

United States Senate

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

October 20, 2014

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

The Honorable Sylvia Mathews Burwell
Secretary
U.S. Department of Health and Human
Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Attorney General Holder and Secretary Burwell:

As the co-chairs of the Senate Caucus on International Narcotics Control, we oppose the legalization of any Schedule I substance, including marijuana, and like many respected medical organizations, we do not support the use of smoked marijuana as medicine. We also understand the importance of preventing the diversion of controlled substances, and support efforts to do so, including the registration and security requirements currently in place to conduct research on marijuana.

However, we are concerned that existing regulations may have the unintended consequence of inhibiting additional research on potential medical uses for marijuana; specifically cannabidiol, a compound derived from the marijuana plant and administered in the form of an oil. Given that there appears to be some evidence that cannabidiol could have medicinal value for those suffering from serious diseases, such as intractable epilepsy, additional research with appropriate safeguards in place is critical and may lead to the development of important new medicines. Therefore, we respectfully urge you to closely examine and strongly consider revising the regulations governing this research.

Current regulations require registrants to submit new requests to the Drug Enforcement Administration (DEA) if, after approval of the relevant research protocol, the quantity of marijuana needed for the research changes.¹ A time-consuming process then ensues: the DEA reviews the request and forwards it to the Food and Drug Administration (FDA), which ultimately approves or denies it.

¹ See 21 C.F.R. § 1301.18(c).

Existing regulations also stipulate that if the approved protocol for research changes even slightly, the registrant must submit supplemental documentation describing the new protocol.² According to the regulations, the researcher is essentially back to square one: the new protocol “shall be processed and approved or denied in the same manner as original research protocols.”³

These regulations present significant practical problems for researchers. However, neither the quantity of the controlled substance nor the change in research protocol impacts the researcher’s previously-obtained registration or security qualifications. Therefore, as long as the change in protocol does not involve the addition of a controlled substance that was not contained in the original approval, it seems that a less cumbersome process – but one that still requires relevant agencies to be notified of any changes – could be implemented.

In addition to the above regulations, those who wish to conduct research on marijuana without government funding are *also* required to have their proposal reviewed and approved by the Department of Health and Human Service’s Public Health Service (PHS).⁴ According to staff at the FDA, the PHS review was established to provide an assessment of the scientific quality of these studies. However, it is unclear why marijuana is the only Schedule I substance for which this review and approval is required.

In light of the above concerns, we strongly encourage you to consider revising existing regulations, as well as the need for the PHS evaluation, to ensure that important research related to marijuana, specifically cannabidiol, is not being unduly hampered. Thank you for your prompt attention to this matter. We look forward to your response by November 15, 2014. We hope that we can continue to work together to prevent the diversion and abuse of illicit drugs, while at the same time ensuring that responsible medical research is not burdened by any unnecessary restrictions.

Sincerely,



Dianne Feinstein
Chairman



Charles Grassley
Co-Chairman

² See 21 C.F.R. § 1301.18(d).

³ *Id.*

⁴ Guidance on Procedures for the Provision of Marijuana for Medical Research: <http://grants.nih.gov/grants/guide/notice-files/not99-091.html>