

Americans for Safe Access
Statement for the Record
Senate Subcommittee on Crime and Terrorism
Hearing: Researching the Potential Medical Benefits and Risks of Marijuana
July 13, 2016

**Introduction and Support for the Compassionate Access, Research Expansion,
and Respect States (CARERS) Act of 2015 S.683**

Americans for Safe Access (ASA) would like to thank Chairman Lindsey Graham (R-SC), Ranking Member Sheldon Whitehouse (D-RI) and the entire Senate Judiciary Subcommittee on Crime and Terrorism for the opportunity to discuss the benefits and relative harms of medical cannabis (marijuana). As the nation's largest member-based organized working exclusively on advancing safe and legal access to medical cannabis for patients under the recommendation of their physician, ASA would like acknowledge that a Senate hearing on looking into the potential benefits of whole plant cannabis is unprecedented. We hope that it is the first of many, and ASA applauds Chairman Graham and Ranking Member Whitehouse for initiating this long-overdue discussion.

Pre-clinical, observational, and clinical research has demonstrated therapeutic applications for cannabis and cannabis products in conditions such as Cancer, HIV/AIDS, Hepatitis-C, Chronic/Neuropathic Pain, Multiple Sclerosis, Movement Disorders, Arthritis, Alzheimer's Disease, Epilepsy and Seizures, Glaucoma, and PTSD. A lack of viable treatment options from conventional medicine for these conditions is driving a global movement to create safe and legal access to medical cannabis as there are significant numbers of Americans suffering from them. For example, approximately 5.1 million Americans have been diagnosed with epilepsy or seizures, of that number, about 1.7 million do not respond to pharmaceutical treatment.¹ Furthermore, It is estimated that more than 100 million people in this country suffer from chronic pain.²

¹ Kobau R, Luo Y, PhD, Zack M, Helters S, Thurman D. Epilepsy in adults and access to care — United States, 2012. *MMWR*. 2012;61(45):909-913. Accessed February 2, 2016. [pdf](#) [863KB].

US Census Bureau, Population Division [database online]. Annual estimates of the resident population by sex, age, race, and Hispanic origin for the United States, States, and Counties: April 1, 2010, to July 1, 2013. Release Date: June 2014. [html](#). Accessed February 2, 2015.

Russ SA, Larson K, Halfon N. A national profile of childhood epilepsy and seizure disorder. *Pediatrics* 2012;129:256–64. DOI: 10.1542/peds.2010-1371.

² Johannes et al. The prevalence of chronic pain in United States adults: results of an Internet-based survey. *J Pain*. 11(11):1230-9. (2010); Gallup-Healthways Well-Being Index.

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Cannabis has been used medicinally for thousands of years due to its safety profile and vast interactions in the human body. A lethal toxic overdose of cannabis has never been documented.³ Unlike opiates, cannabis compounds, such as THC, do not depress respiration or heart function, and lifetime use is not significantly associated with increased morbidity, brain damage, or cerebral atrophy.⁴

After 20 years of experimentation, medical cannabis programs now include robust regulations that address public health and safety issues such as diversion for non-medical use and product safety protocols. Studies on these programs have shown little to no negative impact, and in some areas, positive effects on public health outcomes. In 2014, an article from the *Journal of American Medicine* found that, “States with medical cannabis laws had a 24.8% lower mean annual opioid overdose mortality rate compared with states without medical cannabis laws.”⁵ Recently the National Bureau of Economic Research reported, “Our findings suggest that providing broader access to medical marijuana may have the potential benefit of reducing abuse of highly addictive painkillers.”⁶

³ McAllister, S. D. et al. Cannabinoids selectively inhibit proliferation and induce death of cultured human glioblastoma multiforme cells. *J Neurooncol* 74, 31–40 (2005).

van den Heuvel, M. J. et al. The international validation of a fixed-dose procedure as an alternative to the classical LD50 test. *Food and Chemical Toxicology* 28, 469–482 (1990).

Young, F. L. In the matter of marijuana rescheduling petition. (Drug Enforcement Agency, 1988).

