Congress of the United States

Washington, DC 20510

April 12, 2016

The Honorable Barack Obama
President of the United States
The White House
1600 Pennsylvania Avenue
Washington, DC 20500

Dear Mr. President:

We write to request your help in removing the administrative barriers to scientific research on medical treatments derived from the cannabis plant, also known as "medical marijuana." We have heard from numerous patients across the U.S. and parents whose children have treatment-resistant conditions about the benefits they have experienced from using cannabis to treat serious illnesses. Many prominent physicians and physician groups, including the American Medical Association, the American College of Physicians, the American Academy of Neurology, and the American Academy of Family Physicians, have joined patients and families in calling for more research about the use of medical cannabis.[i] Twenty-three states have passed laws establishing medical cannabis programs and an additional seventeen have passed laws regarding the medical use of cannabidiol (CBD), a compound derived from cannabis. Despite these developments, researchers, doctors, and patients in these forty states are still subject to several federal barriers impeding innovation and medical research.

While legislation has been introduced to address the legal barriers, many impediments to research could be removed with no change to existing law. To address these federal barriers, members of both houses of Congress have engaged with the Department of Health and Human Services (HHS), the Office of National Drug Control Policy (ONDCP), and the Drug Enforcement Administration (DEA) on multiple occasions through correspondence[ii], hearings[iii] and staff-level briefings. While the Administration's most recent response from HHS Secretary Burwell, ONDCP Director Botticelli, and DEA Acting Administrator Rosenberg on April 4, 2016 provides additional context on the current system, it still offers no clear plan to remove existing barriers or stimulate new research. In 2015, only two researchers in the United States received a DEA-approved supply of cannabis for medical research in humans. At the recent National Institutes of Health (NIH) neuroscience summit on cannabinoids, multiple researchers said that the federal government's current administrative barriers dissuade qualified scientists and doctors from even applying to research cannabis. Therefore, we ask you to take the following two actions to remove barriers and encourage medical research:

I. Direct the DEA to Conduct a Fair and Transparent Review of Schedule I Restrictions on Medical Cannabis.

The Controlled Substances Act (CSA) of 1970 classified cannabis as a Schedule I substance, reserved for drugs with "no currently accepted medical use," without citing any scientific evaluation of its medical use. The Schedule I status means it is more difficult to conduct medical research on cannabis than on cocaine or methamphetamines, even though almost half of all Americans live in states which have passed medical cannabis laws. The FDA's Deputy Director for Regulatory Programs testified before Congress in June 2015 that rescheduling could "expand opportunities for research" and "send a message that it is important to do [research] and it is possible to do it."

Rescheduling a substance from Schedule I requires establishing that one of the following conditions is true: that the substance has "accepted medical use," that the substance has "accepted safety under medical supervision," or that the substance does not have "high potential for abuse." Over the past 43 years, multiple petitions[iv] have been filed to reschedule cannabis. The first petition was filed in 1972, and in 1988 DEA Chief Administrative Law Judge Francis recommended that it be rescheduled. However, that recommendation was overruled by the DEA Administrator in 1989. Subsequent petitions have been rejected, and the most recent petition, filed in 2011 by Governor Chafee of Rhode Island and Governor Gregoire of Washington, has not yet been responded to by the DEA. In a November 2015 briefing to Senate staff, representatives of the Administration refused to provide information regarding the current status of the 2011 petition. However, in September 2015, the Department of Justice had already responded to Congressman Earl Blumenauer's inquiry regarding the petition by stating that the DEA had "received the HHS scientific and medical evaluations as well as a scheduling recommendation." According to the April 4 letter, DEA acknowledged that the agency "hopes to release its determination in the first half of 2016." We welcome the announcement that the Administration has set a timeline for this determination. Given previous issues with transparency in the scheduling process, we request that public hearings also be held to allow researchers, doctors, and patients an opportunity to inform this decision in an open, transparent manner.

II. End the DEA-Mandated NIDA Monopoly.

Currently, the University of Mississippi, through a National Institute on Drug Abuse (NIDA) contract, possesses the only DEA license to grow cannabis for medical research in the United States. This monopoly on a medical research supply does not exist for other Schedule I substances. NIDA Director Dr. Nora Volkow testified before Congress in June 2015 that there is "no scientific reason" for the monopoly, that it "is not something NIDA chose to do," and that without it, "efficiency, effectiveness, availability for research would be better."

