



October 15, 2015

The Honorable Elizabeth Warren
United States Senate
Senate Office Building
Washington, DC 20510

Dear Senator Warren:

We are writing in response to the July 9, 2015, letter sent by you and seven of your Senate colleagues concerning efforts by the Federal Government to support research into the potential health benefits of marijuana and its constituent components. An identical response is being sent to the other signatories to your letter.

We support research on marijuana and its components that complies with the Controlled Substances Act (CSA) and the Single Convention on Narcotic Drugs (Single Convention). We are also aware of the desire of researchers, patients, and their loved ones to have safe and effective therapies developed as quickly as possible. Our agencies are committed to working together, along with other Federal, state and local entities, to address these interests and facilitate the research and development efforts in accordance with the law. The Drug Enforcement Agency (DEA) has currently registered 265 researchers to conduct bona fide research with marijuana and marijuana extracts. To date, DEA has not denied any research application that has met the CSA requirements.

Under the Single Convention on Narcotic Drugs, cannabis is designated a Schedule I substance, and participating countries are required to restrict production, manufacture, possession, and distribution of marijuana. The DEA regulates the cultivation of marijuana for research purposes through licensing requirements and establishment of annual aggregate production quotas under the authority of the CSA, which implements the Single Convention. Marijuana and its constituent components for research purposes can be obtained through the National Institute on Drug Abuse's Drug Supply Program.

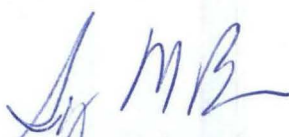
Substances classified under Schedule I of the CSA have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. The CSA and the Federal Food, Drug, and Cosmetic Act contain provisions to allow for clinical research and treatment with investigational drugs, including Schedule I substances, provided certain steps are taken to protect the rights, safety, and welfare of human subjects. The Food and Drug Administration's (FDA) drug approval process represents the best way to ensure that safe and effective new medicines, including those derived from constituents of marijuana, are appropriately reviewed for safety and effectiveness.

As you are aware, considerable interest has emerged recently in the therapeutic potential of marijuana and its components, such as cannabidiol (CBD). In response, and using its authorities to respond to urgent health issues, FDA granted Fast-track designation to Sativex in April 2014. Sativex is composed primarily of CBD and tetrahydrocannabinol (THC), and it is administered as a metered-dose oromucosal spray for the treatment of pain in patients with advanced cancer. In June 2014, FDA granted Fast-track designation to the investigational CBD product Epidiolex for the treatment of Dravet syndrome, a rare and catastrophic treatment-resistant form of childhood epilepsy.¹ In February 2015, FDA granted Fast-track designation to another CBD formulation that is being developed for the same condition.² In addition to epilepsy, the therapeutic potential of CBD is currently being explored for a number of indications, including anxiety disorders, substance use disorders, schizophrenia, cancer, pain, and inflammatory diseases.


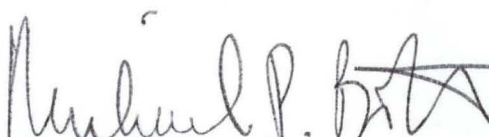
As you noted, on June 23 the Department of Health and Human Services announced the elimination of Public Health Service review of non-Federally funded research protocols involving marijuana.³ This action may facilitate more research into the potential therapeutic benefits of marijuana and its components by removing overlapping requirements with FDA's review process for investigational new drugs. Recognizing our departments have distinct, but interconnected roles in this space, the relevant Federal agencies are planning to convene an interagency meeting to review additional actions that may be taken to encourage marijuana research. While discussions are still ongoing, we would like to brief your staff and staff of the other signatories to your letter to discuss the Federal Government's existing and future actions concerning research on marijuana and its components. Our legislative affairs staffs will be in contact with your staff to coordinate this briefing.

We recognize the concerns expressed in your letter and share a mutual interest in discovering safe and effective treatments to improve the health of our Nation while maintaining a commitment to rigorous clinical research. Please let us know if we can be of further assistance.

Sincerely,



Sylvia Mathews Burwell
Secretary
Department of Health and
Human Services



Michael P. Botticelli
Director
Office of National Drug Control
Policy

Chuck Rosenberg
Acting Administrator
Drug Enforcement
Administration

¹<http://www.gwpharm.com/GW%20Pharmaceuticals%20Announces%20Epidiolex%20Receives%20Fast%20Track%20Designation%20from%20FDA%20for%20the%20Treatment%20of%20Dravet%20Syndrome.aspx>

² <http://www.insysrx.com/investors/recent-news/>

³ Announcement of Revision to the Department of Health and Human Services Guidance on Procedures for the Provision of Marijuana for Medical Research as Published on May 21, 1999. 80 Fed. Reg. 35960-61 (Jun. 23, 2015). Available: <https://www.federalregister.gov/articles/2015/06/23/2015-15479/announcement-of-revision-to-the-department-of-health-and-human-services-guidance-on-procedures-for>.