	5.4	3,036	1.0
2011	41,340	13.2	16,917	5.4	4,397	1.4
2012	41,502	13.1	16,007	5.1	5,925	1.9

NOTES: Deaths are classified using the International Classification of Diseases, Tenth Revision (ICD—10). Drug-poisoning deaths are identified using ICD—10 underlying cause-of-death codes X40—X44, X60—X64, X85, and Y10—Y14. Opioid-analgesic drug-poisoning deaths are drug-poisoning deaths with a multiple cause-of-death code of T40.2, T40.3, or T40.4. Heroin drug-poisoning deaths are drug-poisoning deaths with a multiple cause-of-death code of T40.1. Approximately 25% of drug-poisoning deaths lack information on the specific drugs involved. Some of these deaths may have involved heroin, opioid analgesics, or both.

SOURCE: CDC/NCHS, National Vital Statistics System, Mortality File

Table 2. Prescribing rates per 100 persons, by State and drug type—IMS Health, United States, 2012

State	Opioid pain relievers		Long-acting/extended-release opioid pain relievers		High-dose opioid pain relievers		Benzo-diazepines	
		Rank		Rank		Rank		Rank
Alabama	142.9	1	12.4	22	6.8	4	61.9	2
Alaska	65.1	46	10.7	31	4.2	26	24.0	50
Arizona	82.4	26	14.5	12	5.5	12	34.3	33
Arkansas	115.8	8	9.6	37	4.1	29	50.8	8
California	57.0	50	5.8	49	3.0	42	25.4	47
Colorado	71.2	40	11.8	24	4.1	31	28.0	44

Table 2. Prescribing rates per 100 persons, by State and drug type—
IMS Health, United States, 2012—Continued

State	Opioid pain relievers	Rank	Long-acting/ extended-re- lease opioid pain relievers	Rank	High-dose opioid pain relievers	Rank	Benzo- diazepines	Rank
Connecticut	72.4	38	14.1	13	5.4	13	46.2	11
Delaware	90.8	17	21.7	2	8.8	1	41.5	19
District of Columbia	85.7	23	13.7	17	5.7	10	38.4	24
Florida	72.7	37	11.3	26	6.6	5	46.9	10
Georgia	90.7	18	8.6	43	4.1	30	37.0	27
Hawaii	52.0	51	8.8	42	3.9	36	19.3	51
Idaho	85.6	24	10.3	33	3.9	34	29.1	42
Illinois	67.9	43	5.2	50	2.0	50	34.2	34
Indiana	109.1	9	10.7	30	4.9	20	42.9	17
Iowa	72.8	36	7.3	47	2.2	48	37.3	26
Kansas	93.8	16	10.3	34	4.0	32	38.9	23
Kentucky	128.4	4	11.6	25	5.0	19	57.4	5
Louisiana	118.0	7	7.8	46	3.6	39	51.5	7
Maine	85.1	25	21.8	1	5.6	11	40.7	22
Maryland	74.3	33	16.0	6	5.0	18	29.9	40
Massachusetts	70.8	41	14.9	8	3.5	41	48.8	9
Michigan	107.0	10	9.1	40	4.5	22	45.5	14
Minnesota	61.6	48	10.2	35	2.2	49	24.9	48
Mississippi	120.3	6	7.2	48	2.9	43	46.2	12
Missouri	94.8	14	9.5	38	3.5	40	42.6	18
Montana	82.0	27	14.0	15	4.4	23	33.7	35
Nebraska	79.4	28	7.8	45	2.3	46	35.0	32
Nevada	94.1	15	14.8	10	8.2	3	37.5	25
New Hampshire	71.7	39	19.6	3	6.1	7	41.2	21
New Jersey	62.9	47	11.3	27	5.8	9	36.5	28
New Mexico	73.8	35	12.7	21	3.8	38	31.5	37
New York	59.5	49	9.5	39	4.3	24	27.3	45
North Carolina	96.6	13	13.7	18	4.3	25	45.3	15
North Dakota	74.7	32	10.5	32	2.3	47	31.1	39
Ohio	100.1	12	11.2	28	4.2	27	41.3	20
Oklahoma	127.8	5	12.8	20	6.0	8	44.5	16
Oregon	89.2	20	18.8	4	5.2	16	31.4	38
Pennsylvania	88.2	21	14.9	9	5.4	14	46.1	13
Rhode Island	89.6	19	14.0	14	5.2	17	60.2	4
South Carolina	101.8	11	11.0	29	3.9	33	52.6	6
South Dakota	66.5	45	9.0	41	2.5	45	28.0	43
Tennessee	142.8	2	18.2	5	8.7	2	61.4	3
Texas	74.3	34	4.2	51	1.9	51	29.8	41
Utah	85.8	22	12.1	23	5.3	15	35.9	30
Vermont	67.4	44	13.9	16	4.7	21	35.5	31
Virginia	77.5	29	9.9	36	3.8	37	36.4	29
Washington	77.3	30	14.6	11	4.1	28	27.1	46
West Virginia	137.6	3	15.7	7	6.2	6	71.9	1
Wisconsin	76.1	31	13.1	19	3.9	35	33.4	36
Wyoming	69.6	42	8.0	44	2.7	44	24.1	49
Mean	87.3	—	12.0	—	4.5	—	39.2	—
Standard deviation	22.4	—	3.9	—	1.6	—	11.1	—
Coefficient of variation	0.26	—	0.32	—	0.36	—	0.28	—
Median	82.4	—	11.3	—	4.2	—	37.3	—
25th percentile	71.7	—	9.5	—	3.7	—	31.1	—
75th percentile	96.6	—	14.1	—	5.4	—	46.1	—
Interquartile ratio	1.3	—	1.5	—	1.4	—	1.5	—

APPENDIX 1

DECEMBER 5, 2013 REPORT RECOMMENDATIONS OF THE BEHAVIORAL HEALTH COORDINATING COMMITTEE OF THE PRESCRIPTION DRUG ABUSE SUBCOMMITTEE OF HEALTH AND HUMAN SERVICES

- Enhance surveillance:
 - Review current surveillance systems to identify ways to better detect changing patterns of abuse and health outcomes, and inform policy decisions and programmatic interventions.
 - Explore the predictive value of potential measures of abuse such as doctor-shopping metrics in claims data and other data sources.
 - Examine the role of prescriber dispensing in prescription drug abuse and overdose.
 - Better understand the relationship of opioid dose and duration that increases the risk of abuse and overdose.
 - Explore risk factors for addiction among patients receiving opioids for legitimate medical purposes.
 - Examine potential unintended consequences that may result of interventions aimed at reducing prescription drug abuse, such as a decrease in legitimate access to pain treatment.
- Enhance drug abuse prevention (through HHS funded research)
 - Evaluate the effectiveness of drug abuse prevention programs to reduce prescription drug abuse in order to inform the implementation of evidence-based programs.
 - Conduct social science research to understand the initiation of prescription drug abuse and to identify risk and protective factors to prevent initiation.
 - Evaluate the impact of medication disposal programs on prescription drug abuse and overdose. Evaluations should include sampling to determine the proportion of returned drugs that are controlled substances.
- Enhance patient and public education.
 - Convene Federal agencies to assure that patient education activities and messaging is evidence-based and consistent across agencies.
 - Leverage DEA’s National Take Back Days, International Overdose Awareness Day, National Substance Abuse Prevention Month, National Drug Facts Week, and other special occasions as opportunities to highlight the dangers of prescription drug abuse to patients across the U.S.
 - Partner with professional societies, patient education organizations, and others to expand targeted patient education programs, focusing on the addiction risks of medications, the dangers of mixing medications or mixing them with alcohol, and what patients can do to safeguard their medications.
 - Work with public and private insurers and pharmacy benefit managers to include targeted educational information to beneficiaries receiving opioid analgesics and other prescription drugs prone to abuse based on demographics, medications prescribed, and conditions being treated.
 - Conduct research to determine the effectiveness of patient education programs and use the findings to inform future educational programs.
- Enhance provider education.
 - Convene Federal agencies to further coordinate the development and dissemination of provider education programs to ensure maximum reach and benefit.
 - Partner with health professional schools, educational accrediting bodies and professional societies to continue development of targeted educational programs to meet the needs of different types of providers and practice settings.
 - Evaluate educational programs to determine the most effective programs with respect to changing provider behavior, improving prescribing, and reducing abuse and overdose.
 - Conduct research to determine the most effective ways to provide educational programs and training to providers.
- Enhance Clinical Practice Tools
 - Convene professional societies to identify barriers and potential incentives to increase provider use of Prescription Drug Monitoring Programs (PDMPs).
 - Partner with electronic health record (EHR)/Health Information Technology (HIT) stakeholders to expand the ongoing work of the Health eDecisions (HeD) project to identify, define, and harmonize standards to transmit data for use in clinical decision support, including incorporating data from state PDMPs,

screening tools such as Screening, Brief Intervention, and Referral to Treatment clinical decision support, and other relevant clinical information.

- Work with stakeholders to harmonize the data standards necessary for the interoperable exchange of PDMP data with EHRs.
- Support pilot projects focused on the use of EHRs and health information exchanges (HIEs) to improve clinical decisionmaking through real-time access to intrastate and interstate PDMP data.
- Support efforts to integrate clinical tools into EHRs and other electronic media to provide just in time information to improve clinical decisionmaking.
- Convene professional societies and subject matter experts to synthesize information from available pain management guidelines and the published literature to develop a set of prescribing recommendations that can be incorporated into clinical decision support tools.
- Conduct research to determine the impact of opioid prescribing guidelines on prescribing behaviors and health outcomes such as opioid abuse and overdose.
- Test the effectiveness of clinical decision support tools designed to improve care and reduce prescription drug abuse and overdose.
- Partner with health information technology developers and healthcare providers to validate electronic screening tools and clinical decision support tools in EHRs.
- Opportunities to enhance regulatory oversight
 - Convene partners to develop indicators of inappropriate prescribing and patient abuse that can be applied in regulatory and oversight settings.
 - Encourage insurers and pharmacy benefit managers to regularly review claims data and PDMP data, where available, to identify and address health-care providers prescribing outside of accepted medical standards and patients at high-risk for overdose.
 - Collaborate with state Medicaid programs, other public and private insurers, and pharmacy benefit managers to identify and implement robust programs that improve oversight of high-risk prescribing.
 - Collaborate with stakeholders to research the effectiveness of insurer benefit designs aimed at reducing prescription drug abuse, and pill mill and doctor shopping laws, including unintended consequences of these laws.
- Enhance drug abuse treatment
 - Partner with professional societies to identify barriers and promote the integration of drug abuse treatment, including SBIRT and medication assisted treatment, and primary care.
 - Collaborate with states, national associations, insurers, and PBMS to assure standard benefit packages cover medication-assisted treatment and SBIRT, and to develop reimbursement strategies that will increase the number of primary care providers offering such treatment in a variety of medical settings.
 - Partner with public and private insurers to develop and disseminate materials to inform healthcare providers about SBIRT billing codes and other administrative information.
 - Work with researchers and drug manufacturers to develop additional medical treatments for opioid addiction and new medical treatments for addiction to other abused prescription drugs.
 - Support the development and testing of behavioral interventions for screening and treating prescription drug abuse, including interventions targeting youth and pregnant women.
- Enhance overdose prevention
 - Expand efforts to support the development of new formulations of naloxone, such as nasal spray or auto-injector formulations.
 - Partner with national, state and local EMS and other first responder organizations to disseminate information on the use of naloxone.
 - Evaluate naloxone programs to better understand how and under what conditions it is most effectively being used.
 - Examine the impact of immunity from prosecution laws.

