United States Senate
WASHINGTON, DC 20510

July 9, 2015

The Honorable Sylvia Mathews Burwell
Secretary
Department of Health and Human Services
200 Independence Ave, SW
Washington, D.C. 20201

The Honorable Michael Botticelli
Director
Office of National Drug Control Policy
The White House
1600 Pennsylvania Ave NW
Washington, D.C. 20500

The Honorable Chuck Rosenberg
Acting Administrator
Drug Enforcement Administration
8701 Morrisette Drive
Springfield, VA 22152

Dear Secretary Burwell, Director Botticelli, and Acting Administrator Rosenberg,

We write to inquire about the efforts of the Department of Health and Human Services (HHS), Office of National Drug Control Policy (ONDCP), and the Drug Enforcement Administration (DEA) to facilitate scientific research on the potential health benefits of marijuana when used for medical purposes ("medical marijuana"). As you know, a number of states have enacted laws providing access to medical marijuana, for patients suffering from diseases such as cancer, multiple sclerosis, HIV, and epilepsy. Additionally, some states have enacted or are considering enacting statutes allowing broader marijuana use. While these state-level efforts have been pursued without the involvement of the federal government, there is both a unique opportunity and an important role for federal agencies to collaborate with states to conduct population-based, clinical, and other basic research on medical marijuana.

Currently, twenty-three states and the District of Columbia have passed laws allowing for medical marijuana use, and an additional fifteen states have laws specifically allowing access to cannabadiol (CBD). While the federal government has emphasized research on the potential harms associated with the use of marijuana, there is still very limited research on the potential health benefits of marijuana – despite the fact that millions of Americans are now eligible by state law to use the drug for medical purposes. There is no substitute for rigorous preclinical and clinical research on the potential benefits of medical marijuana. With the patient pool of medical marijuana users growing in the United States, we believe that federal agencies have both an

opportunity and a responsibility to craft a sensible research and public health strategy that allows us to generate meaningful data and conclusions from this ongoing natural experiment. While we appreciate the recent action of HHS to eliminate the burdensome and unnecessary Public Health Service Board, there are additional barriers that still stand in the way of researchers who wish to study the potential health benefits of medical marijuana in well-controlled studies.

As an increasing number of Americans consult with their doctors about marijuana treatment options, it is important that we make a concerted effort to understand how this drug works and how it can best serve patients through appropriate methods of use and doses, like any other prescribed medicine. HHS has tools to collect data, conduct surveillance, and perform large scale clinical trials while states continue to focus on implementation. HHS also has the capacity to facilitate interstate communication in order to derive a more accurate picture of medical marijuana use and treatments across the country. It is time for the federal government to pick up those tools and use them.

In addition to facilitating population research, federal agencies should find ways to support independent scientists conducting basic research on the marijuana plant itself. This includes eliminating extraneous regulatory barriers for researchers who wish to perform scientific studies on the use of marijuana for various diseases – including research on different methods of use and strains of marijuana. This research can help to establish firm scientific data that can be used to inform patients, physicians, and policy makers.

In order to better understand how HHS, ONDCP, and the DEA plan to coordinate their agencies to address the data shortfall on the potential health benefits of medical marijuana use, we respectfully request answers to the following questions:

(1) We applaud the elimination of the HHS Public Health Service review board. This is one important step to reduce barriers to research. How do you plan to work together to make sure that qualified research proposals are swiftly reviewed by the DEA, the Food and Drug Administration, and local Institutional Review Boards in order to begin research in a timely manner?

(2) The DEA is charged with issuing permits for the bulk manufacture of marijuana for research purposes. The National Institute on Drug Abuse (NIDA) holds the only bulk manufacture permit granted by the DEA. NIDA, in turn, has an exclusive contract with the University of Mississippi to grow its entire research supply of marijuana. NIDA's director, Nora Volkow, indicated in her testimony at a June 24th hearing of the Senate Caucus on International Narcotics Control that this NIDA-held monopoly on supply of marijuana for research purposes has compromised the ability of scientists to access adequate supply and appropriate strains and quality for specific research protocols.

    a. Please describe in detail any regular and organized communication planned or taking place between agencies, including but not limited to HHS, the DEA, and the ONDCP, to address and coordinate efforts to reduce administrative barriers to obtaining a permit for the purpose of bulk manufacture of marijuana for research purposes to ensure the federal government isn't preventing qualified researchers from accessing what they need to complete research.

b. Please describe in detail any plans by the DEA to provide additional permits which can lead to the availability of marijuana for clinical trials, or alternatively explain why you have no plans to do so.