The DEA has previously claimed that licensing sources of cannabis for medical research outside of the NIDA drug supply program would be a violation of the 1961 Single Convention on Narcotic Drugs. However, the State Department, other signatories to the Single Convention, and even DEA's own Administrative Law Judge have had less rigid interpretations of the treaty. In October 2014, the State Department, which is responsible for interpreting treaties for the U.S. government,

announced a new "flexible interpretation" policy toward the Single Convention.[v] Meanwhile, countries such as Canada, Israel, and the U.K. have implemented programs that adhere to the Single Convention while allowing licensed businesses to cultivate and distribute cannabis for medical purposes. For example, Health Canada currently has 30 licensed producers of medical cannabis. In a 2007 ruling, DEA Administrative Law Judge Mary Ellen Bitner recommended granting an additional license to supply cannabis for medical research, saying that this supply would fall under the "medicinal" exception to the Single Convention and "therefore the government monopoly would not apply." But, the Deputy Administrator overruled Judge Bitner's recommendation in 2009.

Among its justifications for refusing to grant additional licenses, the DEA has cited that cannabis has "no currently accepted medical use,"[vi] as indicated by the drug's Schedule I status. However, researchers will never be able to demonstrate "accepted medical use" to DEA standards[vii] without a sufficient drug supply, hence creating a chicken-and-egg scenario. DEA-licensed researchers have told us that this monopoly is the most significant barrier to research, because the NIDA drug supply program is inadequate to conduct the basic research that physicians and patients need to better inform their decisions and the clinical trials necessary for medical research, including drug development.

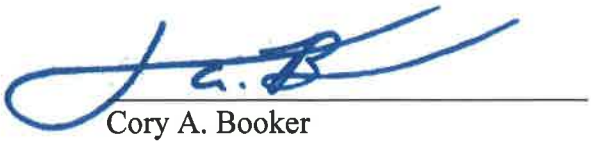
We have repeatedly asked the DEA why it is not following the precedent set by other countries and how it plans to work within the Single Convention to utilize the already existing supply of cannabis being cultivated in states that have passed legislation regarding its medical use. HHS, DEA and ONDCP have stated, "We do not have sufficient information regarding the cultivation of cannabis in these other nations" and production in the United States is not permitted "outside the system of controls described under the treaty." These statements do not provide a rationale for the DEA's narrow interpretation of the Single Convention, nor address the issue of an inadequate supply for medical research. We request that you direct the DEA Administrator to eliminate this barrier to research and grant additional licenses outside of the NIDA drug supply program to provide a supply of cannabis which is adequate to do medical research, up to the standards required by the DEA to prove "accepted medical use."

Together, these two actions will encourage innovation and facilitate new medical research. As states have attempted to expand access to medical treatments for their citizens, the federal government has a responsibility to act in a manner that allows patients to benefit from research on those treatments. Until we have comprehensive scientific research on the medical risks and benefits of cannabis and its derivatives, we will continue to debate this issue on the basis of outdated ideology instead of modern science. We look forward to hearing from you on this matter.

