



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

SEP 22 2014

The Honorable Earl Blumenauer  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Representative Blumenauer:

Thank you for your letter expressing support for increasing scientific research on the potential therapeutic risks and benefits of marijuana. The Department of Health and Human Services (HHS) is aware of shifting state policies regarding the use of marijuana for medical purposes and shares your interest in facilitating scientifically rigorous investigations. Marijuana contains many compounds with the potential to provide new treatments for important diseases, and rigorous studies are needed to assess that potential.

To accomplish these necessary studies, HHS and its agencies have approved or supported several hundred research projects for marijuana and its constituent compounds and uses its authorities to encourage research in this area. For example, as you mention, in 1999 HHS established a Public Health Service review process to stimulate non-federally funded scientific protocols for the investigation of marijuana. These reviews are conducted by a multi-disciplinary review panel comprised of scientific experts across HHS and provide an avenue for obtaining research-grade marijuana. Since its inception, 18 proposals have been received, and 16 of those proposals were approved for the purchase of marijuana through the National Institute on Drug Abuse (NIDA). Ensuring that biomedical research has the maximum public health impact is a priority of HHS and its agencies. And as such, processes like these need to be regularly reviewed to make sure they are achieving their goals, and I appreciate your suggestions.

The Food and Drug Administration (FDA) has supported the development of drugs derived from botanical sources such as marijuana. FDA approved two drugs that contain active ingredients that are present in or similar to those present in botanical marijuana. More recently, FDA has developed flexible and innovative approaches to expedite the development and review of new drugs, approaches that are being applied to developing drugs derived from marijuana. For two recent investigational drugs based on compounds in marijuana, Sativex and Epidiolex, the manufacturer announced that FDA granted 'Fast Track' designation to the investigational drug products. This designation provides additional focused help from FDA to aid drug development. The manufacturer of Epidiolex also announced the availability of expanded access Investigational New Drug Applications for the treatment of approximately 300 patients with epilepsy syndromes with this drug.

The National Institutes of Health is also supporting research using marijuana and its constituents, and has 54 active grants studying the potential therapeutic benefits of cannabinoids in nine disease categories. This year, NIDA released two new funding opportunity

announcements to explore the health impact of changing state marijuana policies and the effects of marijuana on the developing brain.

Finally, as you note, through a contract with the University of Mississippi to grow research grade marijuana, NIDA supplies marijuana for federally and non-federally funded research projects.

In summary, drug development, grounded in rigorous scientific research is essential to determining the risks and benefits of the use of marijuana in the treatment of human disease. HHS is committed to making this process efficient and welcomes your input as we consider improvements.

I hope this information is helpful. Please do not hesitate to contact me if you have additional questions. I will also provide this response to the co-signers of your letter.

Sincerely,

A handwritten signature in black ink, appearing to read 'SMB', with a long horizontal flourish extending to the right.

Sylvia M. Burwell