(3) What are agencies, including but not limited to NIDA and the DEA, doing to assure researchers and study sponsors, such as universities and private industry, that are pursuing studies on the potential therapeutic value of marijuana that such research will not jeopardize their involvement with other NIDA-funded research, simply because they are researching a Schedule I substance?

(4) We understand that many current policies were originally implemented to comply with the United Nations Single Convention on Narcotics of 1961. Many other countries, however, have increased the diversity of sources of marijuana for research while still complying with the Convention. Why hasn't the U.S. followed the efforts of other nations to issue public and private entities licenses for the production of marijuana for research while still complying with the Single Convention on Narcotics?

(5) Marijuana research should include investigations in diverse populations and with multiple modes of administration.

a. What measures are being taken to ensure that studies on the benefits of medical marijuana include diverse populations?

b. What measures are being taken to encourage research that investigates the variable risks, benefits, and efficacy of different modes of administration, including but not limited to smoking, inhalation of vaporized product, oral administration of cannabis, and types of products, including but not limited to purified products or specific compounds?

(6) Marijuana's classification as a Schedule I substance under the Controlled Substances Act (defined as having "no currently accepted medical use") has made it difficult for scientists to conduct research. The DEA has asked the FDA to begin collecting scientific evidence on marijuana to begin making a recommendation on re-scheduling the drug.

a. What is the timeline for FDA to complete this analysis and release a recommendation?

b. Will this analysis include existing data that compares the drug to alcohol and tobacco?

c. Is the FDA including a recommendation for the re-scheduling of CBD?

d. What is the DEA timeline for assessment upon receipt of the FDA recommendation?

(7) Inter-agency cooperation is vital to ensure the best interests of patients are being served.

a. Please describe in detail any regular and organized communication that is taking place between all of the agencies that are charged with marijuana research, policy, or data collection, including but not limited to the Centers for Disease Control (CDC), the NIH, the Substance Abuse and Mental Health Services Administration (SAMHSA), the FDA, and the Office of the Director of National Drug Control Policy (ONDCP), to coordinate efforts and long term plan development.

b. Please describe in detail any regular and organized communication between HHS and state public health departments to coordinate efforts and long term plan development?

(8) Some states have approved the use of CBD for medical use. How are you working to increase the supply of marijuana with high-CBD content for researchers?
(9) Please describe in detail any plans to conduct inter-state studies on medical marijuana, prescriptions, use, or patient outcomes.
(10) Surveillance and epidemiological studies are important to assess how medical marijuana is being used.
    a. Please describe in detail any efforts to collect data about the total number of medical marijuana patients in the United States, the nature of their ailments, modes of use, and patient outcomes?
    b. Please describe in detail plans to work with state public health departments to coordinate local research on medical marijuana patients so that data between states can be comparable.

Many states and localities are moving forward with policies that facilitate the availability of medical marijuana to a greater proportion of the population than ever before. All participants in this important debate will benefit from rigorous, scientific research into the impact of these policies on American public health. Relevant federal agencies must play a leadership role in coordinating and facilitating that research if we are to ensure that public policy in this area is supported by our best science. We look forward to your response on this matter. Please respond no later than August 31, 2015.

Sincerely,

Senator Elizabeth Warren

Senator Jeffrey A. Merkley

Senator Ron Wyden

Senator Barbara A. Mikulski

Senator Edward J. Markey

Senator Barbara Boxer

Senator Cory A. Booker

Senator Kirsten E. Gillibrand

CC:
Dr. Thomas R. Frieden, Director, Centers for Disease Control and Prevention
Ms. Pamela S. Hyde, Administrator, Substance Abuse and Mental Health Services Administration
Dr. Francis S. Collins, Director, National Institutes of Health
Dr. Stephen Ostroff, Acting Commissioner, Food and Drug Administration
Dr. Nora D. Volkow, Director, National Institute on Drug Abuse