

**ORAL ARGUMENT NOT SCHEDULED
No.19-1120**

**IN THE
UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

In re Scottsdale Research Institute, LLC,

Petitioner

ON PETITION FOR A WRIT OF MANDAMUS TO WILLIAM P. BARR, U.S.
ATTORNEY GENERAL, UTTAM DHILLON, ACTING ADMINISTRATOR
OF THE U.S. DRUG ENFORCEMENT ADMINISTRATION, AND THE U.S.
DRUG ENFORCEMENT ADMINISTRATION

**BRIEF OF AMICUS CURIAE
IRAQ AND AFGHANISTAN VETERANS OF AMERICA
IN SUPPORT OF SCOTTSDALE RESEARCH INSTITUTE, LLC'S
AMENDED PETITION FOR A WRIT OF MANDAMUS**

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CERTIFICATE AS TO PARTIES, RULINGS AND RELATED CASES

Pursuant to D.C. Circuit Rules 21(d) and 28(a)(1), counsel for Amicus Curiae states as follows:

A. Parties and Amici

Petitioner Scottsdale Research Institute, LLC (SRI) and Respondents William P. Barr, Uttam Dhillon, and the United States Drug Enforcement Administration (DEA) are the only parties to this matter. Iraq and Afghanistan Veterans of America (IAVA) is not aware of any amici other than itself.

B. Rulings Under Review

Petitioner filed a corrected petition for a writ of mandamus to redress agency action unlawfully withheld and unreasonably delayed by DEA in noticing Petitioner's application. Accordingly, IAVA knows of no agency or judicial decision under review.

C. Related Cases

IAVA knows of no related cases that have been litigated in the district court, in this Court, or elsewhere.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1, Iraq and Afghanistan Veterans of America (IAVA) certifies that it has no parent corporation and issues no stock. No publicly held company has 10% or greater ownership in IAVA.

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GLOSSARY

DEA	U.S. Drug Enforcement Administration
IAVA	Iraq and Afghanistan Veterans of America
PTSD	Post-Traumatic Stress Disorder
SRI	Scottsdale Research Institute, LLC
VA	Veterans Administration

AMICUS CURIAE'S IDENTITY, INTEREST AND AUTHORITY TO FILE

Iraq and Afghanistan Veterans of America (IAVA) is the leading non-profit devoted to the interests of the post-9/11 generation of veterans, with 425,000 members comprised largely of veterans of the wars in Iraq and Afghanistan. IAVA's membership also includes active duty service members, military spouses and dependents, civilian supporters, and other veterans who served domestically or abroad.

Since its founding in 2004, IAVA has been the leader in veteran awareness and advocacy. IAVA began by fighting for body armor for troops and has worked for years to bring national attention to veteran suicide. Many groups support veterans, but IAVA reshapes the landscape and changes history by influencing policy and law that improves the lives of all America's veterans.

IAVA's number one priority for 2019 is to continue the campaign to combat suicide among troops and veterans. Twenty military and veterans die each day by suicide. The IAVA-led Campaign to Combat Suicide and passage of the Clay Hunt Suicide Prevention for American Veterans Act have had an impact, but veterans continue to be more at risk for suicide. The growing need for mental health care continues to stress an already overstressed system. Every day, we are losing more veterans to suicide.

Medical marijuana holds promise for treatment-resistant post-traumatic stress disorder (PTSD), but randomized controlled studies are necessary to determine the efficacy and safety of medical marijuana as a PTSD treatment. A significant percentage of combat veterans develop PTSD, and suicide is more frequent among veterans suffering PTSD. Consequently, the prevention or delay of clinical research into medical marijuana as a safe and effective treatment has a direct impact on IAVA's constituency.

All parties have consented to the filing of this brief.

**STATEMENT OF AUTHORSHIP AND FINANCIAL
CONTRIBUTIONS**

No party's counsel authored the brief in whole or in part, no party or party's counsel contributed money that was intended to fund preparing or submitting the brief, and no person other than the IAVA, its members, or its counsel contributed money that was intended to fund preparing or submitting the brief.

SUMMARY OF ARGUMENT

PTSD related veteran suicide is a national health crisis. The Department of Veterans Administration (VA) estimates that twenty military and veterans die by suicide each day. Veterans suffering from post-traumatic stress disorder (PTSD) experience anxiety, depression, insomnia, anger, and a host of other symptoms strongly correlated with suicide risk. It cannot be reasonably disputed that combat veterans suffering with PTSD are at increased risk for suicide.

There are only two federally approved treatments for PTSD. Those two treatments leave *forty percent* of PTSD sufferers with *no* relief and nearly *eighty percent* of PTSD sufferers with PTSD *symptoms* that decrease their quality of life and increase their risk for suicide. Despite efforts to eliminate veteran suicide, veteran suicide rates are increasing, not decreasing. Sadly, but understandably, our veterans feel that America is not looking out for their interests.

Medical marijuana holds promise as a safe and effective treatment for PTSD. Correlational and observational studies support the conclusion, and there is a neurobiological basis for the reported efficacy. In states where recreational marijuana is legal, veterans suffering with PTSD are self-medicating. In the states where marijuana is available by prescription for

PTSD sufferers, doctors are prescribing marijuana as a PTSD treatment. This use is occurring without the benefit of a randomized controlled study of marijuana as a treatment for PTSD, without the benefit of health insurance, and without the ability for the veteran to coordinate marijuana use with his/her VA medical team.

To the extent that randomized and controlled studies show that medical marijuana is a safe and effective treatment for PTSD, the delay of clinical research of medical marijuana is keeping life-saving treatment away from veterans suffering with PTSD who reside in states where medical marijuana is not available or where medical marijuana is available, but cannot be afforded. To the extent that studies show that medical marijuana is not a safe treatment for PTSD, the delay is harming veterans who are self-medicating with marijuana or being prescribed medical marijuana in states where it is legal to do so.

Nearly all veterans agree that there should be clinical research of medical marijuana as a PTSD treatment and that they would be willing to try medical marijuana as a PTSD treatment if it was approved as such. The veterans who take this position are of all ages, come from both major political parties, and a variety of backgrounds. This is a health issue not a political one.

The DEA's delay in processing Petitioner's application is egregious because it harms veterans' health and welfare. The DEA is preventing clinical research from even having a *chance* to proceed by failing to comply with the law requiring it to process Petitioner's application. That failure is a disgrace. This country, this Court and each of us owe it to our veterans to do everything we can to ensure that the injuries resulting from their service are treated. The IAVA beseeches this Court to order the DEA to process Petitioner's application in accordance with the law.

ARGUMENT

To determine whether the DEA's delay in processing Petitioner's application is "so egregious as to warrant mandamus,"¹ this Court considers:

(1) The time agencies take to make decisions must be governed by a "rule of reason"; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and (6) the court need not "find any impropriety lurking behind agency lassitude in order to hold that agency action is 'unreasonably delayed.'"²

¹ *In re Core Commc'ns, Inc.*, 531 F.3d 849, 855 (D.C. Cir. 2008).

² *Telecomms. Research & Action Ctr. v. FCC*, 750 F.2d 70, 76 (D.C. Cir. 1984).