Sincerely,

Kirsten Gillibrand
United States Senator

Rand Paul
United States Senator



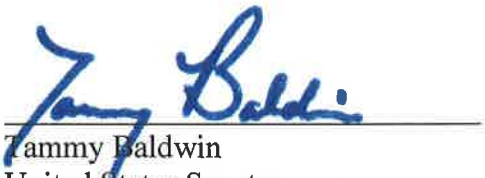
Cory A. Booker
United States Senator

Jeffrey A. Merkley
United States Senator

Barbara Boxer
United States Senator

Patty Murray
United States Senator

Ron Wyden
United States Senator



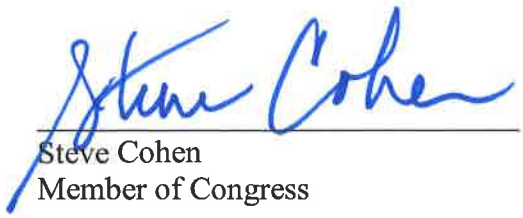
Tammy Baldwin
United States Senator

Michael F. Bennet
United States Senator

Christopher Murphy
United States Senator

Earl Blumenauer
Member of Congress

Morgan Griffith
Member of Congress



Steve Cohen
Member of Congress

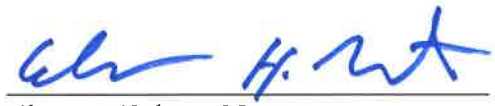
John Conyers
Member of Congress

Sam Farr
Member of Congress

Raúl M. Grijalva
Member of Congress

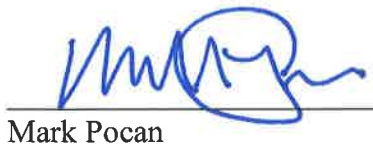
Barbara Lee
Member of Congress

Ted Lieu
Member of Congress

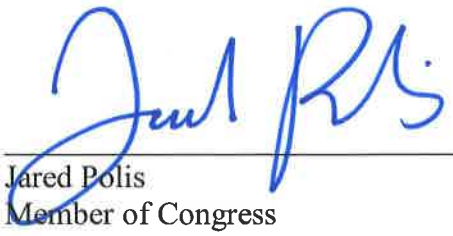


Eleanor Holmes Norton
Member of Congress

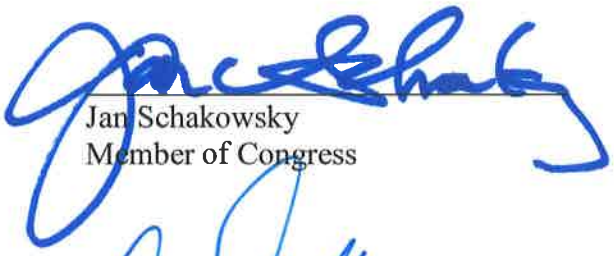
Ed Perlmutter
Member of Congress



Mark Pocan
Member of Congress



Jared Polis
Member of Congress



Jan Schakowsky
Member of Congress

Eric Swalwell
Member of Congress

Adam Smith
Member of Congress

Dina Titus
Member of Congress

Zoe Lofgren
Member of Congress

cc: DOJ AG, DEA, HHS, FDA, ONDCP, NIDA

---

[i] AM. MED. ASS'N, *H-95.952 Cannabis for Medical Use* (2009); AM. COLLEGE PHYS., *Supporting Research into the Therapeutic Rule of Marijuana* (2008); AM. ACAD. NEUROLOGY, *Position Statement: Use of Medical Marijuana for Neurologic Disorders* (2014); AM. ACAD. FAM. PHYS., *Marijuana* (2014); Jonathan N. Adler & James A. Colbert, *Medicinal Use of Marijuana–Polling Results*, 368 NEW ENGL. J. MED. 230 (2013).

[ii] Letter from Rep. Earl Blumenauer et al., to HHS Secretary Sylvia Matthews Burwell (June 17, 2014); Letter from Sen. Elizabeth Warren et al., to HHS Secretary Sylvia Matthews Burwell, ONDCP Director Michael Botticelli, and DEA Acting Administrator Chuck Rosenberg (July 9. 2015); Follow-Up Letter from Sen. Elizabeth Warren et al., to HHS Secretary Sylvia Matthews Burwell, ONDCP Director Michael Botticelli, and DEA Acting Administrator Chuck Rosenberg (Dec. 21, 2015)

[iii] *Cannabidiol: Barriers to Research and Potential Medical Benefits: Hearing Before the S. Caucus on Int'l Narcotics Control*, 114th Cong. (2015); *Mixed Signals: The Administration's Policy on Marijuana: Hearings Before the Subcomm.on Gov't Operations of the H. Comm. on Oversight & Gov't Reform*, 113th Cong. (2014).

[iv] National Organization for the Reform of Marijuana Laws (NORML) (1972-05-18) "Petition to the Bureau of Narcotics and Dangerous Drugs (BNDD)"; Gettman (1995-07-10) "Petition to DEA"; Coalition for Rescheduling Cannabis (2002-10-09) "Petition to DEA"; Krumm (2009-12-17) "Petition to DEA"; Offices of the Governors of the States of Washington and Rhode Island (2011-11-30). "Petition to DEA"

[v] Asst. Secretary of State William Brownfield, Bureau of International Narcotics and Law Enforcement Affairs. "Trends in Global Policy" (Press Conference, Foreign Press Center, October 9, 2014)

[vi] DEA Office of Chief Counsel opinion, 2007

[vii] "Accepted medical use" can be proven by approval of a New Drug Application by FDA or by satisfying five elements: a. the drug's chemistry is known and reproducible b. there are adequate safety studies c. there are adequate and well-controlled studies proving efficacy d. the drug is accepted by qualified experts e. the scientific evidence is widely available. *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994)