⁴ Herkenham, M. et al. Cannabinoid receptor localization in brain. *Proc. Natl. Acad. Sci. U.S.A.* 87, 1932–1936 (1990).

Speijers, G. et al. Safety assessment of botanicals and botanical preparations used as ingredients in food supplements: Testing an European Food Safety Authority-tiered approach. *Molecular Nutrition & Food Research* 54, 175–185 (2010).

Ware, M. A. & Tawfik, V. L. Safety issues concerning the medical use of cannabis and cannabinoids. *Pain Res Manag* 10 Suppl A, 31A–7A (2005).

Ware, M. A., Wang, T., Shapiro, S., Collet, J.-P. COMPASS study team. Cannabis for the Management of Pain: Assessment of Safety Study (COMPASS). *J Pain* 16, 1233–1242 (2015).

Pope, H. G., Gruber, A. J., Hudson, J. I., Huestis, M. A. & Yurgelun-Todd, D. Neuropsychological performance in long-term cannabis users. *Arch. Gen. Psychiatry* 58, 909–915 (2001).

⁵ Bachhuber, M. A., Saloner, B., Cunningham, C. O., & Barry, C. L. (2014). Medical cannabis laws and opioid analgesic overdose mortality in the United States, 1999-2010. *JAMA Internal Medicine*, 174(10), 1668–1673. <http://doi.org/10.1001/jamainternmed.2014.4005>

⁶ Powell, D., Pacula, R.L., Jacobson, M. Do Medical Marijuana Laws Reduce Addictions and Deaths Related to Pain Killers? The National Bureau of Economic Research, No.21345 (2015)

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Surveys of medical cannabis patients have suggested that cannabis is often used to decrease the use of other drugs. A recent study from University of Georgia found Medicare experienced a savings of \$165.2 million on prescription drugs across 17 states and the District of Columbia with medical cannabis laws, and reported savings would have reached \$468 million if all states had medical cannabis programs.⁷

While we can appreciate that the Senate is advancing on the issue of medical cannabis, this progress is difficult for ASA's patient members to appreciate as they are caught in the crossfire of the conflict between state and federal law. For the two million medical cannabis patients with a physician's recommendation and under with state laws, the conflict between state and federal law means that their access to medicine is constantly at risk, depending on the current temperament of the federal government. It means that the added expenses incurred by the businesses who provide them with medicine are passed along to the patients as the businesses are denied access to banking services and cannot make ordinary business tax deductions. Furthermore, due to its Schedule I status, health insurance does not cover this physician-recommended therapy, so patients are not only paying extra expenses, but are doing so completely out of pocket.

Ultimately, states are encouraged to regulate medical cannabis programs not in the way that best serves the medical needs of their patients, but by restricting them enough as to not offend vague and subjective federal guidelines.⁸ While the House and Senate have passed the Rohrabacher-Farr/Mikulski amendments protecting state programs from federal interference for two consecutive years, indicating that Congress agrees that states should be able to set their own medical cannabis policies, nobody would agree that a spending prohibition restricting federal interference is a long-term solution.

If Congress passes the Compassionate Access, Research Expansion, and Respect States (CARERS) Act (S. 683/H.R. 1538), these programs would no longer be in conflict with federal law. Furthermore, federal agencies could better study and inform programs, such as the EPA could create safe pesticide lists or NIH could study cannabis as a tool to fight the nation's opiate crisis. For millions of Americans, medical cannabis is legal under state law, and it is time for the federal government to show leadership and support for the 42 states, the District of Columbia, Puerto Rico, and Guam that are creating medical cannabis programs to address the needs of their residents.

For these reasons, ASA strongly supports the CARERS Act, as it is the only bill that would both lift research barriers and provide immediate protection for medical cannabis

⁷ Bradford, A. C., Bradford, W. D. (2016) Medical Marijuana Laws Reduce Prescription Medication Use In Medicare Part D. *Health Affairs*, 35(7), 1230-1236. <http://content.healthaffairs.org/content/35/7/1230>

⁸ DAG Memo 8-29-13, "Guidance Regarding Marijuana Enforcement," available at: <https://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf>.

