STATEMENT OF
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BEFORE THE
HOUSE COMMITTEE ON VETERANS' AFFAIRS

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Good morning, Chairman Takano, Ranking Member Roe, and Members of the Committee. Thank you for inviting us here today to present our views on several bills that would affect VA health programs and services, including H.R. 712, H.R. 1647, H.R. 2676. H.R. 2677, H.R. 2942, and H.R. 2943. Due to the delay in notification regarding H.R. 485, H.R. 3083, the draft Specially Adapted Housing Improvement bill, and the draft Work-Study Allowance Program Improvements bill, we are unable to provide views on those bills at this time, but will follow up with the Committee as soon as possible.

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 compositions and multiple administration methods 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 exploring pathways to contribute to the overall understanding of the possible contribution of medical cannabis to Veterans' health care. VA is reviewing the clinical state of the evidence regarding medical marijuana, which concluded more research is needed, especially related to clinical trials. VA is currently supporting a clinical trial of cannabidiol for posttraumatic stress disorder (PTSD) based upon a strong design and rationalized mechanism in a trial that will assess risks and benefits. VA has also encouraged other medical marijuana research. 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 presently a schedule I controlled substance. 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 this bill. Though research studies are in progress, the scientific benefit of most products derived from the marijuana plant is still not proven, 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. 2676 – VA Survey of Cannabis Use Act

H.R. 2676 would require VA to enter into an agreement with a federally-funded research and development center to conduct nationwide surveys to measure cannabis use by Veterans. The center selected by VA would have to have: (1) an in-depth knowledge of all state medicinal marijuana programs and the ability to tailor the required surveys accordingly; and (2) expertise and a record of independent, peer-reviewed publications with respect to behavioral health research and conducting independent evaluations of mental health programs using multidisciplinary methods. In conducting the surveys, the center would have to survey Veterans who are enrolled for VA health care and those who are not, collect information from VA health care providers and be conducted in a manner that ensures the anonymity of the individual being surveyed. The surveys of Veterans would have to cover 12 different topics, and the surveys of providers would have to cover 7 different topics. Not later than 1 year from the date of the enactment of this bill, VA would have to submit a report to Congress on the results of these surveys.

We do not support this bill. The legislation would prescriptively define how the surveys would be conducted, but it does not provide the purpose, goals, or objectives for the surveys. We have significant concerns that Veterans will not want to participate, despite the survey being anonymous. The survey of providers would be difficult to complete because it is asking for both overall impressions of cannabis use among Veterans and specific documentation for patients using cannabis. This would produce a significant burden on providers, requiring a review of charts for their patient panels. It is very likely that the response rate would be low, both because of this burden and because of the anonymity of responses (which would make it impossible to identify and follow up with non-responding providers). Moreover, the survey results would likely only be meaningful if we knew where Veterans live and where providers practice, given the variability of state laws, but submitting information on the state could reduce the anonymity of the survey as well (particularly in small states). Finally, we note that the survey of Veterans might be subject to the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), and compliance with the requirements of this Act could delay VA's implementation of this survey beyond the 1-year period the bill would permit.

H.R. 2677 – Training in the Use of Medical Cannabis for All VA Primary Care Providers

H.R. 2677 would require VA, within 1 year of the enactment of the bill, to provide an initial training for all VA primary care providers in the use of medical cannabis. VA would be required to provide supplemental training, as necessary. In developing this training, VA would be required to enter into partnerships with medical schools that have incorporated education on medical cannabis into their curricula.

VA does not support this bill. We do not believe there is sufficient scientific study and research findings to support a comprehensive training program. Marijuana potency

is highly variable, and state laws governing medical marijuana are inconsistent, which would further complicate our ability to develop training for all providers, ultimately making it difficult to construct a curriculum that provides recommendations for a standard of care without a sufficient evidence base. Additionally, we are concerned that the bill requires partnering with medical schools who have incorporated medical cannabis into their curricula. A medical school's curriculum in this area likely reflects the applicable state laws, but any national training VA provided should not be state specific. This would, again, make it difficult to adapt any single school's curriculum to the Federal level. We further note that VA already makes available to all providers information sessions on cannabis, including a course on caring for patients who use marijuana at the end of life, a review of current findings and clinical considerations regarding cannabis use and PTSD, and the latest on marijuana use, effects, and treatment implications for Veterans. VA's Academic Detailing Program also provides resources for providers to have meaningful conversations with their patients. Finally, VA has tried to limit the amount of mandatory training directed at clinical providers. Instead, we have used other mechanisms to spread awareness and information about key clinical issues. Each hour of mandatory training takes over 20,000 doctors, 80,000 nurses, and thousands of other practitioners away from direct patient care duties. This is not only expensive but reduces access to vital services for Veterans.

H.R. 2942 – Women's Health Transition Training Pilot Program

H.R. 2942 would require VA to carry out the Women's Health Transition Training pilot program until at least September 30, 2020. VA and the Department of Defense would be required, by September 30, 2020, to jointly submit a report to Congress on the pilot program including a number of specified elements.

Carrying out this pilot program until at least September 30, 2020, is favored by VA for the reasons stated below, and while we do not believe this bill is necessary in order to do so, we do not oppose the bill. Our authority to operate the pilot program is not limited; VA is conducting the pilot under the direction of the VA/Department of Defense Health Executive Committee. The pilot program is currently funded through December 2019 for an additional 24 face-to-face training sessions and initial virtual training sessions. VA will plan to continue the pilot through 2020 to ensure additional face-to-face sessions are conducted for statistically-meaningful results on the efficacy of the pilot program. Currently, the vast majority of the pilot program participants have been from the Air Force. Extension of the pilot program through Fiscal Year (FY) 2020 will allow for greater inclusion of transitioning Servicewomen from the Navy, Marine Corps, and Army. We anticipate that robust participation from these services could help achieve sample size requirements and greatly inform the full-scale implementation of this program. We also will need until September 2020 to be able to account for at least half of our current cohort's outcomes. We expect that continuing this program through 2020 will allow us to answer questions about the program's efficacy, participant satisfaction, and the impact on participant awareness; it will also provide an opportunity to collect a wealth of qualitative information for women across various Service branches. Understanding the needs of Servicewomen across military branches can help inform future VA health education and training programs, including and beyond

women's health. We believe that completing the pilot program at the end of FY 2020 would allow VA to submit a report to Congress by the end of that calendar year.

H.R. 2943 – Making Fact Sheets Available in English and in Spanish

H.R. 2943 would require VA to make versions of all VA fact sheets in English and Spanish.

We agree with the intent of this legislation, but we do not support the bill because it is unnecessary as VA currently has the authority to produce materials in English and in Spanish, and our efforts already meet the goals of the legislation. Initially, we note that VA is committed to ensuring no individual is subject to discrimination because of national origin. In March 2016, VA adopted a Language Access Plan to ensure equal access to services provided by VA to individuals with Limited English Proficiency (LEP). The Plan aims to eliminate or reduce, to the maximum extent practicable, LEP as a barrier to accessing VA benefits and services. The Plan establishes detailed policies and processes, including the use of bilingual employees in telephone and face-to-face encounters. For written materials, the Plan leaves VA discretion concerning what steps it should take regarding translation of documents into Spanish or other languages. We believe this discretion is necessary given the huge variety and volume of written materials produced by VA. We note that the legislation only refers to "fact sheets," but does not define that term, which could make implementation of this bill difficult if it were enacted. We would be glad to discuss with the Committee VA's efforts toward ensuring all Veterans and beneficiaries are able to access the benefits and services for which they are eligible.

Conclusion

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