STATEMENT OF WITNESS
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DEPARTMENT OF VETERANS AFFAIRS (VA)
BEFORE THE
SENATE COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

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Good morning, Chairman Johnson, Ranking Member Carper, and Members of the Committee. Thank you for the opportunity to speak about the quality and culture of care at the Department of Veterans Affairs Medical Center (VAMC) in Tomah, Wisconsin. I look forward to sharing with you the progress we have made with patient safety, employee engagement, leadership changes, and improvements in opioid safety and pain management. I am accompanied today by Dr. Gavin West, Senior Medical Advisor, Clinical Operations.

Since our March 30, 2015, hearing, we have worked closely with the Wisconsin Congressional delegation and this Committee to investigate harms experienced by Veterans served by the Tomah VA Medical Center (VAMC) and to hold individuals accountable. In addition, we focused efforts on improvements in mental health, pain management, and culture and working environment. Identifying and addressing challenges is vital to our mission, as is responding to the needs of our dedicated employees.

Tomah VAMC

On January 15, 2015, a physician and nurse practitioner were relieved of their clinical care duties and the ability to prescribe any medications pending the outcome of all investigations. In response to whistleblower allegations of unsafe clinical care and prohibited personnel practices at the Tomah VAMC, on January 23, 2015, Dr. Carolyn Clancy, who was the Interim Under Secretary for Health at the time, charged a clinical review team comprised of leading experts outside the facility and network to assess practice patterns, controlled substance prescribing habits, and administrative

interactions between subordinates and clinical leadership related to opioid prescribing practices.

On March 10, 2015, VA released key findings and recommendations of its initial clinical review into opioid prescription practices at the Tomah VAMC. The team made specific findings relating to overall opioid utilization at the Tomah VAMC and found that an apparent culture of fear at the facility compromised patient care and impacted staff satisfaction and morale. Based on these preliminary findings, the team recommended that VA consider a more in-depth evaluation of the clinical and administrative practices at the Tomah VAMC. Additional cases were brought to the review team's attention, with a second in-depth clinical review being conducted by Lumetra, an external quality improvement organization, beginning on March 11, 2015. Investigators from the independent VA Office of Inspector General (OIG) and the Department of Justice's Drug Enforcement Agency have also been on site.

We are deeply concerned and distressed about the allegations that employees who sought to report deficiencies at the Tomah VAMC were ignored, or worse, intimidated into silence. VA will not tolerate intimidation or suppression of concerns. An administrative review team examined allegations of retaliation against employees and other accountability issues related to Tomah VAMC leadership. The clinical review teams identified patient safety concerns for some patients at Tomah VAMC based on opioid prescribing practices outside generally-accepted standards of care. Two physicians were terminated, and two other personnel resigned.

In order to create a more transparent culture and improve communication with Tomah VAMC employees, leadership has taken a number of actions, including town hall meetings, supervisory forums, and expanded all-employee communications. These were to provide staff support and guidance on how employees can directly and confidentially contact and communicate with the team conducting the investigations. In addition to actions taken to address culture and communication, the Tomah VAMC initiated a number of actions to address opioid/pain management issues. Providers transitioned to using an expanded urine drug screen, and facility clinical leadership is updating their pain management policies. Electronic patient record tools were deployed system wide in March 2015 to make pain management information, including adherence

to recommended practices, individual risks associated with other medications and clinical problems, and impact on pain scores, more easily accessible during patient visits. The facility hosted a regional conference on improved pain management, led by national experts, in June 2015.

We have seen tangible improvements; from January 2015 to December 2015, there has been a 16-percent reduction in the number of patients receiving opioids and benzodiazepines together across VA. During the same time frame, Tomah VAMC has achieved a 27-percent reduction.

Veterans Health Administration (VHA)

As the Nation's largest integrated health care system, VA recognizes that challenges confronting any facility may reflect issues occurring throughout VA as well as in health care across the U.S. Chronic pain has an especially profound impact on the Veteran population. Almost 60 percent of returning Veterans from service and more than 50 percent of older Veterans in the VA health care system live with some form of chronic pain. Moreover, 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 can impact their physical abilities, emotional health, and central nervous system. VA is committed to reducing overreliance on opioid medicines, especially in light of the severe negative consequences many patients on opioids risk.

Current VHA Pain Management Collaboration

To implement effective management of pain, VHA's National Pain Management Program oversees several work groups. A National Pain Management Strategy Coordinating Committee includes representatives from 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.

