THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

The Honorable Charles Grassley
Chairman
Senate Caucus on International Narcotics Control
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Thank you for your letter regarding regulations that govern research on marijuana, specifically cannabidiol (CBD). The Department of Health and Human Services (HHS) continues to work with federal partners including the Department of Justice and other agencies to facilitate research on marijuana, including its therapeutic potential and adverse health effects.

On May 21, 1999, the Public Health Service (PHS) review process was established in response to enhanced interest by the biomedical research community in assessing potential therapeutic benefits of marijuana. The PHS process, which includes a committee review of study protocols, helped create a pathway for non-federally funded researchers to conduct these studies.

In order to further facilitate research, HHS recently re-evaluated the PHS review procedures to identify opportunities for increased efficiency. Based on a number of considerations, and in order to streamline the application and approval processes for cannabis research, the committee that manages the PHS review has been eliminated.

The Office of the Assistant Secretary for Health within HHS, in consultation with the National Institutes of Health (NIH) and the Food and Drug Administration (FDA), determined that the PHS review overlaps in several important ways with the FDA's investigational new drug application process and therefore is no longer necessary to support the conduct of scientifically-sound studies into the therapeutic uses of marijuana. While not identical, the two processes have similar goals (e.g., guiding research on drug development and assuring appropriate treatment of human subjects), share criteria for protocol reviews, and possess similar capacity to engage with federal experts for consultation. HHS posted this policy change in the Federal Register on Monday, June 22, 2015.

Additionally, HHS is already in the process of conducting a scientific and medical evaluation to inform a recommendation of the appropriate scheduling of CBD under the Controlled Substances Act (CSA). This evaluation considers the eight factors determinative of control under section 201(c) of the CSA. FDA, in consultation with the National Institute on Drug Abuse (within NIH), is currently reviewing available scientific literature on CBD. The review is intended to summarize what is known about the effects of CBD and to identify additional work that may be

needed to complete an assessment of its abuse liability and any accepted medical use. For instance, in order to recommend the appropriate schedule for CBD to the Drug Enforcement Administration (DEA), an adequate clinical study of abuse potential may need to be conducted. Therefore, this literature review is important not only to inform a scheduling recommendation for CBD, but also to provide a knowledge base that can support scientifically rigorous research into its therapeutic uses. Historically, entities outside the federal government conduct this type of study, which requires a significant financial investment. HHS intends to explore potential options for undertaking and completing such a study.

HHS continues to support research involving CBD and its potential to treat multiple conditions. In June 2014, GW Pharmaceuticals announced that FDA granted Fast Track designation to their investigational CBD product, Epidiolex, for study in the treatment of a rare form of childhood epilepsy.[1] Furthermore, in February 2015, Insys Therapeutics announced that FDA granted Fast Track designation to the CBD formulation they are studying for the same condition.[2] FDA also authorized the use of Epidiolex under expanded access, which facilitates the availability of investigational drug products to patients while those drugs are being studied for approval. GW Pharmaceuticals estimates that approximately 420 children have been treated under this program. HHS continues to support the use of expanded access to provide treatments to patients with serious or immediately life-threatening diseases or conditions for which there is no comparable or satisfactory alternative treatment, while also preserving important protections for those patients.

Thank you for contacting me about these important matters. If you have further questions or need additional information, please contact Jim Esquea, Assistant Secretary for Legislation at 202-690-7267. I will also provide this response to Senator Feinstein, who cosigned your letter.

Sincerely,

Sylvia M. Burwell

[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/ (Link at February 26, 2015)