This Court should find the DEA's delay in processing Petitioner's application so egregious as to warrant mandamus because veterans' health and welfare is at stake; decreasing veteran suicide by prioritizing research activities is a national priority; and veterans' lives are prejudiced by the delay in processing Petitioner's application.

I. PTSD Related Veteran Suicide Is A National Health Problem.

A. Suicides are more frequent among veterans with PTSD.

Studies show that “[s]uicides are more frequent in those who develop PTSD, depression and comorbid states due to war exposure,”³ and “[r]ecent evidence has . . . underscored the importance of PTSD as an underlying risk factor of suicide.”⁴ Indeed, “suicidal ideation [is] some 4-times more frequent in PTSD-sufferers.”⁵ According to a 2012 article published in the CLEVELAND CLINIC JOURNAL OF MEDICINE: “Combat veterans are not only

³ Vsevolod Roznavo and Vladimir Carli, *Suicide among War Veterans*, 9 INT. J. ENVIRON. RES. PUBLIC HEALTH 2504 (July 19, 2012) at “Abstract”, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3407917/>. See also Javier Hasse and Alex Oleinic, *PTSD, Veterans and Suicide: Action Is Needed, And Cannabis May Help*, Yahoo Finance (May 15, 2019), <https://finance.yahoo.com/news/ptsd-veterans-suicide-action-needed-173704113.html> (last visited Aug. 7, 2019) (“The exact cause of why so many veterans choose to end their own lives is hard to determine. One of the most common factors that has been identified in medical studies is post-traumatic stress disorder, or PTSD.”).

⁴ *Id.*

⁵ *Id.*

more likely to have suicidal ideation, often associated with posttraumatic stress disorder (PTSD) and depression, but they are more likely to act on a suicidal plan.”⁶

All of this scientific evidence comports with common sense. Combat veterans witness and experience all sorts of trauma. A certain percentage of people who experience severe trauma develop PTSD.⁷ The symptoms of

⁶ Leo Sher, Maria D. Braquehais, and M. Casas, *Posttraumatic stress disorder, depression and suicide in veterans*, 79 CLEV. CLIN. J. OF MED. 92 at 92 (Feb. 2012), <https://www.ncbi.nlm.nih.gov/pubmed/22301558>.

⁷ The rates of PTSD among veterans are much greater than among non-veterans. See, e.g., Elizabeth Ralevski, Lening A. Olivera-Figueroa, and Ismene Petrakis, *PTSD and comorbid AUD: a review of pharmacological and alternative treatment options*, 5 SUBST. ABUSE REHABIL. 25 at 26 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3953034/> (“The rates among military personnel are much higher than those in the general population. Among male and female soldiers aged 18 years or older returning from Iraq and Afghanistan, rates range from 9% shortly after returning from deployment to 31% a year after deployment. A review of 29 studies that evaluated rates of PTSD in those who served in Iraq and Afghanistan found prevalence rates of adult men and women previously deployed ranging from 5% to 20% for those who do not seek treatment, and around 50% for those who do seek treatment. Vietnam veterans also report high lifetime rates of PTSD ranging from 10% to 31%. 13,14 PTSD is the third most prevalent psychiatric diagnosis among veterans using the Veterans Affairs (VA) hospitals.”); Terri L. Tanielian and Lisa H. Jaycox, *Invisible Wounds of War Psychological and Cognitive Injuries, Their Consequences, and Services to Assist Recovery*, RAND CENTER FOR MILITARY HEALTH POLICY RESEARCH (2008) at 3, https://www.rand.org/content/dam/rand/pubs/monographs/2008/RAND_MG720.pdf (“Upward of 26 percent of returning troops may have mental health conditions (applying broad screening criteria for post-traumatic stress disorder, anxiety disorder, or depression), and the frequency of diagnoses in this category is increasing while rates for other medical

PTSD – depression, anxiety, irritability, anger, and fear – are the type of symptoms that are associated with suicide.⁸

B. PTSD and veteran suicide rates are increasing, not decreasing.

The U.S. Department of Veterans Affairs reports that the veteran suicide rate increased 25.9 percent from 2005 to 2016.⁹ “In 2016, the suicide rate was 1.5 times greater for Veterans than for non-Veteran adults, after adjusting for age and gender.”¹⁰ While some studies may question the conclusion “regarding higher suicide rates among veterans when compared

diagnoses remain constant (Hoge et al., 2004). The most common diagnoses are post-traumatic stress disorder (PTSD), an anxiety disorder that can develop after direct or indirect exposure to a terrifying event or ordeal in which grave physical harm occurred or was threatened; major depression; and generalized anxiety (National Institute of Mental Health Web site, Mental Health Topics page).”

⁸ Cf. *Symptoms of PTSD*, Anxiety and Depression Association of America, <https://adaa.org/understanding-anxiety/posttraumatic-stress-disorder-ptsd/symptoms> (last visited Aug. 7, 2019) (listing PTSD symptoms), *with Risk Factors and Warning Signs*, American Foundation for Suicide Prevention, <https://afsp.org/about-suicide/risk-factors-and-warning-signs/> (last visited Aug. 7, 2019) (listing suicide risk factors).

⁹ *Veteran Suicide Data Report, 2005-2016*, U.S. Dep’t. of Veterans Affairs, Office of Mental Health and Suicide Prevention (September 2018) at 3, https://www.mentalhealth.va.gov/docs/data-sheets/OMHSP_National_Suicide_Data_Report_2005-2016_508.pdf.

¹⁰ *Id.* Cf. Vsevolod Roznavo and Vladimir Carli, *Suicide among War Veterans*, 9 INT. J. ENVIRON. RES. PUBLIC HEALTH 2504 (July 19, 2012) at “Conclusions”, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3407917/> (“... it is difficult to draw a definitive conclusion regarding higher suicide rates among veterans when compared with the general population. . . . On the other hand those who were involved in latter conflicts, as in Iraq, are definitely at higher risk.”).

with the general population,” a survey of available studies concludes that “those who were involved in latter conflicts, as in Iraq, are definitely at higher risk.”¹¹

The increase in veteran suicide rates despite the relative calming of recent conflicts is not surprising. In 2008, a Rand study of all available science in this area concluded that just as Vietnam and Gulf War Veterans experienced delayed onset PTSD, so too would the Veterans of the Afghanistan and Iraq wars, resulting in an “increase over time” of “the need for mental health services” and the burden of caring for our service men and women.¹² The increase in veteran suicide rates since 2008 is the realization of the phenomenon predicted by the RAND study.

¹¹ Vsevolod Roznavo and Vladimir Carli, *Suicide among War Veterans*, 9 INT. J. ENVIRON. RES. PUBLIC HEALTH 2504 (July 19, 2012) at “Conclusions”, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3407917/>.

