STATEMENT OF
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Good morning, Chairwoman Brownley, Ranking Member Dunn, and Members of the Subcommittee. Thank you for inviting us here today to present our views on several bills that would affect VA health programs and services. With me today are Dr. Tracy Gaudet, Director, Office of Patient Centered Care, Veterans Health Administration, and Dr. Larry Mole, Chief Consultant, Population Health, Veterans Health Administration.

We are providing views on H.R. 100, H.R. 712, H.R. 1647, H.R. 2191, and four draft bills relating to Suicide Prevention and Mental Health Memoranda between VA and non-VA entities, VA Suicide Prevention Coordinators, Congressional notifications of Veteran suicides and attempts, and a report on VA's Whole Health Transformation.

H.R. 100 – Veteran Overmedication and Suicide Prevention Act of 2019

H.R. 100 would direct VA to seek to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine (NASEM) to conduct an independent review of the deaths by suicide of certain covered Veterans during the previous 5 years, regardless of whether such deaths have been reported by the Centers for Disease Control and Prevention (CDC).

The review would include the following:

- a description of and the total number of Veterans who died by suicide, violent death, and accidental death;
- a comprehensive list of prescribed medications and legal and illegal substances as annotated on toxicology reports of these Veterans;
- a summary of medical diagnoses by agency physicians or through programs of the agency that led to the prescribing of medications in the comprehensive list in cases of posttraumatic stress disorder (PTSD), traumatic brain injury, military sexual trauma, and other anxiety and depressive disorders;
- the number of instances in which one of these Veterans was concurrently on multiple medications to treat these disorders;
- the number of these Veterans who were not taking any medication prescribed by VA or through a VA program;
- the percentage of these Veterans who received a non-medication first-line treatment compared to the percentage who received medication only;
- the number of instances in which a non-medication first-line treatment was attempted and determined ineffective, which then led to prescribing a medication;
- a description and example of how VA determines and updates the clinical guidelines governing medication prescribing;
- an analysis of VA's use of pain scores during clinical encounters and an evaluation of the relationship between the use of such measurements and the number of Veterans on multiple medications;

- a description of VA efforts to maintain mental health professional staffing levels;
- the percentage of Veterans with combat experience or trauma related to combat;
- identification of VA medical facilities with markedly high prescription rates and suicide rates;
- an analysis of collaboration by VA programs with state Medicaid agencies and the Centers for Medicare and Medicaid Services;
- an analysis of the collaboration between VA medical centers (VAMC) with medical examiners' offices or local jurisdictions to determine Veteran mortality and cause of death;
- an identification and determination of a best practice model to collect and share death certificate data;
- a description of how data relating to death certificates of Veterans is collected, determined, and reported by VA;
- an assessment of any apparent patterns; and
- recommendations for further action to improve the safety and well-being of Veterans.

Not later than 180 days after entering into the agreement, NASEM will complete its review and provide a report to the Secretary containing the results of the review. Not later than 30 days after completion of NASEM's review, the Secretary will submit to the Committees on Veterans' Affairs of the House of Representatives and Senate a report on the results of the review, which will also be publicly available.

VA does not support this proposed legislation. This bill would be redundant because of the current work occurring with NASEM. The Joint Explanatory Statement for the Consolidated Appropriations Act of 2018 stated that VA's appropriations included $500,000 for NASEM to assess the potential overmedication of Veterans during Fiscal Years (FY) 2010 to 2017 that led to suicides, deaths, mental disorders, and combat-related traumas. This protocol can be easily augmented to examine additional psychotropic medications as needed before the study is funded for implementation without additional legislation. In addition, hiring and workforce management for mental health professionals is currently ongoing and being tracked and is easily reportable without legislative action.

Section 2(a)(1) would require that NASEM use data that would likely provide misleading results. VA becomes aware of most suicide deaths through data obtained from the National Death Index established by CDC's National Center for Health Statistics. However, these data are available only after a delay, so the most recent information on individuals dying from suicide would not be available within the bill's required timeframe. CDC data provides the most comprehensive source for determining Veterans' causes of death; utilizing other sources would result in incomplete identification of covered Veterans who died from suicide. Therefore, requesting a review of deaths by suicide regardless of whether these deaths have been reported to CDC, as required by section 2(a)(1), could lead to inaccurate or misleading data results.