LETTER SUBMITTED BY HON. TAMMY BALDWIN FROM NATIONAL ALLIANCE ON
MENTAL ILLNESS



National Alliance on Mental Illness

March 26, 2015

NAMI Statement Submitted to the Senate Veterans Affairs Committee
Hearing on VA Opioid Prescription Policy, Practice and Procedures

NAMI, the National Alliance on Mental Illness, is the nation's largest grassroots mental health organization dedicated to building better lives for the millions of Americans affected by mental illness. Part of our mission is to support our active duty service members, and veterans past and present, who are dealing with mental health issues. In support of that mission, we will often support policy that can improve the lives of our military service members, veterans and their families.

As an organization, we have become aware of the increasing number of veterans who have been prescribed both benzodiazepines and opioids; and about the serious complications that can arise from their use. Although these types of medications are safe and effective when taken as directed for time limited periods, when opioid pain relievers like oxycodone, hydrocodone, hydromorphone, or morphine are combined with other drugs that depress Central Nervous System (CNS) activity, such as benzodiazepines – it can present serious or even life-threatening problems for those who are taking them.

NAMI's concern goes to the issue of veterans' morbidity and mortality with the combined prescription of opioid painkillers and drugs in the benzodiazepine (BZD) class: best known examples are Librium, Valium, Xanax, and Ativan. Like opioid-based pain medications, BZDs are addictive in that they can foster physical and psychological dependence. Mental health providers and primary care physicians, both VA and non-VA, treating Post-Traumatic Stress Disorder (PTSD), Military Sexual Trauma (MST), depression, anxiety, and panic disorder prescribe them. They are also used in the treatment of seizure disorders, insomnia, and alcohol withdrawal. They are best used in low dose and for short to medium time frames, and without other CNS depressants.

In a National Institute of Health study in 2011 by Macey et al., it was found that approximately two-thirds of OEF/OIF veterans with pain issues were prescribed opioids over a one-year timeframe, and that over one-third were prescribed opioids on a long-term basis. This study extends prior literature documenting high rates of opioid use among OEF/OIF veterans suffering from war-related injuries (Clark et al., 2009; Wu et al., 2010). The researchers found that despite prescribers adhering to guidelines for the treatment of chronic pain there were a high number of opioid prescribed veterans with concurrent BZD prescriptions. Macey et al. found that 33% of long-term opioid users in their study were concurrently prescribed benzodiazepines.

SAMHSA's Drug Abuse Warning Network (DAWN) put out an additional report in December 2014. Their report found that combining BZDs with opioid pain relievers significantly increased the risk of more serious emergency department visit outcomes. These facts suggest that individuals are at risk and that the baseline risks are high enough to suggest a public health concern. We are aware that concurrent use of opioids and BZDs pose a formidable challenge for clinicians who manage chronic pain and mental health issues. However, what makes this issue serious is that veterans with chronic pain who are

"I believe that the Department of Veterans Affairs has a responsibility to ensure that its policies and procedures are consistent with the best interests of the veterans it serves."



National Alliance on Mental Illness

prescribed opioid analgesics along with BZDs have been found to be at higher risk for fatal and nonfatal overdose and to have more aberrant behaviors with regard to substance abuse (Gudin et al., 2013).

According to a May 2014 VA Office of Inspector General (OIG) report (NO. 14-00895-163) on opioid therapy practices, it was found that approximately 64% of veterans prescribed take-home opioids had been diagnosed with mental health issues. A subset of these veterans received prescriptions for BZDs. According to the report “the concurrent use of benzodiazepines and opioids can be dangerous because both depress the central nervous system. Benzodiazepines have been strongly associated with death from opioid overdose.”

Given the findings, coming up with a solution and a better way to monitor the opioid and BZD prescribing practices of physicians is critically important. Co-administration of these agents produces an increase in rates of adverse events, overdose, and deaths, warranting close monitoring. One way that monitoring could occur is through H.R. 203, the Clay Hunt SAV act. It requires an annual, independent, and comprehensive evaluation of the VA’s mental health and suicide prevention programs. The Clay Hunt SAV Act is an opportunity to build on the oversight work that will already be in place by ensuring that the third-party evaluation includes opioid use by veterans in mental health care and suicide prevention programs. This would be an opportunity to also review clinical guidelines and standards of care for the combined prescription of opioids and BZDs by veterans in mental health and suicide prevention treatment programs, as Senator Baldwin has suggested.

Based on this information and the gravity of the issues in the studies we’ve discussed, NAMI also seeks the Committee’s support with respect to the following course of action:

1. A call for an independent, VHA system-wide review to verify that appropriate protocols governing combined opioid and BZD prescription management and monitoring are in place at VA hospitals, and
2. Assessment of the presence or absence of consistent, integrated case management for veterans receiving combined prescriptions of opioids and BZDs.

We applaud Senator Baldwin’s proposal that H.R. 203, the Clay Hunt SAV Act, include language clarifying that opioid prescribing practices be covered as part of the Act’s third-party evaluation of the Department of Veteran’s Affairs (VA) mental health care and suicide prevention programs.

The National Alliance on Mental Illness supports Senator Baldwin’s call for better coordination of care, and recommends a third party evaluation that includes the combined prescriptions of opioids and BZDs for our veterans receiving care through the VA.

NAMI deeply appreciates the Committee’s commitment to ensuring that the physical and mental healthcare needs of our nation’s veterans are met quickly, effectively, and completely. We look forward to working with you and supporting your vitally important work to help achieve those outcomes.

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“The National Alliance on Mental Illness (NAMI) is a national organization that provides support, advocacy, and information for individuals with mental illness and their families. NAMI is committed to improving the lives of people with mental illness through education, advocacy, and support.”

REVIEW

Annals of Internal Medicine

Opioid Prescribing: A Systematic Review and Critical Appraisal of
Guidelines for Chronic Pain

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Background: Deaths due to prescription opioid overdoses have increased dramatically. High-quality guidelines could help clinicians mitigate risks associated with opioid therapy.

Purpose: To evaluate the quality and content of guidelines on the use of opioids for chronic pain.

Data Sources: MEDLINE, National Guideline Clearinghouse, specialty society Web sites, and international guideline clearinghouses (searched in July 2013).

Study Selection: Guidelines published between January 2007 and July 2013 addressing the use of opioids for chronic pain in adults were selected. Guidelines on specific settings, populations, and conditions were excluded.

Data Extraction: Guidelines and associated systematic reviews were evaluated using the Appraisal of Guidelines for Research and Evaluation II (AGREE II) instrument and A Measurement Tool to Assess Systematic Reviews (AMSTAR), respectively, and recommendations for mitigating opioid-related risks were compared.

Data Synthesis: Thirteen guidelines met selection criteria. Overall AGREE II scores were 3.00 to 6.20 (on a scale of 1 to 7). The AMSTAR ratings were poor to fair for 10 guidelines. Two received high AGREE II and AMSTAR scores. Most guidelines recommend that clinicians avoid doses greater than 90 to 200 mg of morphine

equivalents per day, have additional knowledge to prescribe methadone, recognize risks of fentanyl patches, titrate cautiously, and reduce doses by at least 25% to 50% when switching opioids. Guidelines also agree that opioid risk assessment tools, written treatment agreements, and urine drug testing can mitigate risks. Most recommendations are supported by observational data or expert consensus.

Limitation: Exclusion of non-English-language guidelines and reliance on published information.

Conclusion: Despite limited evidence and variable development methods, recent guidelines on chronic pain agree on several opioid risk mitigation strategies, including upper dosing thresholds; cautions with certain medications; attention to drug–drug and drug–disease interactions; and use of risk assessment tools, treatment agreements, and urine drug testing. Future research should directly examine the effectiveness of opioid risk mitigation strategies.

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www.annals.org

Across the United States, opioid-related overdoses have been implicated in increasing numbers of emergency department visits, hospitalizations, and deaths. Annual fatalities associated with prescription opioids increased from 4000 in 1999 to nearly 14 000 by 2006 (1). Several factors may explain these trends. First, over the past several decades, the number of patients receiving opioids and the number of doses prescribed have increased dramatically (2–4). Treating chronic pain with opioids went from being largely discouraged to being included in standards of care (2, 5, 6), and titrating doses until patients self-report adequate control has become common practice (5, 7). Today, 8% to 30% of patients with chronic noncancer pain receive opioids, with average doses typically ranging from 13 to 128 mg of morphine equivalents daily; some receive much higher doses (8). Second, the public seems to consider prescription opioids safer to abuse than illicit drugs,

influencing patterns of overdose deaths (9, 10). Third, common drug–drug and drug–disease interactions contribute to overdoses. Half of fatal opioid overdoses involve the concomitant use of sedative-hypnotics, particularly benzodiazepines (1).

Given current rates of opioid overdose, policymakers are seeking solutions and standards of care are again evolving. The White House has issued action items, and an Institute of Medicine (IOM) report provides recommendations for policy audiences (11, 12). High-quality clinical practice guidelines would assist clinicians in making informed prescribing decisions and would mitigate the risks associated with using opioids. The objective of the current study was to systematically search for and evaluate the quality of guidelines addressing the use of opioids for chronic pain. A secondary objective was to compare guidelines' recommendations related to mitigating the risk for accidental overdose and misuse, including considering the quality of the evidence that guidelines provide in support of their recommendations.

METHODS

Study steps included searching for guidelines, applying selection criteria, assessing guideline quality, and extracting relevant content.

See also:

Web-Only
Supplement
CME quiz

Data Sources and Searches

We searched for guidelines addressing the use of opioids in the treatment of chronic pain, which is generally defined as pain that persists beyond normal tissue healing time, assumed to be 3 months (13, 14). The long-term use of opioids has been variably defined as use for 3 to 6 months or longer (14, 15).

Information sources included MEDLINE via PubMed, the National Guideline Clearinghouse, 12 Web sites of relevant specialty societies listed on the American Medical Association Web site (16), Web sites of selected state workers' compensation agencies (17–19), and 12 international search engines (20–31) (**Appendix Figure**, available at www.annals.org). The search was last updated in July 2013.

Search terms included "opioid," "opiate," "narcotic," "chronic pain," and "pain management." For the National Guideline Clearinghouse, names of specific opioids were also used. For PubMed, "narcotic" was omitted (all results addressed substance abuse); this search was limited to documents published after 31 December 2006 because selection criteria included recent updating.

Guideline Selection

We selected English-language documents meeting the following definition: "Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options" (32). Guidelines had to have been published after 2006 because half of guidelines can be outdated after 5 to 6 years (33).