¹² Terri L. Tanielian and Lisa H. Jaycox, *Invisible Wounds of War Psychological and Cognitive Injuries, Their Consequences, and Services to Assist Recovery*, RAND CENTER FOR MILITARY HEALTH POLICY RESEARCH, (2008) at 59, https://www.rand.org/content/dam/rand/pubs/monographs/2008/RAND_MG720.pdf (“In addition, research conducted many years after previous conflicts, such as Vietnam (Dohrenwend et al., 2006) and the first Gulf War (Stimpson et al., 2003), have produced prevalence estimates equal to if not higher than those presented here, which may be due to the emergence of symptoms over time (i.e., a “delayed onset” PTSD) or increases in treatment seeking behaviors. We hypothesize that, regardless of its cause, the need for mental health services for service members deployed to Afghanistan and Iraq will increase over time, given the prevalence of information available to date and prior experience with Vietnam. Policymakers may therefore consider the

IAVA's 2019 Member Survey (Survey) echoes these findings.¹³ Fifty-nine percent of Survey respondents *know personally* a post-9/11 Veteran who *died* from suicide, and sixty-five percent of Survey respondents *know personally* a post-9/11 Veteran who *attempted* suicide.¹⁴ Shockingly, forty-three percent of IAVA members surveyed reported suicidal ideation *since* joining the military.¹⁵ The Survey reflects that percentage is more than a thirty-five percent increase from the percentage of IAVA members who answered similarly to the same question just four years prior!¹⁶ It is no wonder that seventy-seven percent of Survey respondents believe that our nation is not making progress in combating military/veteran suicide.¹⁷

figures presented in these studies to underestimate the burden that PTSD, depression, and TBI will have on the agencies that will be called upon to care for these servicemembers now and in the near future”).

¹³ IAVA 2019 Member Survey, Iraq and Afghanistan Veterans of America (2019) at 23, <https://iava.org/survey2019/IAVA-2019-Member-Survey.pdf> (last visited July 26, 2019). 4,600 IAVA Members took and completed the Survey, and the Survey has a 1% margin of error at the 95% confidence interval. *Id.* at 68.

¹⁴ *Id.* at 22.

¹⁵ *Id.* at 22.

¹⁶ *Id.* at 22.

¹⁷ *Id.* at 22.

II. Medical Marijuana Should Be Studied To Determine Its Safety And Efficacy For Treating PTSD.

A. Where legal, marijuana is being used by veterans and doctors to treat PTSD.

The use of medical marijuana is currently legal in thirty-three states, the District of Columbia, Puerto Rico and Guam.¹⁸ The vast majority of these jurisdictions permit doctors to prescribe cannabis for treatment of PTSD,¹⁹ and “in states that allow for use of medical marijuana for traumatic intrusions and PTSD, this was listed as the primary indication in 38.5% of registered users.”²⁰ This use is occurring even though doctors have no

¹⁸ *Map of Marijuana Legality State by State*, DISA Global Solutions, <https://disa.com/map-of-marijuana-legality-by-state> (last visited Aug. 7, 2019) (providing links to each states laws).

¹⁹ *See Medical Marijuana Pros and Cons. 33 legal medical marijuana states and DC: laws, fees, and possession limits*, ProCon.org (July 24, 2019), <https://medicalmarijuana.procon.org/view.resource.php?%20resourceID=000881> (last visited Aug. 7, 2019) (collecting statutes and listing PTSD as among the approved conditions for which medical marijuana can be prescribed in 27 states among the 33 states and the District of Columbia where medical marijuana is legal); Alicia Wallace, *List: U.S. states and territories that allow medical marijuana for PTSD*, The Cannabist.com (Nov. 13, 2017) <https://www.thecannabist.co/2017/02/14/ptsd-marijuana-qualifying-conditions-list-us-states-territories/72574/> (listing twenty-five states, the District of Columbia, Puerto Rico and Guam as jurisdictions where PTSD is a listed condition for which treatment with medically prescribed cannabis is approved or where doctors have broad discretion to prescribe cannabis for conditions, including PTSD).

²⁰ Stephanie Yarnell, *The Use of Medicinal Marijuana for Posttraumatic Stress Disorder: A Review of the Current Literature*, PRIMARY CARE COMPANION FOR CNS DISORDERS at “Results” (May 7, 2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4578915/>.

randomized controlled study to establish the appropriateness of the treatment or the strain and dosage that should be prescribed.

Veterans suffering the debilitating effects of PTSD are also self-medicating with medical marijuana. The IAVA Survey reveals that twenty percent of Survey respondents have tried cannabis or other cannabinoid products for medicinal use.²¹ Given that forty percent of Veterans suffering with PTSD obtain *no* relief from the only treatments currently approved by the Federal Drug Administration and the small percentage of such patients who obtain complete relief from such treatments,²² it is no wonder that veterans who can afford to pay out of pocket are self-medicating with – or seeking out medical prescriptions for – medical marijuana.

B. There is a scientific basis for believing medical marijuana is a safe and effective treatment for PTSD.

In addition to the anecdotal evidence cited by Petitioner in the declaration of Dr. Sisley and evidence of veterans using and doctors

²¹ IAVA 2019 Member Survey, Iraq and Afghanistan Veterans of America, (2019) at 46, <https://iava.org/survey2019/IAVA-2019-Member-Survey.pdf>.

²² Walter Alexander, *Pharmacotherapy for Post-traumatic Stress Disorder In Combat Veterans Focus on Antidepressants and Atypical Antipsychotic Agents*, 37 PHARMACY & THERAPEUTICS 32 at 32 (Jan. 2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278188/> (“The only FDA-approved drugs for the treatment of PTSD are the selective serotonin reuptake inhibitors (SSRIs) sertraline (Zoloft, Pfizer) and paroxetine HCl (Paxil, GlaxoSmithKline). . . . Although SSRIs are associated with an overall response rate of approximately 60% in patients with PTSD, only 20% to 30% of patients achieve complete remission”).

prescribing medical marijuana where legal to treat PTSD, published scientific studies suggest a decrease in PTSD symptoms with marijuana use.²³ Because Petitioner would be the first to complete a randomized controlled study and because the DEA is preventing that study by failing to even process Petition's application, the studies published so far are "correlational and observational in basis."²⁴ However, "there is a growing amount of neurobiological evidence and animal studies suggesting potential neurologically based reasons for the reported efficacy."²⁵

C. Nearly all Veterans want clinical studies of medical marijuana as a PTSD treatment.

Ninety percent of Survey respondents agree that cannabis should be researched for medicinal use,²⁶ and ninety percent of Survey respondents

²³ Stephanie Yarnell, *The Use of Medicinal Marijuana for Posttraumatic Stress Disorder: A Review of the Current Literature*, PRIMARY CARE COMPANION FOR CNS DISORDERS at "Studies Evaluating Use in PTSD" (May 7, 2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4578915/>.

²⁴ *Id.*

²⁵ *Id.* See also Robert T. Muller, Ph.D., *Medical Marijuana for PTSD?*, PSYCHOLOGY TODAY (Dec. 14, 2017), <https://www.psychologytoday.com/us/blog/talking-about-trauma/201712/medical-marijuana-ptsd> (last visited Aug. 7, 2017) ("A recent study published in *Molecular Psychiatry* showed that treatment using particular compounds found in marijuana may benefit those with PTSD, and that "plant-derived cannabinoids [psychoactive chemicals] such as marijuana may possess some benefits in individuals with PTSD by helping relieve haunting nightmares and other symptoms of PTSD.")

