STATEMENT OF
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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 aNational 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. . the

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, PhD 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 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

[1] Edlund MJ et al, Patterns of opioid use for chronic noncancer pain in the Veterans Health Administration from 2009 to 201. PAIN 155(2014) 2337-2343

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 information 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 posttraumatic 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 decision making, 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-threating 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.