Because we sought to evaluate guidelines that address the use of opioids for chronic pain in adults in general, we excluded guidelines focusing on specific conditions (for example, low back pain or cancer), populations (for example, pediatric patients or homeless persons), types of pain (for example, neuropathic pain or postoperative pain), or settings (for example, long-term care). We excluded guidelines derived entirely from another guideline and those for which we could not identify detailed information on development. Two reviewers applied criteria independently and reached agreement; a third reviewer was available to resolve disputes.

Guideline Quality Assessment

We evaluated guideline quality by using the Appraisal of Guidelines for Research and Evaluation II (AGREE II) instrument (34–36) and the systematic review supporting each guideline by using A Measurement Tool to Assess Systematic Reviews (AMSTAR) (37).

AGREE II

With AGREE II, appraisers rate 23 items across 6 domains (from 1 [strongly disagree] to 7 [strongly agree]), rate the overall quality of each guideline (1 to 7) and recommend for or against use. Scaled domain scores (0% to

100%) are based on the sum of ratings across all appraisers and the difference between the maximum and minimum possible scores (38).

The guidelines were rated by 4 to 6 appraisers, including 5 clinician investigators (2 of whom had limited availability) and 1 trained graduate student. One author who was also the author of a guideline (13) provided general input on content and methods but played no role in appraisals.

AMSTAR

In the original version of AMSTAR, appraisers answer 6 domain questions (yes, no, can't answer, or not applicable). Each domain question typically addresses multiple concepts. For example, 1 question states that "At least two electronic sources should be searched [concept 1] . . . Key words and/or MeSH terms must be stated [concept 2] . . ." (37).

Because including multiple concepts could lead to inconsistent scoring of "yes" or "no" responses, we modified AMSTAR by dividing the original domain questions into separate subquestions addressing single concepts (**Supplement**, available at www.annals.org). Appraisers scored each subquestion (yes, no, can't answer, or not applicable), each of the 6 domains overall (poor, fair, good, excellent, or outstanding), and the overall quality of the review (same categories as for the domains). Four to 5 appraisers rated each review individually and then met to discuss ratings and reach agreement.

Guideline Synthesis and Analysis

Three appraisers abstracted recommendations from each guideline on dosing limits, medications and formulations, titration of dose, switching from one opioid to another, drug–drug interactions, drug–disease interactions, and risk mitigation strategies (opioid risk assessment tools, written treatment agreements, and urine drug testing).

Role of the Funding Source

The Commission on Health and Safety and Workers' Compensation provided funding for this study. The funding source commissioned a synthesis of recent information on the risks and benefits of opioids for chronic pain but had no role in the design or execution of this evaluation.

RESULTS

Search and Selection of Guidelines

Of 1270 documents identified, 1132 unique records were eligible for screening, 19 full-text guidelines were considered for evaluation, and 13 were eligible (**Appendix Figure**). An online report includes a previous version of the search (39). Of 6 guidelines considered but found ineligible, 1 was derived from another guideline (18) and 5 lacked details on development methods (17, 40–43).

Table. Selected Guideline Recommendations Related to Mitigating the Risks of Opioid Therapy During Long-Term Use for Chronic Noncancer Pain

Recommendation	Guideline Development Group (Reference)*			
	ACOEM (55)	AGS (51, 52)	APS-AAPM (13, 57, 58)	ASIPP (49, 59)
Dose that warrants scrutiny, mg of morphine equivalents per day				
Most patients successfully treated with lower doses; higher doses associated with adverse effects and overdose	—	—	200†‡ (adverse effects)	90†§ (risk for overdose)
Medications and formulations				
Methadone: risks for QTc prolongation and bioaccumulation; only experienced providers should prescribe methadone	✓	✓ ‡	✓ ‡	✓ ‡
Fentanyl patch: limit to opioid-tolerant patients; variable absorption, exercise, and heat increase risk for overdose	✓	—	—	✓ ‡
Immediate-release fentanyl: limit to opioid-tolerant patients; safety unknown for CNCP; risk for overdose and misuse	✓	—	—	—
Meperidine: do not use for CNCP because of bioaccumulation and central nervous system toxicity	✓	—	—	✓ ‡
Codene: ability to convert to morphine varies greatly	—	—	—	✓ ‡
Initiation and titration of dose				
Strategies to minimize risk for overdose	Start low-dose, short-acting opioid as needed; visit in 2–3 d	Start low-dose opioid; titrate carefully; reassess often	Trial; individualize dosing§	Start low-dose, short-acting opioid; use caution
Switching between opioids				
Dose reduction: equianalgesic dosing tables omit variability	Decrease dose by 25%–50%	—	Decrease dose moderately‡	—
Switching to methadone: conversion ratios vary with dose	—	✓	✓ ‡	—
Drug-drug interactions				
Sedative-hypnotics: risk for sedation, cognitive impairment, motor vehicle accidents, and overdose	Discusses risks‡	High risk from BZDs; rarely justified	Discusses risks	If patient is receiving BZDs, opioids are contraindicated‡
Pharmacokinetic interactions: other medications affect the metabolism of specific opioids	Limited list	—	—	Many occur
Drug-disease interactions				
Preexisting substance abuse disorders: increased risk for overdose and misuse	✓	✓ ‡	✓ ‡	
Mood, personality, and cognitive disorders: increased risk for overdose and misuse	✓	—	✓ ‡	✓ ‡
Sleep and obstructive pulmonary disorders: opioids exacerbate	—	—	✓ ‡	✓ ‡
Chronic kidney disease	—	—	Slowly increase methadone	—
Active metabolites of morphine accumulate	—	—	—	✓
Screening tools for assessing risk for misuse (used in addition to patient history)				
Recommends use	✓§	✓ ‡	✓ ‡	Consider
Provides examples	✓	—	✓	✓
Written treatment agreements (used in addition to informed consent)				
Recommends use	✓§	If concerned§	Consider‡	✓ ‡
Provides example	✓	—	✓	✓
Urine drug testing				
Recommends use	Baseline and at least quarterly thereafter‡	—	If risk is high; consider otherwise‡	Must use; baseline and at random thereafter‡

AAPM = American Academy of Pain Medicine; ACOEM = American College of Occupational and Environmental Medicine; AGS = American Geriatrics Society; APS = American Pain Society; ASIPP = American Society of Interventional Pain Physicians; BZD = benzodiazepine; CNCP = chronic noncancer pain; DoD = Department of Defense; DWC = Division of Workers' Compensation; ICS = Institute for Clinical Systems Improvement; NOUGG = National Opioid Use Guideline Group; UDOSH = Utah Department of Health; UMHS = University of Michigan Health System; VA = Veterans Affairs.

* Guidelines by the American Society of Anesthesiologists (53), Fine and colleagues (54), and the Work Loss Data Institute (56) are omitted. The American Society of Anesthesiologists guideline did not address topics in the table. The guideline by Fine and colleagues addressed switching from one opioid to another but not the other topics. The Work Loss Data Institute guideline content is proprietary.

† Evidence from randomized, controlled trial.

‡ Evidence from observational study.

§ Evidence from expert consensus.

|| Evidence from another guideline.

Table—Continued

	Guideline Development Group (Reference)*				
	NOUGG (46, 60–62)	Colorado DWC (19)	ICSI (47)	UMHS (44)	UDOH (48, 50)
200†§ (adverse effects)	120‡ (adverse effects)	200‡ (adverse effects)	100	120–200‡	200§ (trials used ≤300†)
✓‡	✓	✓‡	✓	✓	✓‡
✓‡	✓	✓‡	✓	✓	✓
✓	Never use for CNCP	Risk for fatal overdose‡	—	—	✓
✓‡	✓	✓	—	✓	✓
✓‡	✓	✓	—	—	✓
Start low-dose opioid; increase gradually; monitor§	Trial; visits every 2–4 wk; multidisciplinary pain management	Titrate to maximize benefits and minimize risks	Visits weekly to monthly§	Trial; visits every 2–4 wk	Titrate up no more than every 5 half-lives†
Decrease dose by 25%–50%	—	Decrease dose by 30%	—	Decrease dose by 25%–50%	Decrease dose by 30%–50%
—	—	—	✓‡	✓	✓
Try to taper BZDs‡	Avoid sedatives or use very low doses	Sedatives sometimes indicated; decrease doses	Avoid prescribing BZDs with opioids	Discusses risks	Watch for increased adverse effects‡
—	List for tramadol	Lists for several opioids	—	Look for interactions	Lists for several opioids
✓‡	Comanage with addiction specialist	Comanage with addiction specialist	✓	✓	✓
✓‡	✓‡	✓	✓	✓	✓‡
✓‡	Consider screening	Use hydromorphone	—	—	Decrease oxycodone
✓‡	✓	Morphine, codeine	—	Decrease dose	✓
Consider‡	—	✓‡	Consider‡	✓	✓‡
✓	—	✓	✓	✓	✓
May be helpful, particularly if risk is high§	✓	✓§	Strongly consider, particularly if risk is high§	Agree on plan; signature is optional	Request that patient sign†
✓	—	✓	✓	✓	✓
If using, consider pros and cons§	Mandatory	✓	Baseline and at least yearly thereafter§	Consider	Baseline and at random thereafter‡

Selected Guidelines

Appendix Table 1 (available at www.annals.org) lists the 13 eligible guidelines; all were published in 2009 or later. Systematic reviews were conducted in 2008 or later (among guidelines that reported this).

Seven guidelines apply broadly to adults with chronic pain (13, 44–50). Six have slightly narrower scopes: The American Geriatrics Society guideline addresses adults older than 65 years (51, 52); the American Society of Anesthesiologists guideline emphasizes procedures (53); a guideline by Fine and colleagues addresses opioid rotation (54); and guidelines from the American College of Occupational and Environmental Medicine, the Work Loss Data Institute, and the Colorado Division of Workers' Compensation consider individuals with pain due to work-related conditions (19, 55, 56).

Guideline Quality Assessment

AGREE II

Overall guideline assessment scores were 3.00 to 6.20 (**Appendix Table 2**, available at www.annals.org). Rigor-of-development scores were 20% to 84%, clarity-of-presentation scores ranged from 37% to 93%, applicability scores were 13% to 56%, and editorial independence scores ranged from 0% to 88%.

Ratings were highest for a guideline by the American Pain Society and the American Academy of Pain Medicine (APS-AAPM) (13) and one by the Canadian National Opioid Use Guideline Group (46), the only guidelines that more than 50% of appraisers voted to use without modification. Most appraisers recommended against using 4 other guidelines because of limited confidence in development methods, lack of evidence summaries, or concerns about readability (19, 44, 53, 54).

Among the low- to intermediate-quality guidelines (19, 44, 45, 47–56), shortcomings included limited or no descriptions of input from guideline end users or patients; criteria for selecting evidence, strengths and limitations of evidence, and methods for formulating recommendations; external reviews before publication; plans for updating; barriers to implementation, resource implications, and how to implement guideline recommendations; monitoring and auditing criteria; and measures taken to ensure editorial independence.