²⁶ IAVA 2019 Member Survey, Iraq and Afghanistan Veterans of America, at 46 (2019), <https://iava.org/survey2019/IAVA-2019-Member-Survey.pdf>

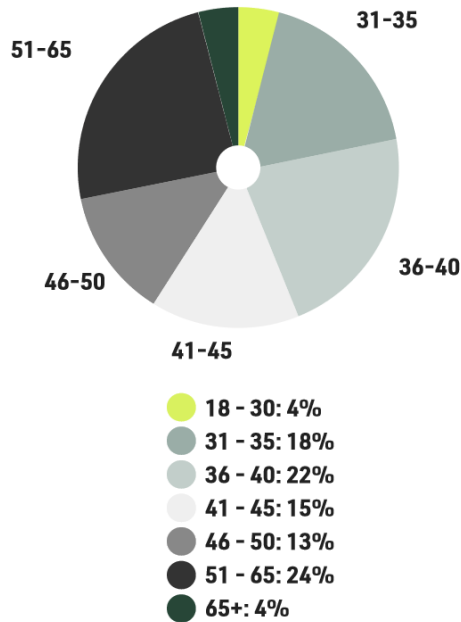
would be interested in using cannabis or cannabinoid products as a treatment option if it was available as a treatment option.²⁷

The tremendous support among veterans for clinical studies of medical marijuana as a PTSD treatment is not a reflection of age, geography or political orientation. Only four percent of Survey respondents are younger than thirty, more self-identified Republicans than Democrats, and the percentages of survey respondents reporting as living in rural versus urban communities are roughly even:

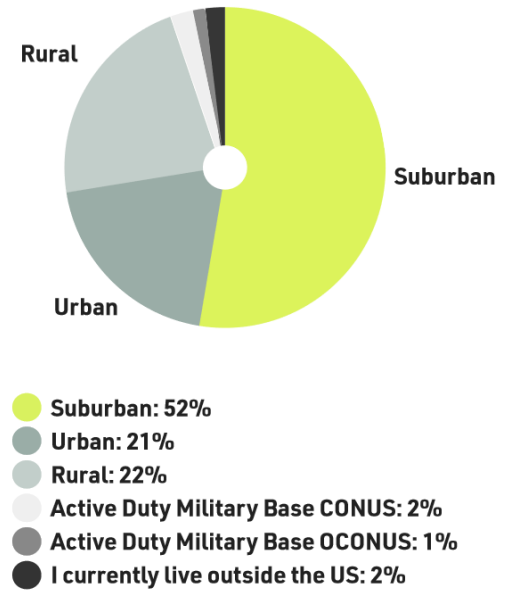
(reflecting that 72% strongly agree and 18% somewhat agree with the statement “Cannabis should be researched for medicinal purposes.”).

²⁷ *Id.* (reflecting that 68% strongly agree and 17% somewhat agree with the statement that “The VA should allow for research into cannabis as a treatment option.”).

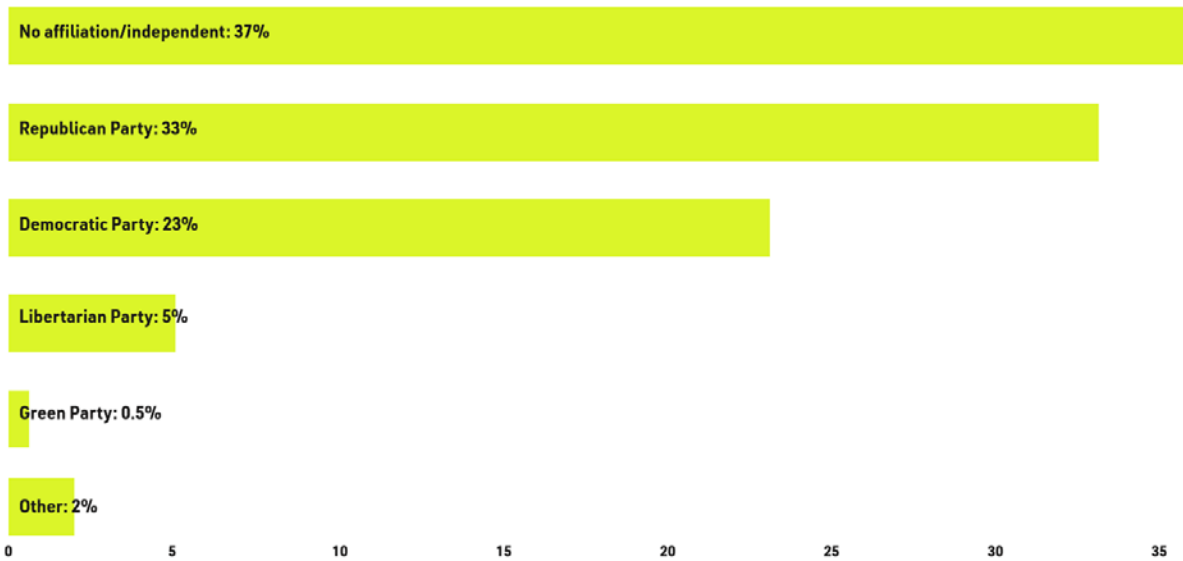
Age



Community



Political Party Affiliation



28

Veterans suffering from PTSD, their loved ones, and America as a whole can only benefit from knowing more about the safety and efficacy of

²⁸ *Id.*

medical marijuana as a treatment for PTSD. If the treatment is safe and effective, more veterans will find relief from a debilitating disorder. If the treatment is not safe or effective, then veterans will stop self-medicating with and doctors will stop prescribing medical marijuana for PTSD, and scientists can turn their focus to other potential treatments or cures.

III. Decreasing Veteran Suicide By Prioritizing Medical Research Is A National Priority.

Congress has passed legislation that prioritizes both suicide prevention for veterans²⁹ and applications to manufacture medical marijuana for the purposes of clinical research.³⁰ In fact, in 2015, the House and Senate voted *unanimously* to pass the Clay Hunt Suicide Prevention for American Veterans Act.³¹ Both acts were signed into law by the President of the United States.

Congress is currently working on additional legislation that would prioritize clinical research of medical marijuana for PTSD treatment. Seventy-five legislators, including Republicans and Democrats, are co-

²⁹ H.R. No. 203, Pub. L. No. 114-2, 129 Stat. 30 (2015).

³⁰ 21 U.S.C. §823(i)(2); Ex. 18 at A168-69.

³¹ H.R. No. 203, Pub. L. No. 114-2, 129 Stat. 30 (2015). *See also* <https://www.congress.gov/bill/114th-congress/house-bill/203/all-actions?overview=closed&q=%7B%22roll-call-vote%22%3A%22all%22%7D> (reflecting unanimous votes of House and Senate on Clay Hunt Suicide Prevent for American Veterans Act) (last visited Aug. 7, 2019).

sponsors of legislation that “direct[s] the Secretary of Veterans Affairs to carry out a clinical trial of the effects of cannabis on certain health outcomes of adults with chronic pain and post-traumatic stress disorder, and for other purposes.”³² This legislative proposal further evidences the national priority of decreasing veteran suicide by prioritizing medical research of cannabis as a potential PTSD treatment.³³

Moreover, as Petitioner notes, in March 2019, the President issued an Executive Order declaring:

It is the policy of the United States to end veteran suicide through the development of a comprehensive plan to empower veterans and end suicide through coordinated suicide prevention efforts, *prioritized research activities*, and strengthened collaboration across the public and private sectors.³⁴

The Executive Order directs a task force to “identify barriers to or gaps in research, and facilitate opportunities for improved consolidation, integration, and alignment.”³⁵

The DEA’s delay in processing Petitioner’s application directly contradicts the national priorities set forth by our executive and legislative

³² VA Medicinal Cannabis Research Act of 2018, S. 2796, 115th Cong. (2017-2018); VA Medicinal Cannabis Research Act, H.R. 5520, 115th Cong. (2017-2018).