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patients who currently rely on state programs to provide them with their medicine. While there are number of other bills that have been introduced that focus on medical cannabis research, these bills do not provide relief to patients who need medical cannabis today. Any Congressional action taken on medical cannabis must include immediate protection for current patients and the state programs upon which they rely.

Removal of Cannabis from Schedule I

ASA supports the rescheduling of cannabis under the federal Controlled Substances Act. While the Department of Justice (DOJ) is currently contemplating a decision on rescheduling cannabis, ASA is worried that the decision will, as in the past, be marred by a combination of political influence and incomplete science. To provide a second opinion on the potential medical value and relative harms of cannabis, ASA published an independent 8-factor analysis, which is being submitted along with this written statement for the record.⁹ The analysis looks at several studies that have been ignored by the federal government in previous official 8-factor analysis reviews.

To reside in Schedules II-IV and be approved for diagnosing, mitigating, treating, or curing a specific medical condition, a substance or botanical must proceed through a rigorous FDA process proving safety and efficacy. Different forms of Cannabis have been through rigorous clinical testing including whole plant Cannabis, hash oil extracts dissolved in ethanol, and purified extracts.

To be approved a medicine the FDA requires the following five criteria to be addressed, which are addressed in indepent 8-factor analysis:¹⁰

- 1) The drug's chemistry is known and reproducible.
- 2) There are adequate safety studies.
- 3) There are adequate and well-controlled studies proving efficacy.
- 4) The drug is accepted by qualified experts.

⁹ Marcu, Jahan, et al., "Scheduling Cannabis: A Preparatory Document for FDA's 8-Factor Analysis on Cannabis," Americans for Safe Access, June, 2016, available at: http://www.safeaccessnow.org/8_factor_analysis_on_cannabis.

¹⁰ "One of the criteria preventing the rescheduling of Cannabis is the notion that information about this medicine is not widely available. There are tens of thousands of peer reviewed articles available through online portals, journal websites, and other resources for health professionals to access clinical information about Cannabis, including but not limited to: Springer, Wiley, Pubmed, Public Libraries, medical and graduate school libraries, and websites of expert groups such as Americans for Safe Access, theAnswerpage.org, and the International Cannabis and Cannabinoid Institute.

The Internet has also revolutionized research and science by allowing the generation of and access to large amounts of information that would have previously been nearly impossible to obtain. People across the globe can now access hordes (a search for 'cannabis research' through web of science yields 120,000 articles) of previously unavailable scientific and clinical information."

Id. at 82.

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5) The scientific evidence is widely available.

Gateway Drug Perceptions vs Realities

While cannabis has often been portrayed as a gateway drug that leads people on to more dangerous substances, the evidence does not support this theory.

Moreover, long-term cognitive harms are not supported by science. An often cited study supposedly concludes that marijuana reshapes the brain, however, the study does not adequately control for other factors.¹¹ A study that did control for other factors, such as alcohol use, found no change as the result of marijuana use.¹² In fact, a peer reviewed study in the Journal of School Health found that alcohol was the most gateway-like substance.¹³

The independent 8-factor analysis addresses the gateway theory in Sections 4 and 5, History and Current Pattern of Abuse and Scope, Duration, and Significance of Abuse, with detail provided in the subsection entitled Cannabis as Gateway Drug.¹⁴ Notably:

"Patterns in progression of drug use from adolescence to adulthood are strikingly regular. Because it is the most widely used illicit drug, marijuana is predictably the first illicit drug most people encounter. Not surprisingly, most users of other illicit drugs have used marijuana first. In fact, most drug users begin with alcohol and nicotine before marijuana—usually before they are of legal age.

