



U.S. Department of Justice
Drug Enforcement Administration

Office of the Administrator

Springfield, VA 22152

August 11, 2016

The Honorable Gina M. Raimondo
Governor of Rhode Island
82 Smith Street
Providence, Rhode Island 02903

The Honorable Jay R. Inslee
Governor of Washington
P.O. Box 40002
Olympia, Washington 98504-0002

Mr. Bryan A. Krumm
[REDACTED]
[REDACTED]

Dear Governor Raimondo, Governor Inslee, and Mr. Krumm:

The enclosed materials provide the legal and factual bases for our decision, in response to your petitions, regarding the rescheduling of marijuana.¹ I will get to that decision, but I will first highlight broader considerations with respect to (1) the law regarding drug scheduling and (2) the current state of marijuana research.

The Law Regarding Drug Scheduling:

The Controlled Substances Act (CSA) mandates that scheduling decisions be based on medical and scientific data and other data bearing on the relative abuse potential of the drug. Under the CSA, the Food and Drug Administration (FDA), in consultation with the National Institute on Drug Abuse (NIDA), reviews, analyzes, and assesses that data and its medical and scientific conclusions legally bind the Drug Enforcement Administration (DEA).

The FDA and the DEA make a determination based on a full review of the relevant scientific and medical literature regarding marijuana. That process, too, is outlined in the enclosed materials.

A substance is placed in Schedule I if it has no currently accepted medical use in treatment in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse. These criteria are set by statute.

¹ Governors Raimondo and Inslee succeeded petitioner Governors Chafee and Gregoire, respectively.

Schedule I includes some substances that are exceptionally dangerous and some that are less dangerous (including marijuana, which is less dangerous than some substances in other schedules). That strikes some people as odd, but the criteria for inclusion in Schedule I is not relative danger.

In that sense, drug scheduling is unlike the Saffir-Simpson scale or the Richter scale. Movement up those two scales indicates increasing severity and damage (for hurricanes and earthquakes, respectively); not so with drug scheduling. It is best not to think of drug scheduling as an escalating “danger” scale – rather, specific statutory criteria (based on medical and scientific evidence) determine into which schedule a substance is placed.

Marijuana Research:

Research is the bedrock of science, and we will – as we have for many years – support and promote legitimate research regarding marijuana and its constituent parts. For instance, DEA has never denied an application from a researcher to use lawfully produced marijuana in a study determined by the Department of Health and Human Services (HHS) to be scientifically meritorious.

In fact, during the last two plus years, the total number of individuals and institutions registered with DEA to research marijuana, marijuana extracts, derivatives, and tetrahydrocannabinols (THC) has more than doubled, from 161 in April 2014 to 354 at present. Some of the ongoing research includes studies of the effects of smoked marijuana on human subjects. Folks might be surprised to learn that we support this type of research. But, we do.

DEA and NIDA have also increased the amount of marijuana available for research. Indeed, we consistently meet legitimate demand by researchers for marijuana. Currently, NIDA is filling requests for research marijuana in an average of 25 days.

We will continue to work with NIDA to ensure that there is a sufficient supply of marijuana and its derivatives (in terms of quantity and the variety of chemical constituents) to support legitimate research needs. This includes approving additional growers of marijuana to supply researchers. Details of this proposal to support legitimate research will be published in the Federal Register.

Further, in December 2015, we waived certain regulatory requirements for researchers conducting FDA-authorized clinical trials on cannabidiol (CBD), a constituent part of marijuana. These waivers, when granted, enable researchers to modify or expand the scope of their studies more easily. Currently, there are 90 researchers registered with the DEA to conduct CBD research on human subjects. We have approved every waiver application that has been submitted by these researchers – to date, a total of 47.

If, for instance, CBD proves to be safe and effective for the treatment of a specific medical condition, such as childhood epilepsy (some trials have shown promise), that would be a wonderful and welcome development. But we insist that CBD research – or any research – be sound, scientific, and rigorous before a product can be authorized for medical use. That is specifically – and properly – the province of the FDA.

DEA continues to work on other measures to support marijuana research. For instance, DEA is building an online application system for researchers to apply for Schedule I research registrations, including for marijuana. DEA also is drafting clear guidance to assist Schedule I researchers in that application process.

The Decision:

The FDA drug approval process for evaluating potential medicines has worked effectively in this country for more than 50 years. It is a thorough, deliberate, and exacting process grounded in science, and properly so, because the safety of our citizens relies on it.²

Using established scientific standards that are consistent with that same FDA drug approval process and based on the FDA's scientific and medical evaluation, as well as the legal standards in the CSA, marijuana will remain a schedule I controlled substance. It does not have a currently accepted medical use in treatment in the United States, there is a lack of accepted safety for its use under medical supervision, and it has a high potential for abuse.

If the scientific understanding about marijuana changes – and it could change – then the decision could change. But we will remain tethered to science, as we must, and as the statute demands. It certainly would be odd to rely on science when it suits us and ignore it otherwise.

² The FDA's scientific assessment determines the safety and efficacy of drugs intended for human consumption. The FDA's team, charged with conducting that assessment, consists of clinical pharmacologists, epidemiologists, toxicologists, physicians, chemists, statisticians and other scientists, working together to ensure approved drugs are safe and effective. As our partners at HHS note, "[An] expert [in this discipline] is an individual qualified by scientific training and experience to evaluate the safety and effectiveness of a drug." Although medical doctors are highly trained and qualified to treat patients with FDA-approved drugs, as HHS notes, "[m]edical practitioners who are not experts in evaluating drugs are not qualified to determine whether a drug is generally recognized as safe or effective or meets NDA (New Drug Application) requirements." 57 FR 10499. Simply put, evaluating the safety and effectiveness of drugs for their intended use is a highly specialized endeavor undertaken by the FDA's Center for Drug Evaluation and Research.

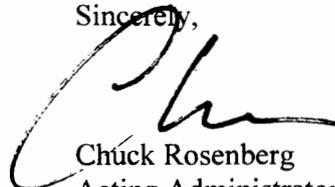
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The DEA and FDA continue to believe that scientifically valid and well-controlled clinical trials conducted under investigational new drug applications are the proper way to research all potential new medicines, including marijuana. Furthermore, we believe that the drug approval process is the proper way to assess whether a product derived from marijuana or its constituent parts is safe and effective for medical use.

We fully support legitimate medical and scientific research on marijuana and its constituent parts and we will continue to seek ways to make the process for those researchers more efficient and effective.

Sincerely,



Chuck Rosenberg
Acting Administrator

Enclosures