The Opioid Safety Initiative (OSI) Toolkit Task Force has published and promoted 15 evidenced-based documents and presentations to support provider education in OSI through Academic Detailing. More information on the OSI Toolkit can be found at the following 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 DoD that aim to standardize high-quality pain care across DoD and VHA.

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 and remains committed to using non-pharmacologic measures as well as medications safely. 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 safety improvement in the use of opioids, both in terms of the number of Veterans on chronic opioid therapy and the absolute doses. The Specialty Care Access Network-Extension for Community Healthcare Outcomes (SCAN-ECHO) and the OSI have been designed to integrate with our Academic Detailing which is a proven method in changing clinician behavior by providing educational outreach to address 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.

Rigorous investigations take time, but we did not wait for the completion of the investigation to take action to improve care both at Tomah VAMC and across the system. 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 on Drug Abuse, was published in the journal *PAIN*. 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 the following:

- About 50 percent of Veterans with chronic non-cancer pain in this cohort received an opioid as part of treatment;
- 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);
- The daily opioid dose in VA is generally modest, with a median of 20 Morphine Equivalent Daily Dose (MEDD);
- 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.

By virtue of VA's central national role in medical student education and residency training of primary care physicians and providers, VA will be playing a major role in this nationwide transformation 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 Joint Incentive Fund (JIF) training programs with DoD, and dissemination of the OSI Toolkit.

The Opioid Safety Initiative (OSI)

OSI was implemented nationwide in August 2013. OSI's 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 OSI from Quarter 4, Fiscal Year (FY) 2012 (beginning in July 2012) to Quarter 2, FY 2016 (ending in March 2016) are as follows:

- 151,982 fewer patients receiving opioids (679,376 patients to 527,394 patients, a 22-percent reduction).
- 51,916 fewer patients receiving opioids and benzodiazepines together (122,633 patients to 70,717 patients, a 42-percent reduction);
- 94,045 more patients on opioids that have had a urine drug screen to help guide treatment decisions (160,601 patients to 254,646, a 37-percent increase);
- 122,065 fewer patients on long-term opioid therapy (438,329 to 316,264, a 28-percent reduction);

Also, the overall dosage of opioids is decreasing in the VA system as 18,883 fewer patients (59,499 patients to 40,616 patients, a 32-percent reduction) are receiving greater than or equal to 100 MEDD, a figure associated with greater overdose risk[1]. It is important to note that these desired results of the OSI have been achieved during a time in which VA has seen an overall growth of 136,944 patients (3,959,852 patients to 4,096,796 patients, a 3-percent increase) that have utilized VA outpatient pharmacy services.

The OSI dashboard metrics indicate that overall trends are moving steadily in the desired direction. OSI is being implemented in a 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.

VA expects this trend to continue as it renews its efforts to promote safe pain management therapies. VA intends to implement safe opioid prescribing training for all prescribers; 70 percent of prescribers have received training to date.

Psychotropic Drug Safety Initiative

The Psychotropic Drug Safety Initiative (PDSI) is a VA nationwide psychopharmacology quality improvement (QI) program that was launched in December 2013, with the aim of improving the safety and effectiveness of psychopharmacologic treatment across VA. The initial Phase 1 program broadly looked across multiple

[1]Liang Y1, Turner BJ2. Assessing risk for drug overdose in a national cohort: role for both daily and total opioid dose? J Pain. 2015 Apr;16(4):318-25. doi: 10.1016/j.jpain.2014.11.007. Epub 2014 Dec 5. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4385393/

classes of medications and mental health diagnoses. Facilities, on average, identified 3 prescribing measures from among the 20 that served as the focus for their local QI efforts during Phase 1 (priority measures). Facilities were required to prioritize any measure where local performance was a significant outlier compared to the rest of the VA system (defined as local score > 2 standard deviations worse than the national score), but were otherwise given the freedom to identify their own local priorities. Key components of the program implemented during Phase 1 included the following:

- Providing quarterly data on national, Veterans Integrated Service Network (VISN), and facility-level performance on prescribing measures to participants;
- Facilitating clinical review of treatments for Veterans who may benefit from improvement in their psychotropic medication regimen via actionable patient lists updated daily on the PDSI Clinical Management Dashboard;
- Providing feedback and technical assistance to VISNs and facilities for QI action planning;
- Coordinating a national QI learning collaborative; and
- Developing and disseminating training and educational resources.