In the sense that marijuana use typically precedes rather than follows initiation of other illicit drug use, it is indeed a "gateway" drug. But because underage smoking and alcohol use typically precede marijuana use, marijuana is not the most common, and is rarely the first, "gateway" to illicit drug use. There is no conclusive evidence that the drug effects of marijuana are causally linked to the subsequent abuse of other illicit drugs. An important caution is that data on drug use progression cannot be assumed to apply to the use of drugs for medical purposes. It does not follow from those data that if marijuana were available by

¹¹ Gilman, John, et al., Cannabis Use Is Quantitatively Associated with Nucleus Accumbens and Amygdala Abnormalities in Young Adult Recreational Users, The Journal of Neuroscience, 16 April 2014, 34(16): 5529-5538

¹² Weiland, Barbara, et al., Daily Marijuana Use Is Not Associated with Brain Morphometric Measures in Adolescents or Adults, The Journal of Neuroscience, 28 January 2015, 35(4): 1505-1512.

¹³ Kirby, T., Barry, A.E., Alcohol as a gateway drug: a study of US 12th graders, J Sch Health. 2012 Aug; 82(8):371-9.

¹⁴ Marcu at 70-84, citing Joy, J. E., Watson, S. J., Jr, and Benson, J. A., Jr, 1999, Marijuana and Medicine: Assessing the Science Base, National Academies Press, Washington, D.C. Additionally, see Factor 1: Cannabis' Actual or Relative Potential for Abuse (Pg 8-32) and Factor 7: Its Psychic or Physiological Dependence Liability (pg. 90).

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prescription for medical use, the pattern of drug use would remain the same as seen in illicit use."

Real Efficacy, Not Just a Placebo Effect

While skeptics of the efficacy of medical cannabis assert that the substance does not have evidence of providing actual benefit to patients, there is plenty of science to support the efficacy of medical cannabis. This is explored in great detail in Factor 3: The State of Current Scientific Knowledge Regarding the Drug or Other Substance.¹⁵

The medical value from cannabis should also be established through the fact that its main active ingredient has been approved for medical use. While oral THC (marinol) is available by prescription, and therefore meets criteria for efficacy, patients do report it as having a poor bioavailability and an unpredictable onset, compared to inhaled cannabis. In fact, there are several dozen clinical studies that attest to the medical value of cannabis in treating chronic pain, muscle spasticity, cachexia, and other variously debilitating conditions.¹⁶

Federal Prohibition Forces Patients to Make Suboptimal Choices

While states have taken the lead on regulating safe and legal access to medical cannabis, the federal prohibition of cannabis has a number of indirect effects the harm patients. Most of these issues are obvious, for example, patients know that this therapy is in violation of federal law, therefore they are constantly under the threat of federal arrest and prosecution. Other impacts are less obvious.

The Schedule I status of cannabis means that there is great stigma for physicians who wish to make it part of their medical practices. While the chilling effect that this stigma has on research has been known to the Senate since Dr. John "Brad" Ingram testified to the existence of it during the 2016 Senate Drug Caucus hearing on CBD, the chilling effect does not stop there.¹⁷

Many patients report that their physicians refuse to discuss the potential benefits and risks of medical cannabis therapy. Sometimes this is the result of the personal beliefs of the physician, but often times it is the result of physicians and health care provider organizations erring on the side of caution because they do not want to risk any potential for federal interference with their medical practice. As a result, clinics specializing in medical cannabis therapy have been emerging. There would be less of a demand for

¹⁵ Id. at 39-68.

¹⁶ Id. 45-46.

¹⁷ *Drug Caucus Hearing on Barriers to Cannabidiol Research*, June 24, 2015, available at: <http://www.drugcaucus.senate.gov/content/drug-caucus-hearing-barriers-cannabidiol-research-0>.

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such services if patients and physicians could have open discussions about the potential risks and benefits of medical cannabis. Therefore, removing cannabis from Schedule I and providing explicit protections for patients and the state programs they rely on is the best solution to this problem. The CARERS Act would address both of these issues and encourage patients to have these conversations with their primary care physicians and specialist whom they see on a regular basis.

Conclusion

There is only one bill in Congress that provides the type of comprehensive solution to the issues facing medical cannabis patients. While patients certainly welcome more research and greater academic knowledge regarding medical cannabis therapy, the most pressing issue facing patients is the conflict between state and federal laws. Fortunately, there is a legislative vehicle that addresses both research and protecting access to the existing state programs. ASA reiterates its support for the CARERS Act, as it is the only bill that adequately meets these needs.

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