

United States Senate

WASHINGTON, DC 20510

December 21, 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,

Thank you for responding to our July 9, 2015 letter inquiring about the efforts of the Department of Health and Human Services (HHS), Office of National Drug Control Policy (ONDCP), and Drug Enforcement Administration (DEA) to facilitate scientific research on the potential health benefits of marijuana when used for medical purposes (“medical marijuana”), and for providing a briefing for our staff on November 13, 2015. However, we remain disappointed that responses given to issues raised by our letter and at the briefing failed to answer key substantive questions.

As we noted in our initial letter, there is a need and unique opportunity for federal agencies to collaborate with each other and with states to conduct population-based, clinical, and other basic research on the risks and benefits of medical marijuana. However, there are currently numerous federal and state regulatory barriers to researching marijuana. This regulatory scheme which limits medical marijuana research is outdated and in desperate need of serious and immediate review. These problems are only exacerbated by a lack of coordination between the agencies and states.

As you stated in your response to our letter, patients and their families want to have “safe and effective therapies developed as quickly as possible.” Reducing barriers to research on the potential health benefits of marijuana is therefore a time-sensitive matter that warrants immediate attention from federal agencies.

We are therefore writing to you again in order to better understand how HHS, ONDCP, and the DEA plan to address the research gaps on medical marijuana use, and to receive

answers to inquiries raised in our original letter and in the briefing. We respectfully request a detailed, written response to the following questions no later than January 31, 2016:

- (1) **The supply of marijuana for research purposes.** The DEA is charged with issuing permits for the bulk manufacture of marijuana for research purposes. The National Institute on Drug Abuse (NIDA) has an exclusive contract with the University of Mississippi (which holds the only bulk manufacture permit granted by the DEA) to grow its entire research supply of marijuana. In our July 2015 letter, we raised concerns that this NIDA-held monopoly on supply of marijuana for research purposes limits access to adequate supply and appropriate varieties of marijuana and presents significant barriers to research.

At the November briefing, ONDCP and the DEA indicated that they did not view supply limits as a barrier, citing a recent overproduction of one variety of marijuana for research and noting that the DEA has only received one request for an additional bulk manufacture permit to date. But the DEA assertions only applied to one strain of marijuana and do not reflect feedback we have heard from researchers in our states. Because the format of the briefing did not allow for discussion of this issue in appropriate detail, we therefore seek the following additional information:

- a. Please provide detailed information on the current supply of marijuana at the University of Mississippi, including a breakdown of all strains, amounts available in each strain, amount of each strain that has been requested, and the amount of each strain that is in surplus.
- b. Please describe how agencies, including HHS, DEA, Department of Justice (DOJ), National Institutes of Health (NIH), NIDA, and the ONDCP, plan to increase the number of permits for the bulk manufacture of marijuana for research purposes. If there is no plan, please describe why not.
- c. Please indicate how many applications have been received for permits for bulk manufacture of marijuana for research purposes to date, what their status is, and the length of time between initial application and denial.
- d. Your response to our July letter indicates that DEA has approved 265 researchers to conduct medical marijuana research. For each of these approvals, please provide information on the requested strain, and how long it has taken to fulfill the researchers request for marijuana after the study has been approved.
- e. How are your agencies planning to work within the bounds of the Single Convention on Narcotics Drugs to allow researchers to utilize the already existing supply of marijuana in states that have enacted laws to make the drug available for medical or recreational use?
- f. The United Kingdom, Canada, Israel, the Netherlands, Czech Republic, Portugal, and Uruguay have acted to increase the diversity of sources for the production of marijuana for research while still complying with the Single Convention on Narcotic Drugs. Why has the United States not taken similar actions?

(2) **Assessment of marijuana rescheduling.** In our July letter, we asked about the timeline for the Food and Drug Administration (FDA) to complete its analysis on the rescheduling of marijuana and to make a recommendation to the DEA. We also asked what the DEA timeline was for assessment upon receipt of the FDA recommendation. These questions were not answered in the written response from your agencies, and at the staff briefing you repeatedly informed our staff that you could not provide the requested information. However, after the briefing we learned that in fact the FDA has already made the recommendation. In a September 30, 2015 letter to Congressman Earl Blumenauer, the Department of Justice wrote that the “DEA recently received the HHS scientific and medical evaluations as well as a scheduling recommendation,” which indicates the FDA has completed its evaluation, and that the “DEA is currently reviewing these documents ... to make a scheduling determination in accordance with the Controlled Substances Act.” The failure to provide us with this information at the briefing leaves us with continued questions about the process and timeline for a re-scheduling determination. We therefore ask that you provide us with the following information:

- a. Please confirm whether or not the DEA has received the HHS evaluations and scheduling recommendations.
- b. What is the DEA timeline for assessment upon receipt of the FDA recommendation?
- c. Has the DEA requested that the FDA complete a scientific analysis for the re-scheduling of cannabidiol (CBD)? If so, please describe how the FDA will conduct the review.