Much of the data required to be collected under section 2(a)(2) would be difficult to obtain and accurately interpret. Physicians are not the only providers who prescribe

medications, toxicology reports may not always be done following death by suicide, and obtaining complete and accurate information about what is (or is not) taken by the patient outside VA would be challenging.

Section 2(a)(3) discusses the compilation of data, and to the extent that any of these data could be re-identified to a specific Veteran, then an analysis of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Act and any other applicable laws or regulations meant to protect personal health information would be required.

Finally, the deadline for completion and review of the report in section 2(a)(4) is unrealistic. It does not seem possible to provide the sheer volume of data the bill demands and have NASEM analyze it within 180 days, particularly given that probably hundreds of different offices at the local and state levels would have to be contacted to provide certain information. Requiring VA's response within 30 days of NASEM's findings could also limit our ability to thoughtfully and carefully review the evidence they present, which could limit the utility of this information.

H.R. 712 – VA Medical Cannabis Research Act 2019

H.R. 712 would require VA conduct a clinical trial of a size and scope to include multiple strains of cannabis and multiple routes of administration and to collect, analyze, and report data on covered Veterans with multiple medical diagnoses and a multitude of clinical outcome measures.

VA has a rich history of scientifically driven contributions that have advanced health care through planning and implementing high quality clinical trials so that we can all better understand the results and potential for changing clinical practice when trials

are complete. VA's Office of Research and Development has a program in place to fund clinical trials that are submitted to our expert peer review system for evaluation of scientific merit based upon the rationale, design, and feasibility of a proposal. Such trials could include the topic of medical uses of cannabis for conditions that impact Veterans. Clinical trial applications must detail the underlying rationale for the use of an experimental intervention such as cannabis for use in humans.

The proposed legislation with the mandated requirements is not consistent with the practice of scientific design for randomized clinical trials nor is it possible to conduct a single trial to obtain the information desired. The specification in the legislation of the multiple requirements such as type and content, administration route, diagnostic specifications representing potential inclusion and exclusion criteria, and outcome measures are not consistent with the current state of scientific evidence, which suggests that smaller, early phase controlled clinical trials with a focused set of specific aims are warranted to determine initial proof of concept for medical marijuana for a specific condition. Any trial with human subjects must include evaluation of risks and benefits/safety and include the smallest number of participants needed to avoid putting subjects at risk unnecessarily. In any study, the size of the experimental population is determined statistically so that the power or ability to detect group differences (between control and experimental groups) is based on known effects that can be shown using a specific outcome measure. For a cannabis trial, some of these effects are not known, thus a circumscribed approach to determine dose, administration modality, and best outcome measure(s) must still be studied or shown in a proof of concept approach to ensure the research would have the ability to detect the impact of the intervention in a

controlled way. Typically, smaller early phase trial designs, instead of the extremely large study suggested in legislation, would be used to advance our knowledge of benefits and risks regarding cannabis before moving to the type of more expansive approach described in this proposed legislation, which is more akin to a program of research than a single clinical trial. The requirements to simultaneously address different modes of administration, different compositions, and different medical diagnoses without consideration of underlying rationale and mechanisms would not be a good use of taxpayer money, and in fact would not engender a favorable scientific peer review evaluation or regulatory approval. A plan forward to determine the legislative mandate should start with a scientific query or review of what is known for diagnostic categories of interest and what is logically called for in exploring next level clinical investigation.

VA is actively encouraging a logical pathway to contribute to the overall understanding of the possible contribution of cannabis and derivative compounds and products to Veterans' health care. VA is reviewing the current clinical evidence regarding use of marijuana for medical purposes, and has concluded more research is needed, especially related to clinical trials. VA is currently supporting a clinical trial of cannabidiol for PTSD based upon a strong design and rationalized mechanism in a trial that will assess risks and benefits. VA has also encouraged other research on possible medical uses for marijuana and compounds or products derived from it. For all these reasons, VA is not supportive of this proposed legislation.