³³ *Id.*

³⁴ Exec. Order No. 13,861, 84 Fed. Reg. 8,585 (Mar. 5, 2019) (emphasis added).

³⁵ *Id.*

branches of government. Indeed, the DEA's failure to process Petitioner's application on a timely basis is a barrier to research of the type the President's Executive Order expressly directs be eliminated.

CONCLUSION

The United States of America is morally compelled to address injuries – both physical and psychological – veterans suffer as a result of their military service. There is overwhelming evidence that PTSD is a severe injury suffered by a significant percentage of veterans and that veterans with PTSD are more likely to take their own lives than veterans with no such psychological injury. Our country should be doing everything it can as quickly as it can to find treatments for PTSD and help prevent veteran suicide. Both the executive and legislative branches of government have made the prevention of veteran suicide and related medical research national priorities, and yet the DEA has unreasonably and egregiously delayed processing Petitioner's application effectively preventing from proceeding the only approved clinical research study of medical marijuana as a PTSD treatment.

The DEA's refusal to process Petitioner's application is impacting veterans by preventing any chance for controlled randomized clinical studies of medical marijuana as a treatment for PTSD. Without such clinical studies,

veterans who live in states where medical marijuana is not available as a treatment for PTSD cannot obtain the treatment, and veterans who can obtain the treatment in states where it is legal do so at their own personal expense, without coordination with their VA medical teams, and without any scientific evidence to establish the promise of the efficacy and safety of the treatment.

This Court should grant the writ and order the DEA to comply with its legal duty to process Petitioner's application so that Petitioner might be able to complete the Phase III trials already approved by the FDA.

Dated: August 12, 2019

Respectfully submitted,

SUSMAN GODFREY L.L.P.

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*ATTORNEYS FOR AMICUS
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CERTIFICATE OF SERVICE

I hereby certify that I caused the foregoing to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system on August 12, 2019.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: August 12, 2019

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), the document contains 3,915 words. I further certify that this document complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because the brief has been prepared in Georgia 14-point font for text and footnotes using Microsoft Word.

Dated: August 12, 2019

Respectfully submitted,

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ADDENDUM

Except for the following, all applicable statutes, etc. are contained in the Amended Petition for a Writ of Mandamus filed by SRI.

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H.R. No. 203, Pub. L. No. 114-2, 129 Stat. 30 (2015).....1

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 (2017-2018).14

PUBLIC LAW 114-2—FEB. 12, 2015

CLAY HUNT SUICIDE PREVENTION FOR
AMERICAN VETERANS ACT

129 STAT. 30

PUBLIC LAW 114–2—FEB. 12, 2015

Public Law 114–2
114th Congress

An Act

Feb. 12, 2015
[H.R. 203]

To direct the Secretary of Veterans Affairs to provide for the conduct of annual evaluations of mental health care and suicide prevention programs of the Department of Veterans Affairs, to require a pilot program on loan repayment for psychiatrists who agree to serve in the Veterans Health Administration of the Department of Veterans Affairs, and for other purposes.

Clay Hunt
Suicide
Prevention for
American
Veterans Act.
38 USC 101 note.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Clay Hunt Suicide Prevention for American Veterans Act” or the “Clay Hunt SAV Act”.

SEC. 2. EVALUATIONS OF MENTAL HEALTH CARE AND SUICIDE PREVENTION PROGRAMS OF DEPARTMENT OF VETERANS AFFAIRS.

(a) EVALUATIONS.—

(1) IN GENERAL.—Subchapter I of chapter 17 of title 38, United States Code, is amended by adding at the end the following new section:

38 USC 1709B.

“§ 1709B. Evaluations of mental health care and suicide prevention programs

Deadline.

“(a) EVALUATIONS.—(1) Not less frequently than once during each period specified in paragraph (3), the Secretary shall provide for the conduct of an evaluation of the mental health care and suicide prevention programs carried out under the laws administered by the Secretary.

“(2) Each evaluation conducted under paragraph (1) shall—

“(A) use metrics that are common among and useful for practitioners in the field of mental health care and suicide prevention;

“(B) identify the most effective mental health care and suicide prevention programs conducted by the Secretary, including such programs conducted at a Center of Excellence;

“(C) identify the cost-effectiveness of each program identified under subparagraph (B);

“(D) measure the satisfaction of patients with respect to the care provided under each such program; and

“(E) propose best practices for caring for individuals who suffer from mental health disorders or are at risk of suicide, including such practices conducted or suggested by other departments or agencies of the Federal Government, including the Substance Abuse and Mental Health Services Administration of the Department of Health and Human Services.

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- “(3) The periods specified in this paragraph are the following: Time periods.
- “(A) The period beginning on the date on which the Secretary awards the contract under paragraph (4) and ending on September 30, 2018.
- “(B) Each fiscal year beginning on or after October 1, 2018. Effective date.
- “(4) Not later than 180 days after the date of the enactment of this section, the Secretary shall seek to enter into a contract with an independent third party unaffiliated with the Department of Veterans Affairs to conduct evaluations under paragraph (1). Deadline. Contracts.
- “(5) The independent third party that is awarded the contract under paragraph (4) shall submit to the Secretary each evaluation conducted under paragraph (1).
- “(b) ANNUAL SUBMISSION.—Not later than December 1, 2018, and each year thereafter, the Secretary shall submit to the Committee on Veterans’ Affairs of the Senate and the Committee on Veterans’ Affairs of the House of Representatives a report that contains the following: Deadline. Reports.
- “(1) The most recent evaluations submitted to the Secretary under subsection (a)(5) that the Secretary has not previously submitted to such Committees.
- “(2) Any recommendations the Secretary considers appropriate.”.
- (2) CLERICAL AMENDMENT.—The table of sections at the beginning of such chapter is amended by inserting after the item relating to section 1709A the following new item: 38 USC prec. 1701.
- “1709B. Evaluations of mental health care and suicide prevention programs.”.
- (b) INTERIM REPORTS.—Not later than September 30 of each of 2016 and 2017, the Secretary of Veterans Affairs, in coordination with the independent third party awarded a contract by the Secretary pursuant to section 1709B(a)(4) of title 38, United States Code, as added by subsection (a)(1), shall submit to the Committee on Veterans’ Affairs of the Senate and the Committee on Veterans’ Affairs of the House of Representatives a report on the mental health care and suicide prevention programs carried out under the laws administered by the Secretary that includes, with respect to each such program, the following: Coordination.
- (1) A description of the program.
- (2) The number of veterans served by the program.
- (3) The budget of the program.
- (4) The number of full-time equivalent employees assigned to the program.
- (5) Whether veterans may repeat participation in the program or participate in the program in addition to other similar programs.
- (6) Any study results or research published regarding the efficacy of the program.
- (7) Any other information the Secretary determines appropriate.
- SEC. 3. PUBLICATION OF INTERNET WEBSITE TO PROVIDE INFORMATION REGARDING MENTAL HEALTH CARE SERVICES.** 38 USC 1712A note.
- (a) IN GENERAL.—Using funds made available to the Secretary of Veterans Affairs to publish the Internet websites of the Department of Veterans Affairs, the Secretary shall survey the existing Internet websites and information resources of the Department Survey.