(3) **Interagency coordination and research applications.** At the briefing, you explained to us that ONDCP is coordinating regular meetings with relevant federal agencies about encouraging research, and you explained that these discussions ultimately led to the elimination of the HHS Public Health Service Review Board. This was a positive step, because this board significantly delayed research approval and existed for no other Schedule I substance. However, we continue to hear from the research community that the research application approval process is long, cumbersome, and difficult to navigate. We therefore ask that you:

- a. Please clarify how you plan to work together to encourage qualified research applications.
- b. Please describe the application process for qualified researchers who wish to conduct research using marijuana, including all steps at the DEA, FDA, and local Institutional Review Boards, from initial application to receipt of marijuana from NIDA, including data on how long the entire process has taken for previously approved applications.

(4) **Surveillance and epidemiological studies.** Federal agencies should work to facilitate surveillance and epidemiological studies to assess how medical marijuana is being used. This should also include investigations in diverse populations and with multiple modes of administration. We inquired about this work in our initial letter and our briefing, and we are concerned that there was no

mention of efforts to collect these data. We therefore ask that you address the following:

- a. Is the Centers for Disease Control and Prevention (CDC), in collaboration with NIDA and any other federal agencies, collecting data about the total number of medical marijuana patients in the United States, the nature of their ailments, modes of use, and patient reported outcomes?
- b. How are your agencies working with state public health departments in order to coordinate research on medical marijuana use so that data can be compared between states?
- c. How are your agencies ensuring that studies on the benefits of medical marijuana include diverse populations?
- d. Please describe in detail what measures are being taken to encourage research that investigates the variable risks, benefits, and efficacy of different modes of administration, including smoking, inhalation of vaporized product, oral administration of cannabis, and types of products, including purified products or specific compounds?
- e. Canada and the state of California have established medical marijuana patient registries. A patient registry could significantly support the work of researchers and physicians, while also improving our understanding of the population of medical marijuana patients in the United States. We understand that that NIDA is analyzing these programs to determine the feasibility of a national patient registry. Please describe any ongoing work to establish a national patient registry, including any necessary funding that would be necessary to launch this effort, and the timeline for implementation.

(5) **Coordination with states and inter-agency cooperation.** Cooperation is vital to ensure that medical marijuana is being used effectively and appropriately by those who need it. We asked a number of questions about such cooperation in our letter and our briefing and the responses were not complete. For example, you informed us that federal agencies have been in communication and are coordinating on this issue, but failed to describe in detail the nature and type of these communications. We therefore ask that you address the following:

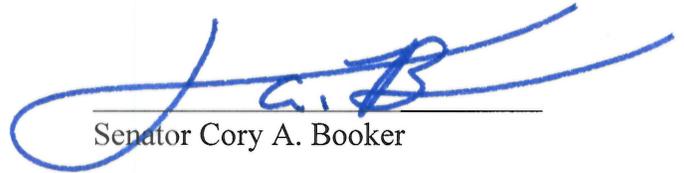
- a. Please describe in detail any regular and organized communication between HHS and state public health departments to coordinate research efforts regarding medical marijuana.
- b. Please describe in detail any efforts by federal agencies to provide guidance to states for testing standards to ensure patient safety and access needs are met.
- c. Please describe in detail any regular and organized communication taking place between agencies that are charged with marijuana research, policy, or data collection (including but not limited to CDC, FDA, NIH, ONDCP, and the Substance Abuse and Mental Health Services Administration (SAMHSA)), to coordinate efforts and long term plan development.

We must ensure that our public policy regarding medical marijuana is guided by the best science available, and in the absence of that science we must ensure that we are taking swift and deliberate steps to facilitate the research that provides for it. We look forward to your prompt, written, and complete response to these questions no later than January 31st, 2016.

Sincerely,



Senator Elizabeth Warren



Senator Cory A. Booker



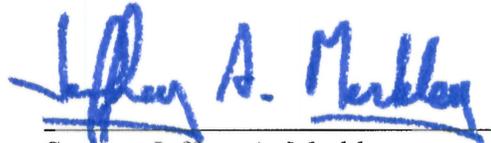
Senator Barbara Boxer



Senator Kirsten Gillibrand



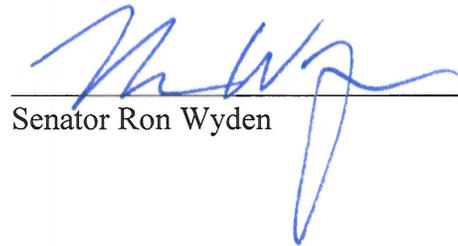
Senator Edward J. Markey



Senator Jeffrey A. Merkley



Senator Barbara A. Mikulski



Senator Ron Wyden

CC:

Loretta E. Lynch, Attorney General, Department of Justice

Dr. Thomas R. Frieden, Director, Centers for Disease Control and Prevention

Kana Enomoto, Acting 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 of Drug Abuse