H.R. 1647 – Veteran Equal Access Act

This bill would require VA to authorize its physicians and other health care providers to provide recommendations and opinions to Veterans who are residents of states with state-approved marijuana programs regarding participation in such programs and to complete forms reflecting such recommendations and opinions.

The Veterans Health Administration's (VHA) policy prohibiting VA providers from recommending or making referrals to or completing paperwork for Veteran participation in state marijuana programs is based on guidance provided to VA by the United States Drug Enforcement Administration (DEA), the agency with authority to interpret the Controlled Substances Act (CSA).

Under CSA, marijuana is a schedule I controlled substance with a high potential for abuse and has no currently accepted medical use in treatment in the United States. DEA has advised VA there is no provision of CSA that would exempt from criminal sanctions a VA physician who acts with intent to provide a patient with the means to obtain marijuana, including by filling out forms for state marijuana programs. VA defers to the Department of Justice (DOJ) to determine the legal effect of the phrase "notwithstanding any other provision of law" on the enforcement of CSA against VA providers who might assist Veterans in participating in state-approved marijuana programs.

VA encourages its providers to discuss marijuana use with Veterans who are participating in state-approved marijuana programs, but we do not support VA providers prescribing marijuana to Veterans and so do not support this bill. The clinical benefit of most products derived from the marijuana plant is still not proven scientifically, and VA

must provide consistent, safe, science-based care for all Veterans. Further, the marijuana industry is largely unregulated, and products are often not accurately labeled, so providers cannot ascertain the strength and levels of active ingredients in the product being used by a particular patient, complicating medication management and treatment.

H.R. 2191 – Veterans Cannabis Use for Safe Healing Act (Veterans CUSH Act)

Section 2(a) of H.R. 2191 would prohibit VA from denying a Veteran a benefit under the laws administered by the Secretary because of their participation in a state-approved marijuana program. Section 2(b) would require the Secretary to ensure that VA providers discuss marijuana use with patients, adjust treatment plans accordingly, and record information about marijuana use in the patient's medical records. In addition, section 2(c) of the bill would authorize VA providers to furnish recommendations and opinions to Veterans who reside in states with state-approved marijuana programs regarding participation in such programs.

VA does not support this bill. Sections 2(a) and 2(b) are unnecessary. VHA policy, VHA Directive 1315, *Access to VHA Clinical Programs for Veterans Participating in State-Approved Marijuana Programs*, is very clear that Veterans may not be denied VHA services solely because they are participating in state-approved marijuana programs. Veterans may continue to receive VHA benefits, and providers should discuss with patients how their use of state-approved medical marijuana to treat medical or psychiatric symptoms or conditions may affect other clinical decisions (e.g., discuss how marijuana use may impact other aspects of the overall care of the Veteran such as treatment for pain management, PTSD, or substance use disorder, or how it may interact with other medications the Veteran is taking). VA treatment plans may be

modified based on marijuana use on a case-by-case basis and in partnership with the Veteran.

The content of Section 2(c) is the same as one of the requirements of H.R. 1647, discussed above. As noted in the previous discussion of that bill, VHA's policy prohibiting VA providers from recommending or making referrals to (or completing paperwork for) Veteran participation in state marijuana programs is based on guidance provided to VA by DEA, the agency charged with interpreting the CSA. Also, as noted, DEA has advised VA that the CSA contains no provision that would exempt a VA physician, who acts with intent to provide a patient with the means to obtain marijuana, including by filling out state marijuana program forms, from criminal sanctions, and VA would defer to DOJ on the enforcement of CSA against VA providers.

If the intent of the bill is simply to authorize VA providers to discuss marijuana use with their patients, such clinical discussions are already allowed under VHA policy, as discussed above.

Draft "GAO MOU and MOA" Bill

This bill would direct the Comptroller General of the United States to conduct an assessment of the effectiveness of all memoranda of understanding and memoranda of agreement entered into by the Under Secretary of Health and non-VA entities relating to (1) suicide prevention activities and outreach and (2) the provision and coordination of mental health services in the last 5 years.