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to publish an Internet website that serves as a centralized source to provide veterans with information regarding all of the mental health care services provided by the Secretary.

(b) ELEMENTS.—The Internet website published under subsection (a) shall provide to veterans information regarding all of the mental health care services available in the Veteran Integrated Service Network that the veteran is seeking such services, including, with respect to each medical center, Vet Center (as defined in section 1712A of title 38, United States Code), and community-based outpatient center in the Veterans Integrated Service Network—

(1) the name and contact information of each social work office;

(2) the name and contact information of each mental health clinic;

(3) a list of appropriate staff; and

(4) any other information the Secretary determines appropriate.

Deadline.

(c) UPDATED INFORMATION.—The Secretary shall ensure that the information described in subsection (b) that is published on the Internet website under subsection (a) is updated not less than once every 90 days.

(d) OUTREACH.—In carrying out this section, the Secretary shall ensure that the outreach conducted under section 1720F(i) of title 38, United States Code, includes information regarding the Internet website published under subsection (a).

38 USC 7681
note.

SEC. 4. PILOT PROGRAM FOR REPAYMENT OF EDUCATIONAL LOANS FOR CERTAIN PSYCHIATRISTS OF VETERANS HEALTH ADMINISTRATION.

(a) ESTABLISHMENT.—The Secretary of Veterans Affairs shall carry out a pilot program to repay loans of individuals described in subsection (b) that—

(1) were used by such individuals to finance education relating to psychiatric medicine, including education leading to—

(A) a degree of doctor of medicine; or

(B) a degree of doctor of osteopathy; and

(2) were obtained from any of the following:

(A) A governmental entity.

(B) A private financial institution.

(C) A school.

(D) Any other authorized entity as determined by the Secretary.

(b) ELIGIBLE INDIVIDUALS.—

(1) IN GENERAL.—Subject to paragraph (2), an individual eligible for participation in the pilot program is an individual who—

(A) either—

(i) is licensed or eligible for licensure to practice psychiatric medicine in the Veterans Health Administration of the Department of Veterans Affairs; or

(ii) is enrolled in the final year of a residency program leading to a specialty qualification in psychiatric medicine that is approved by the Accreditation Council for Graduate Medical Education; and

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(B) demonstrates a commitment to a long-term career as a psychiatrist in the Veterans Health Administration, as determined by the Secretary.

(2) PROHIBITION ON SIMULTANEOUS ELIGIBILITY.—An individual who is participating in any other program of the Federal Government that repays the educational loans of the individual is not eligible to participate in the pilot program.

(c) SELECTION.—The Secretary shall select not less than 10 individuals described in subsection (b) to participate in the pilot program for each year in which the Secretary carries out the pilot program.

(d) PERIOD OF OBLIGATED SERVICE.—The Secretary shall enter into an agreement with each individual selected under subsection (c) in which such individual agrees to serve a period of 2 or more years of obligated service for the Veterans Health Administration in the field of psychiatric medicine, as determined by the Secretary.

Contracts.

(e) LOAN REPAYMENTS.—

(1) AMOUNTS.—Subject to paragraph (2), a loan repayment under this section may consist of payment of the principal, interest, and related expenses of a loan obtained by an individual who is participating in the pilot program for all educational expenses (including tuition, fees, books, and laboratory expenses) of such individual relating to education described in subsection (a)(1).

(2) LIMIT.—For each year of obligated service that an individual who is participating in the pilot program agrees to serve under subsection (d), the Secretary may pay not more than \$30,000 in loan repayment on behalf of such individual.

(f) BREACH.—

(1) LIABILITY.—An individual who participates in the pilot program and fails to satisfy the period of obligated service under subsection (d) shall be liable to the United States, in lieu of such obligated service, for the amount that has been paid or is payable to or on behalf of the individual under the pilot program, reduced by the proportion that the number of days served for completion of the period of obligated service bears to the total number of days in the period of obligated service of such individual.

(2) REPAYMENT PERIOD.—Any amount of damages that the United States is entitled to recover under this subsection shall be paid to the United States not later than 1 year after the date of the breach of the agreement.

(g) REPORT.—

(1) INITIAL REPORT.—Not later than 2 years after the date on which the pilot program under subsection (a) commences, the Secretary shall submit to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives a report on the pilot program.

(2) ELEMENTS.—The report required by paragraph (1) shall include the following:

(A) The number of individuals who participated in the pilot program, including the number of new hires.

(B) The locations in which such individuals were employed by the Department, including how many such locations were rural or urban locations.

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Assessment.

(C) An assessment of the quality of the work performed by such individuals in the course of such employment, including the performance reviews of such individuals.

Determination.

(D) The number of psychiatrists the Secretary determines is needed by the Department in the future.

(3) FINAL REPORT.—Not later than 90 days before the date on which the pilot program terminates under subsection (i), the Secretary shall submit to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives an update to the report submitted under paragraph (1) and any recommendations that the Secretary considers appropriate.

(h) REGULATIONS.—The Secretary shall prescribe regulations to carry out this section, including standards for qualified loans and authorized payees and other terms and conditions for the making of loan repayments.

(i) TERMINATION.—The authority to carry out the pilot program shall expire on the date that is 3 years after the date on which the Secretary commences the pilot program.

38 USC 1712A
note.

SEC. 5. PILOT PROGRAM ON COMMUNITY OUTREACH.

(a) IN GENERAL.—The Secretary of Veterans Affairs shall establish a pilot program to assist veterans transitioning from serving on active duty and to improve the access of veterans to mental health services.

(b) LOCATIONS.—The Secretary shall carry out the pilot program under subsection (a) at not less than five Veterans Integrated Service Networks that have a large population of veterans who—

(1) served in the reserve components of the Armed Forces;

or

(2) are transitioning into communities with an established population of veterans after having recently separated from the Armed Forces.

(c) FUNCTIONS.—The pilot program at each Veterans Integrated Service Network described in subsection (b) shall include the following:

(1) A community oriented veteran peer support network, carried out in partnership with an appropriate entity with experience in peer support programs, that—

(A) establishes peer support training guidelines;

(B) develops a network of veteran peer support counselors to meet the demands of the communities in the Veterans Integrated Service Network;

(C) conducts training of veteran peer support counselors;

(D) with respect to one medical center selected by the Secretary in each such Veterans Integrated Service Network, has—

(i) a designated peer support specialist who acts as a liaison to the community oriented veteran peer network; and

(ii) a certified mental health professional designated as the community oriented veteran peer network mentor; and

(E) is readily available to veterans, including pursuant to the Veterans Integrated Service Network cooperating

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and working with State and local governments and appropriate entities.