AMSTAR

Systematic reviews within 10 guidelines were of poor or fair quality (19, 44, 47–56). The APS-AAPM review was of excellent to outstanding quality, the review by the Canadian National Opioid Use Guideline Group was of good to excellent quality, and the review by the Department of Veterans Affairs and Department of Defense (VA/DoD) was of good quality (**Appendix Table 3**, available at www.annals.org) (13, 45, 46).

Reasons for lower scores included limited information about whether inclusion criteria were selected beforehand,

whether at least 2 reviewers participated in study selection and data extraction, whether more than 1 database was searched, search terms used, inclusion criteria, lists of included studies, whether the scientific quality of the studies was assessed, how information from different studies was combined, and whether publication bias was considered.

Guideline Synthesis and Analysis

The **Table** compares recommendations from 10 guidelines about mitigating risks when prescribing opioids (3 guidelines had little relevant content). The APS-AAPM, Canadian National Opioid Use Guideline Group, American Society of Interventional Pain Physicians, and VA/DoD guidelines make explicit links between each recommendation and original research evidence more frequently than the other guidelines do (13, 45, 46). Among recommendations in the **Table**, only upper dosing thresholds are reported to be supported by evidence from randomized, controlled trials; others are supported by lower-quality evidence or expert opinion. Even the higher-quality guidelines typically relied on modest numbers of lower-quality observational studies for many recommendations (13, 45, 47, 57, 60). Nonetheless, many recommendations are concordant across the guidelines.

Eight guidelines concur that higher doses require caution (19, 44, 45, 47, 50, 57, 59, 60). Four consider higher doses to be 200 mg of morphine equivalents per day, on the basis of randomized, controlled trials showing that most patients achieve pain control with lower doses and observational data showing that the prevalence of adverse effects increases at higher doses (45, 47, 57, 60). Because recent observational studies detected more overdoses with doses greater than 100 mg, the American Society of Interventional Pain Physicians guideline (2012) recommends staying below 90 mg unless pain is intractable (49, 59). The University of Michigan Health System guideline (2012) advises that patients receiving more than 100 mg be treated by pain specialists (44).

Ten guidelines—6 of which cite observational data—agree that methadone poses risks for dose-related QTc prolongation and respiratory suppression due to a long half-life and unique pharmacokinetics (13, 19, 44–47, 49, 50, 52, 55, 57, 60). These guidelines generally recommend that only knowledgeable providers prescribe methadone. Eight guidelines recommend caution with the fentanyl patch, including limiting use to opioid-tolerant patients and being aware that unpredictable absorption can occur with fever, exercise, or exposure to heat (19, 44, 45, 47, 49, 50, 55, 60, 61). Cited evidence includes an observational study investigating fentanyl overdoses in Ontario, Canada, as well as case reports submitted to the U.S. Food and Drug Administration (47, 49, 60, 63).

Ten guidelines make variable consensus-based statements about initiating and titrating opioids, such as using a trial period, individualizing therapy, engaging multidisciplinary pain management teams, increasing doses slowly,

and scheduling regular follow-up visits (13, 19, 44–48, 50, 52, 55, 59).

Regarding switching from one opioid to another, 7 guidelines agree that reducing doses by at least 25% to 50% is necessary to avoid inadvertent overdose; the guideline by Fine and colleagues provides nuanced recommendations (13, 45, 47, 48, 50, 54, 55, 60). Two guidelines cite a systematic review of observational studies, which found that patients respond variably to different drugs (13, 54). Five guidelines mention that many persons of Caucasian or Chinese ancestry cannot metabolize codeine to morphine and are therefore less responsive to its analgesic effects and cannot develop tolerance (19, 45, 47, 59–61). Conversely, 5 guidelines note that some patients metabolize codeine to morphine ultra-rapidly, potentially resulting in overdose (19, 47, 49, 59, 60); certain ethnicities are at greater risk, particularly persons from North Africa and the Middle East (45).

Ten guidelines concur, on the basis of observational data, that benzodiazepines and opioids are a high-risk combination, particularly in elderly adults (13, 19, 44, 45, 47, 48, 50, 52, 55, 59–61). Five recommend against prescribing both together unless clearly indicated (19, 44, 49, 52, 60, 61). Six guidelines describe pharmacokinetic interactions between other medications and opioids, particularly methadone, fentanyl, oxycodone, and tramadol (19, 45, 47–49, 55). Six guidelines mention the accumulation of active, toxic metabolites of morphine among patients with kidney disease (19, 45, 47, 49, 50, 60). Ten guidelines consider the leading risk factors for overdose or misuse as having a personal or family history of substance abuse and having psychiatric issues (13, 44, 45, 47–49, 52, 55, 59–61); 3 cite observational studies (13, 52, 60, 61). Seven guidelines identify obstructive respiratory disorders as risk factors for overdose, also on the basis of observational data (13, 19, 44, 45, 48, 50, 59–61).

In terms of mitigating risks, the evidence for opioid risk assessment tools, treatment agreements (“contracts”), and urine drug testing is weak, but recommendations vary in strength from “may consider” to “must.” Nine guidelines recommend considering or using opioid risk assessment tools and treatment agreements on the basis of observational studies and expert consensus (13, 44, 45, 47, 48, 50, 52, 55, 59–61). Eight guidelines mention or provide specific risk assessment instruments for use when initiating therapy with long-term opioids, such as the Screener and Opioid Assessment for Patients with Pain (SOAPP), version 1 (64); the revised SOAPP (65); and the Opioid Risk Tool, or monitoring tools for use during follow-up, including the Pain Assessment and Documentation Tool (66, 67) and the Current Opioid Misuse Measure (44, 45, 47–50, 55, 57, 60, 68). For detecting aberrant drug-related behaviors, the self-administered SOAPP, version 1, and the Current Opioid Misuse Measure performed well in higher-quality observational studies (57). Treatment agreements may improve adherence and provid-

ers’ willingness to prescribe opioids, on the basis of a few small, observational studies (49, 57, 60).

Nine guidelines find urine drug testing to be helpful, but recommendations vary (13, 19, 44, 45, 47, 48, 55, 59, 60). Two recommend mandatory testing for all patients (19, 49), another advises testing for patients at higher risk for substance abuse disorders (13), and 2 comment that screening low-risk populations increases false-positive results and is less cost-effective (13, 60, 61). False-negative results can occur because a common test, the enzyme-linked immunoassay, does not consistently detect hydrocodone, fentanyl, hydromorphone, oxycodone, methadone, or certain benzodiazepines; gas chromatography or mass spectrometry will identify specific substances when requested (44, 46, 50, 60–62). Nonadherence, diversion, tampering, and lactic acidosis can also cause unexpected negative results. The differential for unexpected positive results includes abuse, consulting multiple physicians, self-treatment of uncontrolled pain, interference by other medications, eating poppy seeds, and laboratory error (13, 44, 46, 49, 59–62).

DISCUSSION

Increasing overdoses on prescription opioids have prompted efforts to redefine standards of care, particularly for patients with chronic pain, who may be prescribed opioids for long-term use. We evaluated the quality of 13 guidelines on using opioids to treat chronic pain and compared recommendations related to mitigating risks for overdose and misuse. Two guidelines received high ratings: one by APS-AAPM (13) and another by the Canadian National Opioid Use Guideline Group (46). Both apply to a broad range of adults, were developed using comprehensive systematic reviews and rigorous methods for formulating recommendations, and frequently link recommendations to evidence. Our appraisers found 7 other guidelines to be of intermediate quality and recommended against using the remaining 4. Systematic reviews supporting 10 guidelines were judged, on the basis of publicly available information, to be of poor to fair quality.

Although the guidelines involve varied development methods and clinical emphases, a consensus has emerged across them on several issues. They generally agree about the need for caution in prescribing doses greater than 90 to 200 mg of morphine equivalents per day, having knowledgeable clinicians manage methadone, recognizing risks associated with fentanyl patches, titrating with caution, and reducing doses by at least 25% to 50% when switching from one opioid to another. They also agree that opioid risk assessment tools, written treatment agreements, and urine drug testing can be helpful when opioids are prescribed for long-term use. Recommendations from earlier guidelines are generally similar to those published recently. Most of these recommendations are based on epidemiologic and observational studies showing associations be-

tween certain exposures, such as drugs or doses, and greater risks for overdose or misuse. Few studies seem to have directly addressed questions of whether changing practice decreases risk. Given the pressing need to address opioid-related adverse outcomes, which some have described as an epidemic (69), developers seem to agree on forging recommendations based on relatively weak or indirect evidence now rather than waiting for more rigorous studies.

It may be unusual for multiple guidelines to make such similar recommendations, but the variability in guideline quality that we observed is not. For example, among 19 breast cancer guidelines, AGREE II rigor-of-development scores were 16.7% to 89.6%, clarity-of-presentation scores ranged from 52.8% to 94.4%, applicability scores were 6.3% to 83.6%, and editorial independence scores ranged from 12.5% to 79.2% (70). Among 3 migraine guidelines, AGREE II rigor-of-development scores were 35% to 93%, clarity-of-presentation scores ranged from 6% to 92%, applicability scores were 20% to 88%, and editorial independence scores ranged from 29% to 86%; overall scores were 2 to 6, and appraisers recommended against using 1 guideline (71). Among 11 mammography guidelines evaluated using the original AGREE instrument and AMSTAR, appraisers recommended against implementing 5 guidelines, and 5 systematic reviews performed poorly (72).

Compared with these previous guidelines, the current opioid guidelines received lower scores on "applicability": None scored higher than 56%. Applicability includes consideration of potential barriers to and facilitators of implementation, strategies to improve uptake by providers, and resource implications of applying the guideline. Barriers to implementation are a major reason that physicians are often slow to incorporate clinical guidelines into their decision making (73). To identify such barriers, guideline developers and implementers are starting to use the Guideline Implementability Appraisal (GLIA) tool (74–76), which assesses "executability" (know what to do), "decidability" (can tell when to do it), validity, flexibility, effect on process of care, measurability, novelty or innovation, and "computability" (can be operationalized in an electronic health record system) (77). Although GLIA is labor-intensive (76), it probably requires fewer resources than pilot testing and is preferable to issuing a guideline that is not used. Developers of opioid guidelines could incorporate GLIA into the next updating process, thereby improving applicability.

Although we selected guidelines that had been updated within the past 6 years, some evidence has already started to change, particularly regarding the risk for overdose. Five guidelines published before 2012 consider doses greater than 200 mg of morphine equivalents per day to confer higher risk. Three observational studies from 2010 and 2011 show that, compared with patients receiving no more than 20 mg, the risk for serious or fatal overdose increases 1.9- to 3.1-fold with doses of 50 to 100 mg and

increases dramatically with doses greater than 100 to 200 mg (78–80). Guidelines published in 2012 use thresholds of 90 to 100 mg. In 2007, the state of Washington implemented workers' compensation guidelines recommending evaluation by a pain management expert for patients receiving more than 120 mg/d as well as other risk mitigation strategies that are similar to or, in some areas, more restrictive than those of the guidelines reviewed here. Although pain control has not been described, the number of patients receiving opioids and the doses prescribed started decreasing in 2007 and fatal overdoses decreased in 2010 (4).