VA defers to the Comptroller General for views on this bill, as the bill relates to action to be taken by the Government Accountability Office and has no direct cost implications for VA. Although VA defers to the Comptroller General on this bill, we note

our belief that the Congress already has the authority to request this information without legislation.

Draft GAO Suicide Prevention Bill

This proposed legislation would direct the Comptroller General of the United States to conduct an assessment of the responsibilities, workload, and vacancy rates of VA suicide prevention coordinators.

VA defers to the Comptroller General for views on this bill, as the bill relates to action to be taken by the Government Accountability Office and has no direct cost implications for VA. In any case, a new Suicide Prevention Coordinator (SPC) program guidebook and Suicide Prevention Program directive are currently in development, which will include guidance on responsibilities, workload, training, and staffing levels for SPCs. VA's Mental Health Hiring Initiative is active and addresses current hiring plans for, as well as retention of, SPCs.

Draft Suicide Notification Bill

This bill would require VA to submit notification of a Veteran suicide death or suicide attempt that occurs in, or on the grounds of, a VA facility to the Committees on Veterans' Affairs of the House of Representatives and Senate and members of Congress representing the district of the facility, within 7 days of the event. Information is to be provided by VA within 60 days regarding the Veteran's VA enrollment status; military service period; marital, employment, and housing status; and confirmation that immediate family members have been provided notice of any VA support or assistance for which the family may be eligible.

VA could support this legislation provided certain clarifying technical changes are made and provided that the Congress provides the necessary resources. We would be pleased to work with the Subcommittee on such changes. Also, it should be noted that section 2(B)(i) of the bill, which calls for providing the enrollment status of the Veteran for health care, might not satisfy the intent of this legislation's reporting requirement, since certain categories of Veterans and certain treatment authorities do not require Veterans to be enrolled.

We estimate that enactment of this bill would result in costs of $507,000 for FY 2020, $2.739 million over the 5-year period from FY 2020 through FY 2024, and $6.054 million over the 10-year period from FY 2020 through FY 2029.

Draft "VA – Whole Health" Bill

This draft bill would require VA to submit to Congress within 180 days after the date of enactment a report on the implementation of VA's memorandum, dated February 1, 2019, on the subject of Advancing Whole Health Transformation Across VHA (hereafter referred to as the "Memorandum"). Specifically, the report would need to include an analysis of the accessibility and availability of each of the following 12 services with respect to the implementation of the Memorandum: (1) massage therapy; (2) chiropractic services; (3) whole health clinician services; (4) whole health coaching; (5) acupuncture; (6) healing touch; (7) whole health group services; (8) guided imagery; (9) meditation; (10) clinical hypnosis; (11) yoga; and (12) tai chi or qi gong. The report must also include the same analysis for any other service the Secretary determines appropriate.

The Whole Health System includes three components: 1) Empower: The Pathway – in partnership with peers, empowers Veterans to explore mission, aspiration, and purpose and begin personal health planning. 2) Equip: Well-being Programs equip Veterans with self-care tools, skill-building, and support. Services may include proactive Complementary and Integrative Health (CIH) approaches such as yoga, tai chi, or mindfulness. 3) Treat: Whole Health Clinical Care – in VA, the community, or both, clinicians are trained in Whole Health and incorporate CIH approaches based on the Veteran's personalized health plan. VA staff have been working with Veterans around the country to bring elements of this Whole Health approach to life. In conjunction with VA's implementation of section 933 of Public Law (P.L.) 114-198, the Comprehensive Addiction and Recovery Act of 2016, VA began implementation of the full Whole Health System at 18 flagship facilities in the beginning of FY 2018. This constituted the first wave of facilities to be included in the national deployment of VA's Whole Health System.

Flagship facility implementation of the Whole Health System is proceeding over a 3-year period (FY 2018 - FY 2020) and is supported by a well-proven collaborative model which drives large scale organizational change. In addition to the implementation guide, flagship facilities are receiving education and training, resources and tools, and on-site support. These sites also have designated funding for the start-up costs needed. In addition, Veteran outcomes, Veteran satisfaction, cost, and utilization rates are being tracked as well as the impact, to the extent determinable, of the Whole Health approach on opioid safety, suicide prevention, and impact on the VHA workforce.