(2) A community outreach team for each medical center selected by the Secretary pursuant to paragraph (1)(D) that—

(A) assists veterans transitioning into communities;

(B) establishes a veteran transition advisory group to facilitate outreach activities;

(C) includes the participation of appropriate community organizations, State and local governments, colleges and universities, chambers of commerce and other local business organizations, and organizations that provide legal aid or advice; and

(D) coordinates with the Veterans Integrated Service Network regarding the Veterans Integrated Service Network carrying out an annual mental health summit to assess the status of veteran mental health care in the community and to develop new or innovative means to provide mental health services to veterans.

(d) REPORTS.—

(1) INITIAL REPORT.—Not later than 18 months after the date on which the pilot program under subsection (a) commences, the Secretary shall submit to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives a report on the pilot program. With respect to each Veterans Integrated Service Network described in subsection (b), the report shall include—

(A) a full description of the peer support model implemented under the pilot program, participation data, and data pertaining to past and current mental health related hospitalizations and fatalities;

(B) recommendations on implementing peer support networks throughout the Department;

(C) whether the mental health resources made available under the pilot program for members of the reserve components of the Armed Forces is effective; and

(D) a full description of the activities and effectiveness of community outreach coordinating teams under the pilot program, including partnerships that have been established with appropriate entities.

(2) FINAL REPORT.—Not later than 90 days before the date on which the pilot program terminates under subsection (e), the Secretary shall submit to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives an update to the report submitted under paragraph (1).

(e) CONSTRUCTION.—This section may not be construed to authorize the Secretary to hire additional employees of the Department to carry out the pilot program under subsection (a).

(f) TERMINATION.—The authority of the Secretary to carry out the pilot program under subsection (a) shall terminate on the date that is 3 years after the date on which the pilot program commences.

Recommendations.

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PUBLIC LAW 114–2—FEB. 12, 2015

38 USC 1720F
note.**SEC. 6. COLLABORATION ON SUICIDE PREVENTION EFFORTS BETWEEN DEPARTMENT OF VETERANS AFFAIRS AND NON-PROFIT MENTAL HEALTH ORGANIZATIONS.**

(a) **COLLABORATION.**—The Secretary of Veterans Affairs may collaborate with non-profit mental health organizations to prevent suicide among veterans as follows:

(1) To improve the efficiency and effectiveness of suicide prevention efforts carried out by the Secretary and non-profit mental health organizations.

(2) To assist non-profit mental health organizations with the suicide prevention efforts of such organizations through the use of the expertise of employees of the Department of Veterans Affairs.

(3) To jointly carry out suicide prevention efforts.

(b) **EXCHANGE OF RESOURCES.**—In carrying out any collaboration under subsection (a), the Secretary and any non-profit mental health organization with which the Secretary is collaborating under such subsection shall exchange training sessions and best practices to help with the suicide prevention efforts of the Department and such organization.

(c) **DIRECTOR OF SUICIDE PREVENTION COORDINATION.**—The Secretary shall select within the Department a Director of Suicide Prevention Coordination to undertake any collaboration with non-profit mental health organizations under this section or any other provision of law.

SEC. 7. ADDITIONAL PERIOD OF ELIGIBILITY FOR HEALTH CARE FOR CERTAIN VETERANS OF COMBAT SERVICE DURING CERTAIN PERIODS OF HOSTILITIES AND WAR.

Paragraph (3) of section 1710(e) of title 38, United States Code, is amended to read as follows:

“(3) In the case of care for a veteran described in paragraph (1)(D), hospital care, medical services, and nursing home care may be provided under or by virtue of subsection (a)(2)(F) only during the following periods:

“(A) Except as provided by subparagraph (B), with respect to a veteran described in paragraph (1)(D) who is discharged or released from the active military, naval, or air service after January 27, 2003, the five-year period beginning on the date of such discharge or release.

“(B) With respect to a veteran described in paragraph (1)(D) who is discharged or released from the active military, naval, or air service after January 1, 2009, and before January 1, 2011, but did not enroll to receive such hospital care, medical services, or nursing home care pursuant to such paragraph during the five-year period described in subparagraph (A), the one-year period beginning on the date of the enactment of the Clay Hunt Suicide Prevention for American Veterans Act.

“(C) With respect to a veteran described in paragraph (1)(D) who is discharged or released from the active military, naval, or air service on or before January 27, 2003, and did not enroll in the patient enrollment system under section 1705 of this title on or before such date, the three-year period beginning on January 27, 2008.”.

Effective date.

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SEC. 8. PROHIBITION ON NEW APPROPRIATIONS.

No additional funds are authorized to be appropriated to carry out this Act and the amendments made by this Act, and this Act and such amendments shall be carried out using amounts otherwise made available for such purposes.

Approved February 12, 2015.

LEGISLATIVE HISTORY—H.R. 203:**CONGRESSIONAL RECORD, Vol. 161 (2015):**

Jan. 12, considered and passed House.

Feb. 3, considered and passed Senate.



115TH CONGRESS
2D SESSION

S. 2796

To authorize the Secretary of Veterans Affairs to use the authority of the Secretary to conduct and support research on the efficacy and safety of medicinal cannabis, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 7, 2018

Mr. TESTER (for himself and Mr. SULLIVAN) introduced the following bill; which was read twice and referred to the Committee on Veterans' Affairs

A BILL

To authorize the Secretary of Veterans Affairs to use the authority of the Secretary to conduct and support research on the efficacy and safety of medicinal cannabis, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “VA Medicinal Cannabis
5 Research Act of 2018”.

1 **SEC. 2. CONDUCT OF RESEARCH INTO EFFECTS OF CAN-**
2 **NABIS ON HEALTH OUTCOMES OF CERTAIN**
3 **VETERANS.**

4 (a) RESEARCH REQUIRED.—In carrying out the re-
5 sponsibilities of the Secretary of Veterans Affairs under
6 section 7303 of title 38, United States Code, the Secretary
7 may conduct and support research relating to the efficacy
8 and safety of forms of cannabis described in subsection
9 (c) on the health outcomes of covered veterans diagnosed
10 with chronic pain, post-traumatic stress disorder, and
11 other conditions the Secretary determines appropriate.

12 (b) DATA PRESERVATION.—Research conducted pur-
13 suant to subsection (a) shall include a mechanism to en-
14 sure the preservation of all data, including all data sets,
15 collected or used for purposes of the research required by
16 subsection (a) in a manner that will facilitate further re-
17 search.

18 (c) FORMS OF CANNABIS TO BE RESEARCHED.—The
19 forms of cannabis described in this subsection are—

20 (1) varying forms of cannabis, including—

21 (A) full plants and extracts;

22 (B) at least three different strains of can-
23 nabis with significant variants in phenotypic
24 traits and various ratios of tetrahydrocannabi-
25 nol and cannabidiol in chemical composition;
26 and

1 (C) other chemical analogs of tetrahydro-
2 cannabinal; and

3 (2) varying methods of cannabis delivery, in-
4 cluding topical application, combustible and non-
5 combustible inhalation, and ingestion.