Since its implementation, the PDSI program has had a robust and positive impact on the care of Veterans. Out of the 20 prescribing metrics tracked in the initial phase of the program, 16 showed improvement in the national score.

There are several areas of prescribing that showed especially strong improvements. Across the system we have decreased use of potentially harmful medications in patients with Posttraumatic Stress Disorder (PTSD), including decreased use of benzodiazepines, antipsychotics, and the use of complex, multiple-drug regimens. We have also decreased the use of benzodiazepines among vulnerable populations, such as Veterans with PTSD or dementia and the elderly, as well as decreased the use of complex, multiple-drug regimens for patients with depression. We have also successfully increased the use of evidence-based medications for treatment of substance use disorders, particularly in Veterans with alcohol and opioid addiction. These improvements have directly and positively impacted the care of thousands of Veterans.

Overdose Education and Naloxone Distribution (OEND)

VA has also undertaken a national initiative to make overdose education and naloxone rescue kits available to patients at risk of accidental or intentional overdose. Naloxone can reverse an opioid overdose, preventing overdose death and morbidity when administered in a timely manner. Distribution of overdose rescue training and naloxone kits is a novel intervention within health care settings, and it is being rapidly adopted by VA. To date, 3,945 VA providers have begun prescribing these kits to at-risk patients, with over 23,330 patients receiving training and kits. Additionally, 172 opioid overdose reversals have been voluntarily reported with the naloxone VA prescribed, demonstrating the potential lifesaving effects of these efforts.

VA has developed a predictive model and clinical decision-support tool to identify patients with opioid prescriptions at risk of suicide-related events and overdose. This Stratification Tool for Opioid Risk Mitigation is available nationally, and it estimates the likelihood of an overdose or suicide event in the next year, providing patient-tailored recommendations for risk mitigation and non-opioid pain management options. VA has continued its efforts to ensure that effective substance use disorder treatments are available for patients with substance use disorders, knowing that they have an elevated risk for suicide and overdose. Greater engagement in VHA substance use disorder programs is associated with lower suicide attempt risk and reduced criminal behavior in Veterans initiating substance use disorder treatment. VHA continues to increase availability of specialty substance use treatment, increasing the number of patients treated per year with specialty treatment services and with opioid antagonist treatment for opioid use disorders.

National Take-Back Initiative

In September 2014, the Drug Enforcement Administration (DEA) published in the Federal Register a final rule, effective October 9, 2014, to implement the Secure and Responsible Drug Disposal Act of 2010. This rule provides three voluntary methods for ultimate users (e.g., Veterans) to dispose of their unwanted/unneeded medications in a secure and responsible manner: 1) Mail Back Packages, 2) On-site Collection Receptacles, and 3) Take Back Events. VA has been a leader in implementing these options for Veterans. We have on-site receptacles in over 70 locations and mail-back

envelopes available at all facilities. Services have been actively marketed to Veterans through the use of facility flyers and with information on MyHealth*e*Vet and on the VA Pharmacy MedSafe website. Both Veterans and staff report a high level of satisfaction with this service, and as of May 1, 2016, approximately 27,000 pounds, almost 14 tons, of unwanted/unneeded medication have been collected and destroyed in an environmentally responsible manner. Removal of this medication from Veterans' homes reduces the risk of diversion as well as intentional and unintentional overdoses and poisonings.

Accountability

In January 2015, the *Milwaukee Journal Sentinel* and other publications ran an article about over-prescription of painkillers by the then-Chief of Staff of the Tomah VAMC, who is a psychiatrist, and cited several former Tomah employees' complaints about retaliatory behavior after they questioned the Chief of Staff's prescribing practices. The article also cited an unpublished March 2014 VA OIG "administrative closure" report finding the Chief of Staff's prescriptions were "at considerable variance compared with most opioid prescribers" and "raised potentially serious concerns." In response to this, we acted quickly to prohibit the Chief of Staff and an affiliated nurse practitioner from providing care to Veterans and initiated a comprehensive evaluation of the quality of the care they provided. The then-interim Under Secretary for Health ordered a series of three clinical reviews to assess practice patterns, prescribing habits, and staff interactions at Tomah. In reports issued between March and August 2015, these review teams found that the Chief of Staff's prescriptive practices were potentially unsafe and that an apparent culture of fear existed at the Tomah facility which compromised patient care and damaged staff satisfaction and morale. Simultaneously, the VA Office of Accountability Review began a series of administrative investigations into alleged mismanagement by Tomah VAMC leadership. Those reviews led to a number of leadership changes at the Tomah facility. The Chief of Staff lost his clinical privileges and was removed from Federal employment; his removal is currently pending appeal. The former Medical Center Director and Associate Director both resigned. Victoria Brahm is the Acting Tomah VAMC Director. Ms. Brahm and her predecessor,

John Rohrer, worked closely with facility leaders, union leaders, employees, and external stakeholders (including Veterans Service Organizations) to ensure that ongoing investigations did not disrupt clinical care and that all voices were heard.