Given that overdoses occur even at lower doses, some may wonder about the overall risks and benefits of using opioids for chronic pain. According to previous systematic reviews of randomized, controlled trials, oral opioids are substantially more effective than placebo or nonsteroidal agents, with 30% to 50% decreases in pain severity and significant improvements in functional status (14, 81–83). However, study quality has not been high, and the duration of follow-up has often been limited (14, 84). At least one third of patients stop opioid use because of adverse effects (46, 81, 82, 85). Abuse occurs in 0.43% to 3.27% of patients and addiction affects 0.042%, but 11.5% engage in aberrant drug-related behaviors or illicit use (14, 85, 86). This evidence has generally been incorporated into the guidelines and is reflected in the supportive but cautious approach that they take toward long-term opioid therapy.

Our evaluation has several limitations. First, we relied on publicly available information, so we were unable to evaluate several guidelines (17, 40–43, 87) or the clarity of the proprietary Work Loss Data Institute guideline. Although AGREE scores can improve when developers provide supplemental information (88), the IOM recently outlined guideline development standards stating, "The processes by which a [clinical practice guideline] is developed and funded should be detailed explicitly and publicly accessible" (32). Second, neither the IOM nor AGREE stipulate how guidelines should select topics. To be useful, guidelines should address the challenges that clinicians face in practice, but developers may exclude clinically important topics when available evidence does not meet minimum standards.

In conclusion, rigorous clinical practice guidelines could help providers to attenuate the increasing rates of opioid misuse and overdose among patients with chronic pain. Recent guidelines make similar recommendations about strategies for reducing these risks despite variability in development methods, suggesting a clinical consensus for practices that could be adopted until more evidence becomes available. They agree on using upper dosing thresholds; cautions with certain medications; attention to drug–drug and drug–disease interactions; and risk assessment tools, treatment agreements, and urine drug testing. Although such recommendations can guide practice now,

future research should directly examine the effectiveness of opioid risk mitigation strategies, including effects on pain control and overdose rates.

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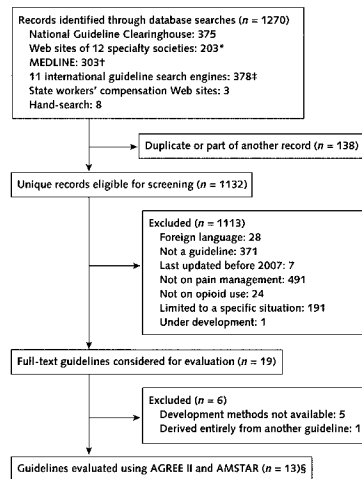
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Appendix Figure. Summary of evidence search and selection.



AGREE II = Appraisal of Guidelines for Research and Evaluation II;
AMSTAR = A Measurement Tool to Assess Systematic Reviews.

* Includes the American Academy of Family Physicians, American Academy of Pain Medicine, American Academy of Physical Medicine and Rehabilitation, American College of Occupational and Environmental Medicine, American College of Physicians, American Geriatrics Society, American Society of Addiction Medicine, American Society of Anesthesiologists, American Society of Interventional Pain Physicians, Association of Military Surgeons of the United States, National Medical Association, and Society of Medical Consultants to the Armed Forces.

† The exact PubMed search terms were "analgesics, opioid"[MeSH], "opioid"[tiab], "opioids"[tiab], "opioid analgesic"[tiab], "opioid analgesics"[tiab], "opiate"[tiab], "opiates"[tiab], "chronic pain"[MeSH], "chronic pain"[tiab], "pain management"[MeSH], and "pain management"[tiab] combined with "guideline"[Publication Type], "guideline"[tiab], "position statement"[tiab], "practice parameter"[tiab], "position paper"[tiab], and "consensus statement"[tiab].

‡ Includes the Guidelines International Network; National Institute for Health and Care Excellence; Canadian Medical Association Infobase; Clinical Practice Guidelines; Clinical Practice Guidelines Portal of the Australian Government; Scottish Intercollegiate Guidelines Network; New Zealand Guidelines Group; Biblioteca de Guías de Práctica Clínica del Sistema Nacional de Salud (Library of Clinical Practice Guidelines from the Spanish National Health System); German Agency for Quality in Medicine; German National Disease Management Guidelines Programme; German Disease Management Guidelines; British Columbia Ministry of Health; and Australian Government National Health and Medical Research Council: Guidelines and Publications.

§ The American Geriatrics Society updated its guideline in 2009 and stated that the 2002 guideline, which covers slightly different material, was still up to date. When counting guidelines, we considered these to be components of 1 document.

Appendix Table 1. Guidelines Meeting All Selection Criteria and Included in Quality Appraisal

Guideline	Development Group	Guideline Last Reviewed	Systematic Review Updated	Reference
ACOEM Guidelines for Chronic Use of Opioids	ACOEM	2011	References to primary literature dated 2007 or earlier*	55
Pharmacological Management of Persistent Pain in Older Persons	AGS Panel on Pharmacological Management of Persistent Pain in Older Persons	2009	References to primary literature dated 2008 or earlier	52
The Management of Persistent Pain in Older Persons	AGS Panel on Persistent Pain in Older Persons	2009	–	51
Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain	APS-AAPM	2009	October 2008	13, 57, 58
Practice Guidelines for Chronic Pain Management: An Updated Report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine	ASA	2010	2009	53
American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain	ASIPP	2012	References to primary literature dated 2012 or earlier	49, 59
Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain	NOUGG	2010	July 2009	46, 60–62
Chronic Pain Disorder Medical Treatment Guidelines	Colorado DWC	2011	November 2011	19
Establishing "Best Practices" for Opioid Rotation: Conclusions of an Expert Panel	Department of Pain Medicine and Palliative Care, Beth Israel Medical Center and Department of Anesthesiology, Pain Research Center, University of Utah School of Medicine	2009	References to primary literature dated 2007 or earlier	54
Assessment and Management of Chronic Pain	ICS†	2011	August 2011	47
Managing Chronic Non-Terminal Pain in Adults, Including Prescribing Controlled Substances	UMHS	2012	January 2010	44
Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain	UDOH	2009	References to primary literature dated 2007 or earlier	48, 50
Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain	VA/DoD	2010	March 2009	45
Pain (Chronic)†	WLDI	2011	Not reported (no references)	56

AAPM = American Academy of Pain Medicine; ACOEM = American College of Occupational and Environmental Medicine; AGS = American Geriatrics Society; APS = American Pain Society; ASA = American Society of Anesthesiologists; ASIPP = American Society of Interventional Pain Physicians; DoD = Department of Defense; DWC = Division of Workers' Compensation; ICS† = Institute for Clinical Systems Improvement; NOUGG = National Opioid Use Guideline Group; UDOH = Utah Department of Health; UMHS = University of Michigan Health System; VA = Veterans Affairs; WLDI = Work Loss Data Institute.

* Excludes such sources as references to other guidelines, narrative and systematic reviews, government reports, and book chapters because these are often identified through means other than systematic reviews of the literature.

† From *The Official Disability Guidelines* product line (including *ODG Treatment in Workers Comp*), which is updated annually.

Appendix Table 2. Results of AGREE II Evaluation

Variable	ACOEI (35)	ACG (51, 32)	APS-AAPM (13, 37, 38) (33)	ASA (33)	ASPP (49, 59) (46, 60-62)	NOUGG (46, 60-62)	Colorado DWC (19)	Finet et al (34)	ICSI (47)	UMHS (44)	UDOH (44)	VA/DoD (43)	WLDI (50)	Mean (Range), %
AGREE II domain score, %														
Scope and purpose (the overall aim of the guideline, the specific health condition, and the target population)	78	68	89	72	85	76	53	39	86	51	49	88	69	69 (39-89)
Stakeholder involvement (the extent to which the guideline was developed by the appropriate stakeholders and represents the views of its intended population)	55	39	73	43	53	77	41	23	69	39	50	58	59	52 (23-77)
Rigor of development (the process used to gather and synthesize the evidence and the methods used to formulate and update the recommendations)	60	44	84	33	56	74	27	24	56	20	43	55	49	48 (20-84)
Clarity of presentation (the language, layout, and format of the guideline)	67	68	84	54	79	93	37	71	80	64	74	78	—*	71 (37-93)
Applicability (the likely barriers to and facilitators of implementation, strategies to improve uptake, and resource implications of applying the guideline)	55	30	41	21	40	56	13	28	41	46	42	42	31	37 (13-56)
Editorial independence (the influence of the funding body on development and disclosure of conflicts of interest)	75	63	88	2	69	56	0	23	52	37	48	8	50	44 (0-88)
Mean domain score	63	49	76	38	61	73	29	33	62	39	49	57	51	52 (28-76)
Overall outcome of guideline development														
Mean overall quality score	4.75	4.00	6.20	3.00	4.67	6.00	3.00	3.40	4.50	3.60	3.60	4.75	3.50	4.23 (3.00-6.20)
Votes to recommend use	2 (50)	1 (20)	5 (100)	0	1 (17)	3 (75)	0	1 (20)	2 (40)	0	0	1 (25)	—*	—
Yes, n (%)	0	4 (80)	0	0	4 (67)	1 (25)	2 (40)	1 (20)	2 (40)	1 (20)	3 (60)	3 (75)	—*	—
Yes, with modifications, n (%)	2 (50)	0	0	4 (100)	1 (17)	0	3 (60)	3 (60)	1 (20)	4 (80)	2 (40)	0	—*	—
No, n (%)	4	5	5	4	6	4	5	5	5	5	5	4	—*	—
Total votes, n														

AAPM = American Academy of Pain Medicine; ACOE = American College of Occupational and Environmental Medicine; AGREE II = Appraisal of Guidelines for Research and Evaluation II; AGS = American Geriatrics Society; ASA = American Society of Anesthesiologists; ASPP = American Society of Professional Pharmacists; CDSR = Clinical Decision Support; Colorado = Colorado Department of Health; DWC = Work Loss Data Institute; ICSI = Institute for Clinical Systems Improvement; NOUGG = National Opioid Use Guidelines Group; UDOH = Utah Department of Health; UMHS = University of Michigan Health System; VA = Veterans Affairs; WLDI = Work Loss Data Institute.

* The guideline is proprietary and text was unavailable; so raters could not assess clarity of presentation or decide whether to recommend use. Domain ratings were based on information the developer has made public about development methods and information related to the other domains.

