

United States Senate

SENATE CAUCUS ON
INTERNATIONAL NARCOTICS CONTROL
HART SENATE OFFICE BUILDING, ROOM 818-C
WASHINGTON, DC 20510

May 13, 2015

The Honorable Loretta Lynch
Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530

Dear Attorney General Lynch:

We are writing to follow up on a letter we sent in October of last year to the Departments of Justice (DOJ) and Health and Human Services (HHS) regarding regulations that govern research on marijuana, specifically on cannabidiol (CBD), a non-psychoactive compound derived from the marijuana plant and administered in the form of an oil (see attached).

DOJ and HHS provided conflicting responses to our letter. While HHS indicated a willingness to streamline the research approval process and that it is taking steps to do so, DOJ indicated a reluctance to amend *any* of its regulations. Therefore, we request that DOJ work with HHS to determine ways to remove any unnecessary barriers that stand in the way of research into the potential medical benefits of marijuana and CBD. In the meantime, so that we may better understand DOJ's position, we request that you answer the questions attached to this letter.

In addition, we request that DOJ, in concert with HHS, immediately evaluate the factors determinative of control or removal from schedules for CBD, and make a scheduling recommendation for it, as described in section 201(a) - (c) of the Controlled Substances Act (21 U.S.C. §§ 811(a) - (c)).

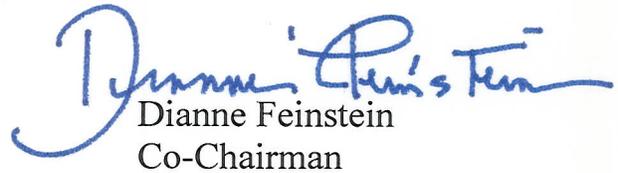
This request is based on the fact that a scientific and medical evaluation of CBD has never been conducted by the federal government, despite the growing anecdotal evidence that it may effectively treat intractable epilepsy in children. Many individuals across the country are suffering from serious medical

conditions that might be alleviated by CBD. It is therefore critical that this evaluation be completed so that it can be determined if CBD should be down-scheduled and used as medicine, or remain as currently scheduled.

Thank you for your prompt attention to these important requests. We respectfully request a response by June 5, 2015.

Sincerely,


Charles Grassley
Chairman


Dianne Feinstein
Co-Chairman

cc: Sylvia Mathews Burwell, Secretary, Department of Health and Human Services
Michele Leonhart, Administrator, Drug Enforcement Administration
Stephen Ostroff, M.D., Acting Commissioner, Food and Drug Administration

Enclosures

So that we may better understand DOJ's position regarding marijuana research and existing regulations, we request that you answer the following questions:

1. Based on the response to our letter, it appears that DOJ has already concluded that none of the regulations regarding this research should be altered. Is this correct?
2. Our letter also outlined concerns with regulatory requirements governing changes to the quantity of marijuana needed for approved research. DOJ's response suggests that additional quantities of controlled substances can be purchased and used for research purposes as soon as DEA returns the receipt. Is this so? If not, what additional steps are required?
3. We understand from staff at the Food and Drug Administration that it takes approximately nine months for federally-funded research on marijuana to be approved. Existing regulations stipulate that if the approved protocol changes, a supplemental protocol must be submitted and is processed in the same manner as the original protocol.
 - a. If a researcher amends their protocol, is it correct that all work must stop until the supplemental protocol is approved, which could take as long as nine months?
 - b. Does DOJ believe that it would be beneficial to amend its regulations to include a timeframe by which a secondary approval will be granted or denied? If not, why not?