6 (d) IMPLEMENTATION.—Not later than 180 days
7 after the date of the enactment of this Act, the Secretary
8 shall—

9 (1) develop a plan to implement this section
10 and submit such plan to the Committees on Vet-
11 erans' Affairs of the House of Representatives and
12 the Senate; and

13 (2) issue any requests for proposals the Sec-
14 retary determines appropriate for such implementa-
15 tion.

16 (e) REPORTS.—During the five-year period beginning
17 on the date of the enactment of this Act, the Secretary
18 shall submit periodically, but not less frequently than an-
19 nually, to the Committees on Veterans' Affairs of the
20 House of Representatives and the Senate reports on the
21 implementation of this section.

22 (f) COVERED VETERAN DEFINED.—In this section,
23 the term “covered veteran” means a veteran who is en-
24 rolled in the patient enrollment system of the Department

4

1 of Veterans Affairs under section 1705 of title 38, United
2 States Code.

○

IB

Union Calendar No. 533

115TH CONGRESS
2D SESSION

H. R. 5520

[Report No. 115-690]

To authorize the Secretary of Veterans Affairs to use the authority of the Secretary to conduct and support research on the efficacy and safety of medicinal cannabis, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 16, 2018

Mr. WALZ (for himself, Mr. ROE of Tennessee, and Mr. CORREA) introduced the following bill; which was referred to the Committee on Veterans' Affairs

MAY 18, 2018

Additional sponsors: Mr. TAKANO, Ms. BROWNLEY of California, Mr. COFFMAN, Ms. KUSTER of New Hampshire, Mr. PETERS, Mr. O'ROURKE, Miss RICE of New York, Ms. ESTY of Connecticut, Mr. BLUMENAUER, Mr. GAETZ, Mr. CLAY, Mr. JONES, Mr. ROHRBACHER, Ms. EDDIE BERNICE JOHNSON of Texas, Mr. COHEN, Mr. YOUNG of Alaska, Mr. RASKIN, Ms. MCCOLLUM, Mr. KIHUEN, Mr. POCAN, Mr. SMITH of Washington, Ms. ROSEN, Mr. PANETTA, Mr. POLIS, Mr. VARGAS, Ms. PINGREE, Ms. TITUS, Mr. CRIST, Mr. JOYCE of Ohio, Ms. LEE, Mr. GRIJALVA, Mr. HECK, Mr. DEFAZIO, Ms. SHEA-PORTER, Mr. YARMUTH, Mr. SWALWELL of California, Ms. DEGETTE, Mr. THOMAS J. ROONEY of Florida, Mr. RUSH, Ms. SCHAKOWSKY, Mr. CURBELO of Florida, Ms. NORTON, Mr. COSTELLO of Pennsylvania, Mr. PERLMUTTER, Mr. KHANNA, Mr. MOULTON, Ms. MICHELLE LUJAN GRISHAM of New Mexico, Mr. BRENDAN F. BOYLE of Pennsylvania, Mr. SOTO, Mr. RUTHERFORD, Mr. LAMB, Mr. CARBAJAL, and Mr. QUIGLEY

MAY 18, 2018

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in *italic*]

[For text of introduced bill, see copy of bill as introduced on April 16, 2018]

2

A BILL

To authorize the Secretary of Veterans Affairs to use the authority of the Secretary to conduct and support research on the efficacy and safety of medicinal cannabis, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 *This Act may be cited as the “VA Medicinal Cannabis*
5 *Research Act of 2018”.*

6 **SEC. 2. CONDUCT OF RESEARCH INTO EFFECTS OF CAN-**
7 **NABIS ON HEALTH OUTCOMES OF CERTAIN**
8 **VETERANS.**

9 *(a) RESEARCH.—In carrying out the responsibilities*
10 *of the Secretary of Veterans Affairs under section 7303 of*
11 *title 38, United States Code, the Secretary may conduct and*
12 *support research relating to the efficacy and safety of forms*
13 *of cannabis described in subsection (c) on the health out-*
14 *comes of covered veterans diagnosed with chronic pain,*
15 *post-traumatic stress disorder, and other conditions the Sec-*
16 *retary determines appropriate. The Secretary shall ensure*
17 *that such research is conducted in accordance with applica-*
18 *ble regulations relating to the oversight of research, includ-*
19 *ing such regulations prescribed by the Office of Research*
20 *and Development of the Department of Veterans Affairs, the*
21 *Department of Health and Human Services (including*
22 *through the National Institute on Drug Abuse), the Food*
23 *and Drug Administration, the Drug Enforcement Adminis-*
24 *tration, and the National Institutes of Health.*

1 (b) *DATA PRESERVATION.*—*Research conducted pursu-*
2 *ant to subsection (a) shall include a mechanism to ensure*
3 *the preservation of all data, including all data sets, collected*
4 *or used for purposes of the research required by subsection*
5 *(a) in a manner that will facilitate further research.*

6 (c) *FORMS OF CANNABIS TO BE RESEARCHED.*—*The*
7 *forms of cannabis described in this subsection are—*

8 (1) *varying forms of cannabis, including—*

9 (A) *full plants and extracts;*

10 (B) *at least three different strains of can-*
11 *nabis with significant variants in phenotypic*
12 *traits and various ratios of tetrahydrocannabinol*
13 *and cannabidiol in chemical composition; and*

14 (C) *other chemical analogs of tetrahydro-*
15 *cannabinol; and*

16 (2) *varying methods of cannabis delivery, in-*
17 *cluding topical application, combustible and non-*
18 *combustible inhalation, and ingestion.*

19 (d) *IMPLEMENTATION.*—*If the Secretary conducts and*
20 *supports research under subsection (a), the Secretary*
21 *shall—*

22 (1) *before conducting and supporting such re-*
23 *search, develop a plan to implement this section and*
24 *submit such plan to the Committees on Veterans' Af-*

1 *fairs of the House of Representatives and the Senate;*
2 *and*

3 *(2) issue any requests for proposals the Secretary*
4 *determines appropriate for such implementation.*

5 *(e) REPORTS.—During the five-year period beginning*
6 *on the date of the enactment of this Act, the Secretary shall*
7 *submit periodically, but not less frequently than annually,*
8 *to the Committees on Veterans' Affairs of the House of Rep-*
9 *resentatives and the Senate reports on—*

10 *(1) the implementation of this section; or*

11 *(2) the rationale of the Secretary with respect to*
12 *determining not to implement this section.*

13 *(f) COVERED VETERAN DEFINED.—In this section, the*
14 *term “covered veteran” means a veteran who is enrolled in*
15 *the patient enrollment system of the Department of Veterans*
16 *Affairs under section 1705 of title 38, United States Code.*

Union Calendar No. 533

115TH CONGRESS
2^D SESSION

H. R. 5520

[Report No. 115-690]

A BILL

To authorize the Secretary of Veterans Affairs to use the authority of the Secretary to conduct and support research on the efficacy and safety of medicinal cannabis, and for other purposes.

MAY 18, 2018

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed