United States Senate WASHINGTON, DC 20510

June 23, 2016

The Honorable Loretta E. Lynch Attorney General U.S. Department of Justice 950 Pennsylvania Avenue NW Washington, DC 20530-0001

The Honorable Chuck Rosenberg Acting Administrator Drug Enforcement Administration 8701 Morrisette Drive Springfield, VA 22152

Concerns regarding the barriers to research on medical marijuana persist among the public, in the research community, and in Congress. As you know, we have been working to address these concerns by engaging in an active dialogue with the Drug Enforcement Administration (DEA), the Office of National Drug Control Policy (ONDCP), and the Department of Health and Human Services (HHS), and have requested that research on the potential health benefits of marijuana when used for medical purposes ("medical marijuana") must be better facilitated and coordinated. Marijuana's classification as a Schedule I drug under the Controlled Substances Act (CSA) – a classification otherwise used for "drugs with no currently accepted medical use and a high potential for abuse" — continues to be a main barrier to this research. ²

We therefore are writing to request an update on the new scheduling determination for marijuana that the DEA indicated would occur in the "first half of 2016."³

Despite marijuana's classification as a Schedule I substance, 25 states and the District of Columbia have passed medical marijuana laws and an additional 16 have passed laws allowing for the medicinal use of cannabidiol (CBD), a marijuana derivative. The dissonance between these state laws and the drug's federal Schedule I status have wide-ranging implications for legitimate marijuana businesses including access to banking services, the ability to deduct business expenses from taxes, and access for veterans.

The conflict between state laws for medical marijuana use and its CSA classification also has significant consequences for preclinical, clinical, and epidemiologic research. In order to begin studying any Schedule I substance, a qualified researcher must overcome a number of regulatory hurdles to receive approval and access to the drug from the DEA and the Food and

¹ Letter from U.S. Senator Elizabeth Warren, et al. to the Department of Health and Human Services, the Office of National Drug Control Policy, and the Drug Enforcement Administration (July 9, 2015 and December 21, 2015)

² http://abcnews.go.com/Health/federal-reclassification-marijuana-major-impact-medical/story?id=38308268

³ Letter from Department of Health and Human Services, the Office of National Drug Control Policy, and the Drug Enforcement Administration to U.S. Senator Elizabeth Warren, et al. (April 4, 2016)

⁴ http://www.safeaccessnow.org/state and federal law

Drug Administration (FDA). These hurdles present a significant barrier for legitimate researchers, making it more difficult to obtain samples and use them in medical studies.

While these barriers are important for substances with a high potential for abuse, we believe that they should be reassessed for marijuana given the widespread use among patients in the U.S. We also understand that the DEA has receive multiple petitions requesting rescheduling, which, in accordance with the CSA, have prompted a mandatory scientific and medical evaluation from HHS (known as the 8-factor analysis, performed by the FDA). ⁵

In two previous letters to the DEA, HHS, and ONDCP, we inquired about the timeline for the assessment and determination of marijuana rescheduling. In their April 4 response, these agencies confirmed that "the DEA has received the HHS scientific and medical evaluations, as well as scheduling recommendation" and that it is currently under review. They also stated that they recognize the "widespread interest" in this matter and "hop[e] to release its [scheduling] determination in the first half of 2016" in response to the two pending petitions.⁶

While we appreciate the DEA's willingness to maintain an open dialogue with our offices, we are concerned that "the first half of 2016" is coming to a close and no rescheduling announcement has been made. We continue to believe that the rescheduling of marijuana and the resolution of other regulatory barriers to research is a time-sensitive matter that requires immediate action.

Therefore, we ask that you provide us with a briefing on the status of the rescheduling decision no later than July 5, 2016.

Thank you for your assistance in untangling this regulatory scheme in order to facilitate research which will help to support patients, doctors, and states.

Sincerely,

Elizabeth Warren

United States Senator

Barbara Boxer

United States Senator

Barbara A. Mikulski

United States Senator

Ron Wyden

United States Senator

⁵ http://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/conf_2013/boos.pdf

⁶ Letter from Department of Health and Human Services, the Office of National Drug Control Policy, and the Drug Enforcement Administration to U.S. Senator Elizabeth Warren, et al. (April 4, 2016)

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