Appendix Table 3. Results of AMSTAR Evaluation

Question	Guideline Development Group (Reference)												
	ACOBIM (55)	AGS (51, 52)	APS-AAPM (13, 57, 58)	ASA (53)	ASIPP (49, 59)	NOJCG (46, 60-62)	Colorado DWC (19)	Fine et al (54)	ICSI (47)	UMHS (44)	UDOH (48, 50)	VA/DoD (45)	WLDI (56)
Was an "a priori" design provided?	F	F	O	F	F	E	P	F	F	G	F	G	G
Was there duplicate study selection and data extraction?	F	P	O	P	P	G	P	P	P	P	P	P	P
Was a comprehensive literature search performed?	G	P	E	P	F	O	F	P	F	F	G	G	G
Was the status of publication (e.g., gray literature) used as an inclusion criterion?	G	F	G	F	F	G	P	P	F	G	F	G	G
Was a list of studies (included and excluded) provided?	P	P	E	F	F	G	F	P	P	P	F	F	P
Were the characteristics of the included studies provided?	P	P	O	P	P	G	F	P	P	P	P	P	P
Was the scientific quality of the included studies assessed and documented?	F	F	E	P	P	G	G	P	F	P	F	G	G
Was the scientific quality of the included studies used appropriately in formulating conclusions?	G	G	O	F	G	G	F	P	F	P	P	E	F
Were the methods used to combine the findings of studies appropriate?	F	F	E	F	F	E	P	P	P	P	P	G	F
Was the likelihood of publication bias assessed?	P	P	P	F	P	G	P	P	P	P	P	P	P
Was the conflict of interest stated?	F	F	O	P	F	F	F	F	P	F	F	F	F
Overall rating	F	P-F	E-O	P-F	F	G-E	P-F	P	P-F	P-F	F	G	F-G

AAIM = American Academy of Pain Medicine; ACOEM = American College of Occupational and Environmental Medicine; AGS = American Geriatrics Society; AMSTAR = A Measurement Tool to Assess Systematic Reviews; APS-AAPM = American Psychiatric Association/American Academy of Pediatrics Practice Guidelines; ASA = American Society of Anesthesiologists; ASIPP = American Society of Inpatient Practice; ICSI = Institute for Clinical Systems Improvement; NOJCG = National Opioid Use Guideline Group; O = outstanding; P = poor; UDOH = Utah Department of Health; UMHS = University of Michigan Health System; VA = Veterans Affairs; WLDI = Work Loss Data Institute.

REPORT SUBMITTED BY G. CALEB ALEXANDER, MD: THE PRESCRIPTION OPIOID AND HEROIN CRISIS: A PUBLIC HEALTH APPROACH TO AN EPIDEMIC OF ADDICTION

The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction

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Keywords

prescription drug abuse, heroin, overdose deaths, chronic pain, opioid, addiction

Abstract

Public health authorities have described, with growing alarm, an unprecedented increase in morbidity and mortality associated with use of opioid pain relievers (OPRs). Efforts to address the opioid crisis have focused mainly on reducing nonmedical OPR use. Too often overlooked, however, is the need for preventing and treating opioid addiction, which occurs in both medical and nonmedical OPR users. Overprescribing of OPRs has led to a sharp increase in the prevalence of opioid addiction, which in turn has been associated with a rise in overdose deaths and heroin use. A multifaceted public health approach that utilizes primary, secondary, and tertiary opioid addiction prevention strategies is required to effectively reduce opioid-related morbidity and mortality. We describe the scope of this public health crisis, its historical context, contributing factors, and lines of evidence indicating the role of addiction in exacerbating morbidity and mortality, and we provide a framework for interventions to address the epidemic of opioid addiction.

INTRODUCTION

Over the past 15 years, the rate of opioid pain reliever (OPR) use in the United States has soared. From 1999 to 2011, consumption of hydrocodone more than doubled and consumption of oxycodone increased by nearly 500% (42). During the same time frame, the OPR-related overdose death rate nearly quadrupled (15). According to the United States Centers for Disease Control and Prevention (CDC), the unprecedented increase in OPR consumption has led to the “worst drug overdose epidemic in [US] history” (58). Given the magnitude of the problem, in 2014 the CDC added opioid overdose prevention to its list of top five public health challenges (13).

Overdose mortality is not the only adverse public health outcome associated with increased OPR use. The rise in opioid consumption has also been associated with a sharp increase in emergency room visits for nonmedical OPR use (69) and in neonatal abstinence syndrome (57). Moreover, from 1997 to 2011, there was a 900% increase in individuals seeking treatment for addiction to OPRs (66, 68). The correlation between opioid sales, OPR-related overdose deaths, and treatment seeking for opioid addiction is striking (**Figure 1**).

Addiction is defined as continued use of a drug despite negative consequences (1). Opioids are highly addictive because they induce euphoria (positive reinforcement) and cessation of chronic use produces dysphoria (negative reinforcement). Chronic exposure to opioids results in structural and functional changes in regions of the brain that mediate affect, impulse, reward, and motivation (83, 91). The disease of opioid addiction arises from repeated exposure to opioids and can occur in individuals using opioids to relieve pain and in nonmedical users.

Another important feature of the opioid addiction epidemic is the relationship between OPR use and heroin use. According to the federal government's National Survey on Drug Use and Health (NSDUH), 4 out of 5 current heroin users report that their opioid use began with OPRs (54). Many of these individuals appear to be switching to heroin after becoming addicted to OPRs because heroin is less expensive on the black market. For example, in a recent sample of

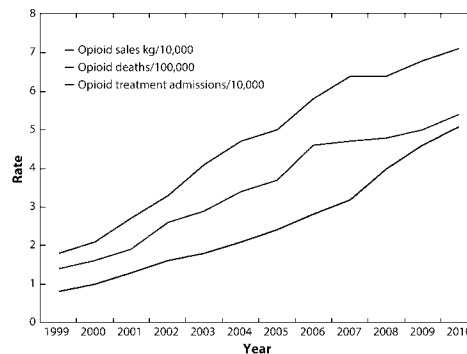


Figure 1
Rates of OPR sales, OPR-related unintentional overdose deaths, and OPR addiction treatment admissions, 1999–2010. Abbreviation: OPR, opioid pain reliever. Source: 10.

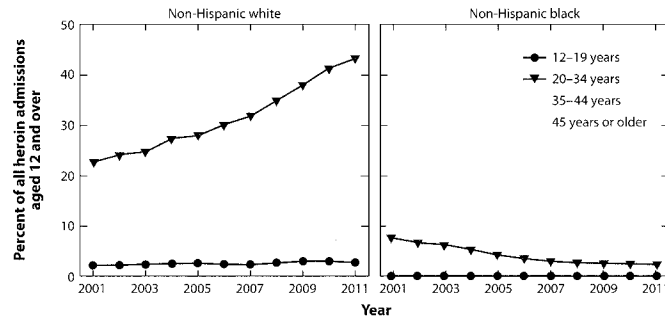


Figure 2

Heroin admissions, by age group and race/ethnicity: 2001–2011. Source: 68.

opioid-addicted individuals who switched from OPRs to heroin, 94% reported doing so because OPRs “were far more expensive and harder to obtain” (16, p. 24).

The increased prevalence of opioid addiction has also been associated with increases in heroin-related morbidity and mortality. For example, since 2001, heroin addiction treatment admissions for whites ages 20–34 have increased sharply (Figure 2). During this time frame, heroin overdose deaths among whites ages 18–44 increased by 171% (14).

HISTORY OF OPIOID ADDICTION IN THE UNITED STATES

The current opioid addiction crisis is, in many ways, a replay of history. America’s first epidemic of opioid addiction occurred in the second half of the nineteenth century. In the 1840s, the estimated national supply of opium and morphine could have supported a maximum of 0.72 opioid-addicted individuals per 1,000 persons (18). Over the next 50 years, opioid consumption soared by 538%. It reached its peak in the mid-1890s, when the supply could have supported a maximum of ~4.59 opioid-addicted individuals per 1,000 persons. The ceiling rate then began to decline, and by 1920 there were no more than 1.97 opioid-addicted individuals per 1,000 persons in the United States.

The epidemic had diverse origins. Mothers dosed themselves and their children with opium tinctures and patent medicines. Soldiers used opium and morphine to treat diarrhea and painful injuries. Drinkers alleviated hangovers with opioids. Chinese immigrants smoked opium, a practice that spread to the white underworld. But the main source of the epidemic was iatrogenic morphine addiction, which coincided with the spread of hypodermic medication during 1870–1895. The model opioid-addicted individual was a native-born white woman with a painful disorder, often of a chronic nature.

Nineteenth-century physicians addicted patients—and, not infrequently, themselves—because they had few alternatives to symptomatic treatment. Cures were scarce and the etiology of painful conditions was poorly understood. An injection of morphine almost magically alleviated symptoms, pleasing doctors and patients. Many patients continued to acquire and inject morphine, the sale of which was poorly controlled.

The revolutions in bacteriology and public health, which reduced diarrheal and other diseases commonly treated with opium; the development of alternative analgesics such as aspirin; stricter

prescription laws; and admonitions about morphine in the lay and professional literature stemmed the addiction tide. One important lesson of the first narcotic epidemic is that physicians were educable. Indeed, by 1919, narcotic overprescribing was the hallmark of older, less-competent physicians. The younger, better-trained practitioners who replaced them were more circumspect about administering and prescribing opioids (5).

For the rest of the twentieth century, opioid addiction epidemics resulted from transient increases in the incidence of nonmedical heroin use in urban areas. After World War II, these epidemics disproportionately affected inner-city minority populations, such as the large, heavily publicized increase in ghetto heroin use and addiction at the end of the 1960s (24, 37).

THE SHARP RISE IN PRESCRIPTION OPIOID CONSUMPTION

In 1986 a paper describing the treatment of 38 chronic pain patients concluded that OPRs could be prescribed safely on a long-term basis (61). Despite its low-quality evidence, the paper was widely cited to support expanded use of opioids for chronic non-cancer pain. Opioid use increased gradually in the 1980s. In 1996, the rate of opioid use began accelerating rapidly (38). This acceleration was fueled in large part by the introduction in 1995 of OxyContin, an extended release formulation of oxycodone manufactured by Purdue Pharma.

Between 1996 and 2002, Purdue Pharma funded more than 20,000 pain-related educational programs through direct sponsorship or financial grants and launched a multifaceted campaign to encourage long-term use of OPRs for chronic non-cancer pain (86). As part of this campaign, Purdue provided financial support to the American Pain Society, the American Academy of Pain Medicine, the Federation of State Medical Boards, the Joint Commission, pain patient groups, and other organizations (27). In turn, these groups all advocated for more aggressive identification and treatment of pain, especially use of OPRs.

For example, in 1995, the president of the American Pain Society introduced a campaign entitled "Pain is the Fifth Vital Sign" at the society's annual meeting. This campaign encouraged health care professionals to assess pain with the "same zeal" as they do with vital signs and urged more aggressive use of opioids for chronic non-cancer pain (9). Shortly thereafter, the Veterans' Affairs health system, as well as the Joint Commission, which accredits hospitals and other health care organizations, embraced the Pain is the Fifth Vital Sign campaign to increase the identification and treatment of pain, especially with OPRs. Similarly, the American Pain Society and the American Academy of Pain Medicine issued a consensus statement endorsing opioid use for chronic non-cancer pain (31). Although the statement cautioned against imprudent prescribing, this warning may have been overshadowed by assertions that the risk of addiction and tolerance was low, risk of opioid-induced respiratory depression was short-lived, and concerns about drug diversion and abuse should not constrain prescribing.