More specifically, the Memorandum announces the launch of *Whole Health Learning Collaborative 2: Driving Cultural Transformation* and requests that each Veterans Integrated Service Network identify 2 sites to participate, for a total of 36 sites across VA (separate from the 18 flagship facilities mentioned previously). This collaborative initiative will help further Whole Health delivery and innovation. The collaborative kick-off is scheduled for June 2019 with selection of sites currently underway. These 36 sites will then be supported through the subsequent 18 months as part of this Learning Collaborative process. At this time, specific start-up funding for the 36 sites has not been identified.

It is unclear if the drafters intended to limit the mandated analysis and report requirement to the 36 sites participating in the Learning Collaborative (under the Memorandum.) In other words, the draft bill's incorporation of the Memorandum by specific reference could, in operation, limit us to the 36 sites participating in the Learning Collaborative initiative. Congress may wish to consider extending the draft bill's reporting requirement to the 170 VAMCs and myriad outpatient sites operated by the Department.

VA supports this draft bill, and we would look forward to working with you. The reporting required by this bill can be produced by current VA staff and would require no additional resources to complete.

Madam Chair, I conclude my remarks with the following highlights of VA's suicide prevention efforts. VA is moving from a purely hospital-based suicide prevention model to a public health model. We continue to care for those in crises, with VA suicide prevention coordinators managing care for almost 11,000 Veterans who are clinically at

high-risk for suicide. VA's Recovery Engagement and Coordination for Health – Veterans Enhanced Treatment (REACH-VET) program uses predictive analytics to identify Veterans with high statistical risk for suicide. Annually, 30,000 Veterans receive care review and outreach to ensure they are well engaged in care and their needs are being met.

Under VA's new universal screening for suicidal intent, more than 2,057,000 Veterans have received a standardized risk screen since October 1, 2018; more than 62,000 of these Veterans have received more complex screening based on a positive initial screen; and more than 8,000 have received a full clinical assessment after screening positive.

At the same time, we are implementing the National Strategy for Veteran Suicide Prevention and are aggressively pursuing partnerships necessary to help us reach all Veterans. Just as suicide is a complex issue with no single cause, no single organization can end Veteran suicide alone. Every person, system, and organization must work together to save lives. We have, for example, in partnership with Johnson & Johnson, released a Public Service Announcement (PSA), "No Veteran Left Behind," featuring Tom Hanks via social media and a communications plan led by Johnson & Johnson. VA continues to use the #BeThere Campaign to raise awareness about mental health and suicide prevention and educate Veterans, their families, and communities about the suicide prevention resources available to them. The National Action Alliance helped spread the #BeThere campaign to hundreds of partners using #BeThere and the Veterans Crisis Line information during 2018 Suicide Prevention Month activities.

We created more than 30 new cross-sector partnerships to involve peers, family members, and communities in preventing Veteran suicide. We also deliver monthly partnership updates to include content about the S.A.V.E. online suicide prevention training video to 60 informal and formal partners, providing communications materials (blog posts, social media, and emails) for use. The acronym S.A.V.E. summarizes the steps needed to take an active and valuable role in suicide prevention (**S**igns of suicidal thinking, **A**sk questions, **V**alidate the person's experience, and **E**ncourage treatment and expedite getting help).

As you may know, this month we started working with you and other Members of Congress to spread awareness about the important topic of Veteran suicide through a PSA drive on Capitol Hill. VA's suicide prevention experts developed two suggested PSA scripts that Members can customize for their specific locations and audiences. The scripts are designed to use safe messaging best practices, provide hope, encourage help-seeking, and direct viewers to available mental health and suicide prevention resources. Thank you to those of you who have already developed your PSAs. If you have not yet developed yours, you can schedule time to record your PSA at either the House or Senate Recording Studio. Please let us know if VA can provide you with any further assistance, and we look forward to our continued collaborations.

Conclusion

This concludes my statement. I would be happy to answer any questions you or other Members of the Committee may have.