Organizational Excellence

VA acknowledges its failures in the Tomah VAMC and is committed to preventing situations like this in the future. VA has strategically aligned specific program offices to ensure that our Nation's Veterans receive the highest quality health care. These aligned offices were incorporated into the Office of the Deputy Under Secretary for Health for Organizational Excellence. This new office brings together vital portions of VA to focus on assessing and improving quality and safety and to provide the field and leadership with analytics and tools to assess how we are performing as an organization. The office synthesizes information from internal and external oversight activities to promote a strong, ethical, and just culture that builds trust and confidence in Veterans health care. The office aims to achieve continuous improvement in health care system performance by integrating oversight, compliance, and accountability functions. The office conducts internal oversight activities such as investigations, audits, risk assessment, and business compliance in accordance with VA policy and industry standards and proactively identifies system vulnerabilities and manages risk across clinical, administrative, business, and financial domains in order to improve organizational efficiency and effectiveness. Because of this new office's oversight and safeguards, VA is better positioned to mitigate the risk events like those that took place in the Tomah VAMC.

Actions since the 100-Day Plan

Over the course of the last year, the Tomah VAMC has undergone many changes and continues to make improvements. Most recently, the Tomah VAMC has taken a series of actions during a 100-day period (November 27, 2015, through March 6, 2016) to enhance the Veteran experience within the medical center and create an environment of sustainable accountability that rebuilds trust with Veterans and the American people. The Veteran experience is at the forefront of all we do and cannot be

decoupled from the employee experience. Improving the employee experience will positively impact the Veteran experience. We continue to strive to create an organization that both Veterans and employees can be proud to call "MyVA." Tomah VAMC leadership has expanded upon initial efforts and delivered a shared strategic direction for the medical center in January. These objectives are designed to improve and standardize the patient experience, making Tomah VAMC the facility of choice for Veterans:

- The FY 2015 All Employee Workforce Satisfaction and Organizational Climate Survey for Tomah VAMC reported nearly all scores were below the national average. Surveys to date demonstrate improvement in 8 of 10 survey areas, meeting or exceeding the national average in half.
- Employee Town Halls are conducted monthly. MyVA initiatives are delivered by leadership to staff members monthly. More than 15 Employee Listening Sessions were held during the 100-Day Plan; they are now conducted monthly.
- Medical center leadership is committed to instituting an Employee Renewal Center to assist in combatting compassion fatigue. The Center opened to staff on Monday, May 16, 2016. This non-clinical area has been dubbed by employees as "R Place."
- Resources have been provided for managers to create a Personal Development Plan (PDP). More than 85 managers and local American Federation of Government Employees (AFGE) officers have completed a PDP during the "Leaders Developing Leaders" curriculum.
- Patient Centered Care training continues for new hires and staff. The goal is for 75 percent of staff to be trained by the end of the year and to create awareness and unity among staff members by sharing the patient perspective.
- VA's Office of Resolution Management was on site February 23-25, 2016, and held supervisor training sessions and two all-employee training sessions on "Conflict Management" and "Alternative Dispute Resolution."

VA has also taken several steps to focus on the importance of and improvement of leadership-employee interactions. VA recognizes that accountability, visibility, and communication are central for effective relationships between supervisors and employees. VA has emphasized the importance of, and has tracked rounding and monthly staff meetings. In January and February 2016, supervisors met more than 90 percent of rounding opportunities. Re-establishing a culture of trust within the medical center was also a significant priority. During the 100-Day Plan, we provided

Psychological Safety Training on Harassment and Workplace Bullying to supervisors and frontline staff. Additionally, 85 managers, supervisors, and local AFGE officers completed the “Leaders Developing Leaders” curriculum.