Prior to the introduction of OxyContin, many physicians were reluctant to prescribe OPRs on a long-term basis for common chronic conditions because of their concerns about addiction, tolerance, and physiological dependence (80). To overcome what they claimed to be "opiophobia," physician-spokespersons for opioid manufacturers published papers and gave lectures in which they claimed that the medical community had been confusing addiction with "physical dependence." They described addiction as rare and completely distinct from so-called "physical dependence," which was said to be "clinically unimportant" (60, p. 300). They cited studies with serious methodological flaws to highlight the claim that the risk of addiction was less than 1% (28, 45, 52, 59, 62).

In addition to minimizing risks of OPRs, the campaign advanced by opioid manufacturers and pain organizations exaggerated the benefits of long-term OPR use. In fact, high-quality,

long-term clinical trials demonstrating the safety and efficacy of OPRs for chronic non-cancer pain have never been conducted. Surveys of patients with chronic non-cancer pain receiving long-term OPRs suggest that most patients continued to experience significant chronic pain and dysfunction (25, 76). The CDC and some professional societies now warn clinicians to avoid prescribing OPRs for common chronic conditions (29).

Although increased opioid consumption over the past two decades has been driven largely by greater ambulatory use for chronic non-cancer pain (8), opioid use for acute pain among hospitalized patients has also increased sharply. A recent study found that physicians prescribed opioids in more than 50% of 1.14 million nonsurgical hospital admissions from 2009 to 2010, often in high doses (34). The Joint Commission's adoption of the Pain is the Fifth Vital Sign campaign and federally mandated patient satisfaction surveys asking patients to rate how often hospital staff did "everything they could to help you with your pain" are noteworthy, given the association with increased hospital use of OPRs.

REFRAMING THE OPIOID CRISIS AS AN EPIDEMIC OF ADDICTION

Policy makers and the media often characterize the opioid crisis as a problem of nonmedical abuse by adolescents and young adults. However, several lines of evidence suggest that addiction occurring in both medical and nonmedical users, rather than abuse per se, is a key driver of opioid-related morbidity and mortality in medical and nonmedical OPR users.

Opioid Harms Are Not Limited to Nonmedical Users

Over the past decade, federal and state policy makers have attempted to reduce OPR abuse and OPR-related overdose deaths. Despite these efforts, morbidity and mortality associated with OPRs have continued to worsen in almost every US state (10). Thus far, these efforts have focused primarily on preserving access to OPRs for chronic pain patients while reducing nonmedical OPR use (89), defined as the use of a medication without a prescription, in a way other than as prescribed, or for the experience or feeling it causes. However, policy makers who focus solely on reducing nonmedical use are failing to appreciate the high opioid-related morbidity and mortality in pain patients receiving OPR prescriptions for medical purposes.

The incidence of nonmedical OPR use increased sharply in the late 1990s, peaking in 2002 with 2.7 million new nonmedical users. Since 2002, the incidence of nonmedical use has gradually declined to ~1.8 million in 2012 (64, 70) (**Figure 3**). Although the number of new nonmedical users has declined, overdose deaths, addiction treatment admissions, and other adverse public health outcomes associated with OPR use have increased dramatically since 2002.

A comparison of age groups of nonmedical OPR users to age groups suffering the highest rates of opioid-related morbidity and mortality suggests that strategies focused exclusively on reducing nonmedical OPR use are insufficient (**Figure 4**). Although past-month nonmedical use of OPRs is most common in teenagers and young adults between the ages of 15 and 24 (65), OPR overdose deaths occur most often in adults ages 45–54, and the age group that has experienced the greatest increase in overdose mortality over the past decade is 55–64 (15), an age group in which medical use of OPRs is common. Opioid overdoses appear to occur more frequently in medical OPR users than in young nonmedical users. For example, in a study of 254 unintentional opioid overdose decedents in Utah, 92% of the decedents had been receiving legitimate OPR prescriptions from health care providers for chronic pain (39).

Middle-aged women and the elderly are more likely than other groups to visit doctors with complaints of pain (4). The development of iatrogenic opioid addiction in these groups may explain why they have experienced the largest increase in hospital stays resulting from opioid user

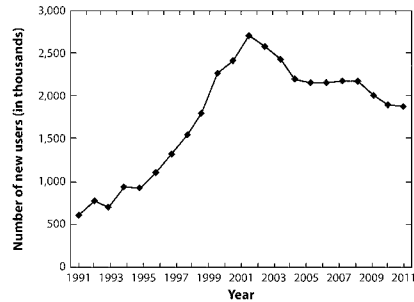


Figure 3

First-time nonmedical use of pain relievers. Source: 64, 70.

disorders since 1993 (56) (Figure 5). Over the past decade, white women ages 55–64 have also experienced the largest increase in accidental opioid overdose deaths (12, 15).

Opioid Addiction Is a Key Driver of Morbidity and Mortality

Accidental opioid overdose is a common cause of death in individuals suffering from opioid addiction (36). Although overdoses do occur in medical and nonmedical OPR users who are not

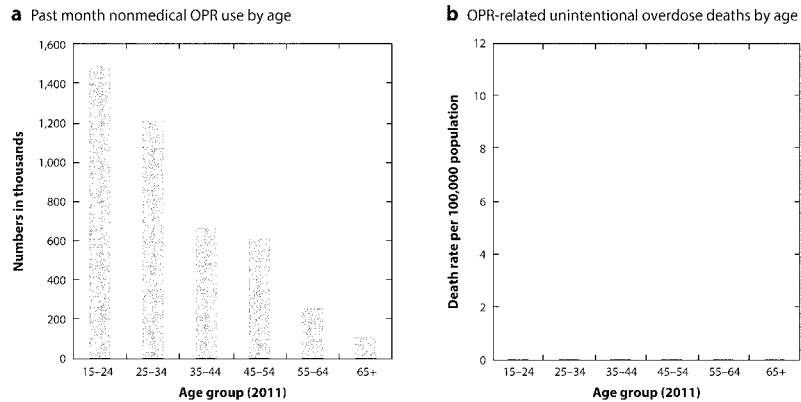


Figure 4

(a) Past month nonmedical OPR use by age versus (b) OPR-related unintentional overdose deaths by age. Abbreviation: OPR, opioid pain reliever. Sources: 58, 68.

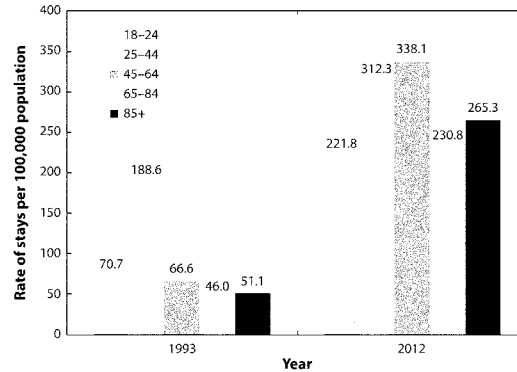


Figure 5

Rate of hospital inpatient stays related to OPR use by adult age group, 1993 and 2012. Source: 56.

opioid-addicted, consistent findings in samples of OPR overdose decedents show that deaths are most common in individuals likely to be suffering from opioid addiction. A study of 295 unintentional OPR overdose deaths in West Virginia found that four out of five decedents (80%) had a history of a substance use disorder (33). Another study found that among 254 opioid overdose decedents in Utah, about three-fourths (76%) had relatives or friends who were concerned about the decedent's misuse of opioids prescribed for pain (39).

The sharp increase in the prevalence of opioid addiction is a key driver of opioid-related morbidity and mortality. The misattribution of the opioid crisis to nonmedical use or abuse rather than to addiction has stymied efforts to address this crisis because it has led to a focus on policies to prevent such nonmedical use at the expense of greater resources committed to preventing and treating opioid addiction in both medical and nonmedical users.

PREVENTION STRATEGIES

This section organizes strategies for curbing the epidemic of opioid addiction into primary, secondary, and tertiary prevention. Although some specific interventions are discussed, we do not provide an exhaustive list. Rather, our purpose is to demonstrate that prevention strategies employed in epidemiologic responses to communicable and noncommunicable disease epidemics apply equally well when the disease in question is opioid addiction. Interventions should focus on preventing new cases of opioid addiction (primary prevention), identifying early cases of opioid addiction (secondary prevention), and ensuring access to effective addiction treatment (tertiary prevention).

Primary Prevention

The aim of primary prevention is to reduce the incidence of a disease or condition. Opioid addiction is typically chronic, life-long, difficult to treat, and associated with high rates of morbidity and mortality. Thus, bringing the opioid addiction epidemic under control requires effort to prevent new cases from developing.

Preventing addiction caused by medical exposure to OPRs. The incidence of iatrogenic opioid addiction in patients treated with long-term OPRs is unknown because adequately designed prospective studies have not been conducted. However, opioid use disorders appear to be highly prevalent in chronic pain patients treated with OPRs. A survey performed by Boscarino et al. of 705 chronic pain patients treated in specialty and primary care outpatient centers found that 26% met the *Diagnostic and Statistical Manual of Mental Disorders* (DSM) IV criteria for opioid dependence, and 35% met DSM V criteria for an opioid use disorder (6, 7). A systematic review of studies utilizing opioids for low back pain found that aberrant drug abuse-related behaviors suggestive of addiction occurred in up to 24% of patients on long-term OPRs (50). Many patients on long-term OPRs worry about dependence and addiction and express a desire to taper or cease opioid therapy (76).

To reduce the incidence of iatrogenic opioid addiction, health care professionals must prescribe opioids more cautiously for both acute and chronic pain. Unfortunately, the campaign to encourage OPR prescribing has left many health care providers with a poor appreciation of opioid risks, especially the risk of addiction, and an overestimation of opioid benefits. Despite these risks and the lack of evidence supporting long-term efficacy, OPR prescribing for chronic non-cancer pain increased over the past decade while use of nonopioid analgesics decreased (20). This pattern highlights the need for prescriber education that explicitly corrects misperceptions about OPR safety and efficacy. If clinicians treating pain more often substituted nonopioid analgesics and nonpharmaceutical approaches for OPRs, evidence suggests the incidence of opioid addiction would decline and outcomes for patients with chronic non-cancer pain would improve.

Many prescribers are unaware that evidence of long-term effectiveness for OPRs is lacking and that risks, in addition to addiction, include respiratory depression leading to unintentional overdose death; serious fractures from falls (71, 77); hypogonadism and other endocrine effects that can cause a spectrum of adverse effects (88); increased pain sensitivity (2); chronic constipation and serious fecal impaction (81); and chronic dry mouth, which can lead to tooth decay (79). Providing prescribers with accurate information about opioid risks and benefits could result in more informed risk/benefit appraisals. Indeed, one of the lessons learned from the nineteenth-century opioid addiction epidemic was that physicians were educable. By the early 1900s, aggressive opioid prescribing had become the hallmark of older, less-competent physicians (5).

Several states, including Iowa, Kentucky, Massachusetts, Ohio, Tennessee, and Utah, have passed mandatory prescriber education legislation (89). In addition, the US Food and Drug Administration (FDA) is requiring manufacturers of extended release and long-acting OPRs to sponsor educational programs for prescribers. Unfortunately, some of these educational programs, including those required by the FDA, imply that OPRs are safe and effective for chronic non-cancer pain instead of offering prescribers accurate information about OPR risks and benefits (84). It remains unclear whether or not educational programs such as these will reduce OPR prescribing for common conditions where risks of use are likely to outweigh benefits.

Some opioid manufacturers have reformulated OPRs to make them more difficult to misuse through an intranasal or injection route. These so-called abuse-deterrent formulations (ADFs) may offer safety advantages over easily snorted and injected OPRs, but they do not render them less addictive. Opioid addiction, in both medical and nonmedical OPR users, most frequently develops through oral use (85). Some opioid-addicted individuals may transition to intranasal or injection use, but most continue to use OPRs orally (47). Thus, ADFs should not be considered a primary prevention strategy for opioid addiction.

In 2013, the New York City Department of Health and Mental Hygiene released emergency room guidelines on OPR prescribing (55). Recommendations included in the guidelines call for substituting nonopioid analgesics when possible, avoiding use of extended-release OPRs, and

limiting the supply to three days. Reducing patient exposure to OPRs and reducing the supply of excess OPRs in the homes of discharged patients may be effective strategies for preventing opioid addiction that can occur from both medical and nonmedical OPR use.

Preventing addiction caused by nonmedical exposure to OPRs. Individuals who use OPRs nonmedically are at risk for developing opioid addiction. Thus, efforts to reduce nonmedical use are an important primary prevention strategy. Adolescents and young adults who experiment with nonmedical use are most likely to obtain OPRs for free from friends or family members who had received a legitimate prescription (70). This information suggests that more cautious prescribing is required to prevent nonmedical use of excess OPRs. Unused OPRs in medicine chests should be immediately discarded or returned to a pharmacy, which became permissible in October 2014 after the Drug Enforcement Administration made a federal regulatory change (82).

Although OPRs have an abuse liability similar to that of heroin (17), they are commonly perceived as less risky. Seventy-three percent of eighth graders surveyed in 2013 perceived occasional use of heroin without a needle as high risk, but only 26% perceived occasional use of Vicodin as high risk (41). Eighth graders also perceived occasional Vicodin use as less risky than occasional marijuana use, less risky than smoking 1–5 cigarettes per day, and less risky than moderate alcohol use.

Individuals who perceive the risk of nonmedical OPR use to be low may be more likely to misuse OPRs. A 2004 survey found that college students who perceive a low level of risk from OPRs were 9.6 times more likely to use OPRs nonmedically, as compared with those who perceive these medications as harmful (3). Although the ability for causal inference from this type of cross-sectional survey is limited, this finding suggests that social marketing campaigns designed to increase perceived harmfulness of OPRs may be an effective prevention strategy.

Secondary Prevention

The aim of secondary prevention is to screen for a health condition after its onset but before it causes serious complications. Efforts to identify and treat opioid-addicted individuals early in the course of the disease are likely to reduce the risk of overdose, psychosocial deterioration, transition to injection opioid use, and medical complications.

Physicians are frequently the source of OPRs for opioid-addicted medical and nonmedical users (43). Contacts with medical professionals present valuable opportunities for early identification of opioid addiction. However, detection of opioid addiction in OPR users can be very difficult. Opioid-addicted chronic pain patients may demonstrate aberrant drug-related behaviors, such as presenting for early refills. However, some opioid-addicted pain patients, especially those prescribed high doses, may not demonstrate drug-seeking behavior. Opioid-addicted individuals receiving OPR prescriptions are often reluctant to disclose their concerns about addiction with prescribers because they fear being judged, being cut off from a legitimate supply, or being labeled as malingerers for feigning pain.

The difficulty of diagnosing opioid addiction in individuals motivated to conceal their condition suggests that prescribers should seek collateral information before prescribing OPRs. Urine toxicology can be used to verify a patient's self-reported drug ingestion history (53). However, urine toxicology of patients on long-term OPRs is not a reliable strategy for identifying opioid addiction. Urine toxicology cannot determine if a patient is taking extra doses or if a patient is using OPRs by an intranasal or injection route.

Opioid-addicted individuals may receive OPR prescriptions from multiple providers, a practice referred to as "doctor shopping." Doctor shoppers can be identified through use of state

prescription drug monitoring programs (PDMPs). Some state PDMPs send unsolicited reports to the medical providers of doctor shoppers. Research suggests that unsolicited reports increase prescribers' ability to detect opioid addiction, sometimes prompting actions such as coordinating care with other providers and modifying their own prescribing practices, as well as screening and referring for addiction treatment (78).

Prescribers in most states can consult their state PDMP before prescribing OPRs. PDMPs may be especially useful in emergency rooms and other settings where opioid-addicted individuals feign pain to obtain OPRs. Too often, however, patients identified as doctor shoppers are simply turned away, without hospital staff attempting to link these patients to addiction treatment services. Efforts must be made to help these clinicians understand that drug-seeking patients are suffering from the chronic, life-threatening disease of opioid addiction.

One challenge to PDMP effectiveness has been the low rate of provider use of these data (48). To increase prescriber utilization, Kentucky, Tennessee, and New York passed legislation mandating that prescribers check the PDMP before prescribing controlled substances. Data from these states indicate that PDMP utilization increased rapidly subsequent to the mandate, which correlated with declines in opioid prescribing (KY, TN, NY) and a sharp drop in visits to multiple providers (TN, NY) (35).

Tertiary Prevention

Tertiary prevention strategies involve both therapeutic and rehabilitative measures once a disease is firmly established. The goal of tertiary prevention of opioid addiction is to prevent overdose deaths, medical complications, psychosocial deterioration, transition to injection drug use, and injection-related infectious diseases. Doing so is accomplished mainly by ensuring that opioid-addicted individuals can access effective and affordable opioid addiction treatment.

Opioid addiction treatment. The need for opioid addiction treatment is great and largely unmet. According to the NSDUH, an estimated 2.1 million Americans are addicted to OPRs, and 467,000 are addicted to heroin (70). Unfortunately, these estimates exclude many opioid-addicted pain patients because NSDUH participants are told by surveyors that "we are only interested in your use of prescription pain relievers that were not prescribed for you or that you used only for the experience or feeling they caused" (67, p. 124).

In 2005, there were an estimated 10 million chronic pain patients receiving daily, long-term treatment with OPRs (8). The continuing increase in opioid consumption from 2005 to 2011 (42) suggests that the number may now exceed 10 million. Applying the prevalence estimates of DSM IV opioid dependence found by Boscarino et al. (6) in pain patients taking long-term opioids would indicate that an additional 2.5 million chronic pain patients may be opioid-addicted. Thus, the total number of Americans suffering from opioid addiction may exceed 5 million.

Treatment of opioid addiction includes pharmacotherapies and psychosocial approaches, including residential treatment, mutual-help programs (e.g., Narcotics Anonymous), and 12-Step treatment programs. These modalities may be used as stand-alone interventions or in combination with pharmacotherapy. Psychosocial opioid addiction treatment approaches show value and are an important treatment option (63). However, research with greater specificity and consistency is needed to better evaluate outcomes.

Pharmacotherapies for opioid addiction include agonist maintenance with methadone and partial-agonist maintenance with buprenorphine and antagonist treatment with naltrexone, which is available in a monthly injection. Methadone and buprenorphine work by controlling cravings. Naltrexone works by preventing opioid-addicted individuals from feeling the effects of opioids.

Naltrexone may be helpful in highly motivated and carefully selected patients. However, patients treated with naltrexone may be at increased risk of overdose death should relapse occur (23).

Multiple well-designed randomized controlled trials provide strong evidence that buprenorphine maintenance and methadone maintenance are safe and effective treatments for opioid addiction (30, 40, 46, 49, 74, 75). Both buprenorphine and methadone treatment are associated with reduced overdose risk and improved maternal and fetal outcomes in pregnancy (19, 44, 51, 72). Despite strong evidence supporting the use of buprenorphine and methadone, fewer than 1 million Americans are receiving these treatments (87).

Methadone poses a substantially greater risk of respiratory depression than does buprenorphine and can be obtained only from licensed opioid treatment programs (OTPs). The lack of OTPs in many communities presents a major challenge to expanding access to methadone. In contrast, buprenorphine, a partial opioid agonist, has a better safety profile than does methadone and can be prescribed in an office-based setting (26). Barriers to accessing buprenorphine include federal limits on the number of patients a physician may treat, ineligibility of nurse practitioners to prescribe it, and inadequate integration of buprenorphine into primary care treatment. Access to buprenorphine treatment could be expanded if the federal government eased or remove regulatory barriers.

Harm-reduction approaches. Tertiary prevention strategies also include harm-reduction approaches to improving health outcomes and reducing overdose deaths. In the subset of opioid-addicted individuals who are heroin injection drug users, evidence suggests that access to syringe exchange programs can prevent HIV infection (22). These efforts have been less effective at preventing hepatitis C infection, which is increasing rapidly in young, white IDUs (32).

Expanding access to naloxone, an opioid overdose antidote, can prevent overdose deaths by reversing life-threatening respiratory depression. In the 1990s, syringe exchange programs began distributing naloxone to injection drug users for the purpose of rescuing peers. Evidence shows that clients of syringe exchange programs demonstrated the ability to successfully reverse overdoses when they had been provided with naloxone and training (73). In addition, providing family members of opioid-addicted individuals and nonparamedic first responders with naloxone may be an effective strategy for rescuing overdose victims (21, 90). At present, there are more than 188 community-based naloxone distribution programs in 15 states and the District of Columbia (11).

CONCLUSION

The increased prevalence of opioid addiction, caused by overprescribing of OPRs, has led to a parallel increase in opioid overdose deaths. Efforts to address this crisis that focus exclusively on reducing nonmedical OPR use have been ineffective. Middle-aged and elderly individuals commonly exposed to OPRs for pain treatment have experienced the largest increase in rates of opioid-related morbidity and mortality. Recognition that opioid addiction in both medical and nonmedical users is a key driver of opioid-related morbidity and mortality will result in a more effective response to this public health crisis. Just as public health authorities would approach other disease outbreaks, efforts must be made to reduce the incidence of opioid addiction, identify cases early, and ensure access to effective treatment.

Preventing opioid addiction requires strategies that foster more cautious and selective OPR prescribing. However, if prescribing is reduced without also ensuring access to addiction treatment, the opioid overdose death rate may remain at a historically high level and the use of heroin may continue to increase. Coordinated efforts from federal agencies, state agencies, health care insurers, and health care providers are required to address the needs of millions of Americans now struggling with this chronic, life-threatening disease.

DISCLOSURE STATEMENT

Dr. Alexander is Chair of the FDA's Peripheral and Central Nervous System Advisory Committee, serves as a paid consultant to IMS Health, and serves on an IMS Health scientific advisory board. This arrangement has been reviewed and approved by Johns Hopkins University in accordance with its conflict of interest policies. Ms. Hwang is a current ORISE Fellow at the FDA.

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