An additional part of this effort was to educate supervisors and managers on increasing the quality of staff evaluations through training at the Supervisor’s Forum, and this will continue during an upcoming 3-day supervisors’ course. Previous results from All Employee Surveys noted a lack of staff recognition and praise. To address this, the “Employee of the Quarter” program was increased to “Employee of the Month” with a panel of frontline employees managing the process and determining who is selected. Other efforts include a “Recognition Toolkit” created for supervisors and non-supervisors. More Patient Experience Cards were displayed and shared, and employees were recognized in the Acting Medical Center Director’s weekly message. “Management by Walking About” is practiced by medical center leadership consistently walking through the medical center and being available for impromptu discussions with employees and Veterans. Also, in January 2016, the Acting Associate Director for Patient Care Services began hosting quarterly Nurse Town Hall Meetings.

Whistleblower Protection

VA recognizes the important role that whistleblowing plays in bringing significant issues to light. I was and am personally invested in ensuring that the quality of care at Tomah VAMC is the best available and that any and all circumstances that led to problems at the Tomah VAMC have been diagnosed and fixed. In addition to the many formal feedback mechanisms VHA has built into our system, we need and want all employees and Veterans to feel empowered to provide a first-hand account of their experiences so that we can identify and rectify any problems. The underlying purpose of whistleblower protection rules is to encourage the candid disclosure of information about problems so that deficiencies are corrected, and unsafe or unlawful behavior is quickly rectified.

There are legal disciplinary options for supervisors who retaliate against whistleblowers; they exist to support the primary focus on the flow of information, including information on quality, safety, or process improvement. VA is fully committed

to correcting deficiencies in its processes and programs and to ensuring fair treatment for whistleblowers that bring these deficiencies to light. Secretary McDonald consistently communicates his vision of “sustainable accountability,” which he describes as a workplace culture where VA leaders provide the guidance and resources employees need to successfully serve Veterans, and employees are empowered and encouraged to inform VA leaders when challenges hinder their ability to succeed. All VA employees should feel safe sharing what they know, for the benefit of Veterans and as good stewards of the taxpayers’ money.

The Department has taken steps to improve how we address operational deficiencies and protect whistleblowers from retaliation. In July 2014, I reorganized and assigned new leadership to the VA Office of the Medical Inspector (OMI). OMI moved quickly to ensure that whistleblower disclosure allegations were investigated objectively, thoroughly, and promptly. Since then, OMI has completed more than 70 initial and supplemental investigation reports in 2015. When an investigation substantiates the whistleblower’s disclosure allegations, OMI and Office of Special Counsel (OSC) work closely to track the status of corrective actions to completion.

VA and OSC also created a process that provides for prompt corrective action, referred to as the “expedited process,” with relief provided to whistleblowers within who have been retaliated weeks of referral, instead of months. This approach allows OSC and VA to work together to reduce duplicate investigations and to quickly protect whistleblowers from retaliation. As of May 2015, VA had received 28 expedited cases and successfully resolved 19 cases. Resolved cases have taken an average of 30 to 60 days to complete. Once cases are resolved under the expedited process the cases are forwarded to the Office of Accountability Review to determine if discipline is appropriate. VA has also improved its collaboration with OSC by training employees on investigating whistleblower retaliation cases and increasing the number who can work these cases.

VA understands that we can also improve on the timeliness of discipline for individuals found responsible for retaliation. One approach is for Congress to support OSC at a level that enables OSC to hire more investigators to complete this work. This would allow VA’s limited investigative assets to focus more in VA’s areas of expertise.

Because it is extremely important that VA hold its employees accountable, if they have retaliated against a whistleblower we welcome OSC's additional assistance on this front.

VA senior leaders, including myself, have made it their practice to meet with whistleblowers when traveling, and to engage with them to identify problems and propose solutions. I have personally participated in the public recognition of several whistleblowers, thanking them for their role in improving Veteran outcomes. This is to acknowledge the critical role whistleblowers play in improving the quality, safety, and effectiveness of VA programs, and to model to supervisors VA-wide the engaged, open, and accepting behavior they should exhibit when subordinates express concerns.

VA is still working toward the full culture change we must achieve to ensure that all employees feel safe disclosing problems, and that those who engage in retaliatory behavior are held promptly and meaningfully accountable. VA continues to work with whistleblowers, OSC, and Congress to resolve these issues, and we remain deeply committed to these endeavors.

Mr. Chairman, because of the events that took place at Tomah VAMC, VA has improved how we manage prescriptions nationwide. We will continue to strive for better employee engagement and accountable leadership, all in the name of fulfilling our mission to serve Veterans. I look forward to answering any questions you or the Committee may have.