October 31, 2018

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
Submitted via the Federal Rulemaking Portal

Dear Dockets Management Staff:

Comments re: International Drug Scheduling [Docket No. FDA-2018-N-3685]

On behalf of the Drug Policy Alliance (DPA), the nation’s leading organization promoting drug policies grounded in science, compassion, health and human rights, I write in response to the Food and Drug Administration’s (FDA) request for comments concerning the international scheduling of 16 drug substances, including cannabis.1

Cannabis does not meet the criteria for a Schedule I substance, as defined by the Controlled Substances Act of 1970, because it has several well-documented medical uses and minimal potential for abuse. For these reasons, and the reasons outlined below, DPA supports removing cannabis entirely from the Schedule of Controlled Substances.

DPA respectfully submits the following comments on the scheduling of cannabis:

1) **Cannabis is inappropriately scheduled.** The current system for classifying controlled substances erroneously places cannabis in the most restrictive class, Schedule I, reserved for drugs with a “high potential for abuse”, “no currently accepted medical use” and a “lack of accepted safety”. Despite unique restrictions on conducting cannabis research, a plethora of scientific evidence has nevertheless emerged that not only confirms cannabis’s medicinal benefits – but also its wide margin of safety.2

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1 For the purpose of this letter, cannabis shall refer to marijuana, as defined in the Controlled Substances Act of 1970, and to Cannabis Plant and Resin; Extracts and Tinctures of Cannabis; Delta-9-Tetrahydrocannabinol; Stereoisomers of Tetrahydrocannabinol

The National Academies of Sciences, Engineering, and Medicine has confirmed that there is conclusive evidence that cannabis and cannabinoids are effective treatments for chronic pain in adults. They are also effective for chemotherapy-induced nausea and vomiting, and at improving multiple sclerosis (MS) spasticity symptoms. There is also evidence showing a number of other medical benefits, including its potential for improving appetite and decreasing weight loss associated with HIV/AIDS, improving symptoms of Tourette syndrome, improving anxiety symptoms and improving symptoms of post-traumatic stress disorder. Cannabis is also effective at treating epilepsy, as demonstrated by the recently approved medication, Epidiolex, which is comprised of isolated cannabis derivatives.

2) Federally-approved cannabis research has been systematically obstructed. Researchers face daunting regulatory hurdles to studying any Schedule I substance, including a rigorous approval process by both the Drug Enforcement Administration (DEA) and FDA for every trial. Researchers seeking to conduct research on cannabis must go through substantial layers of bureaucracy, adhere to strict storage requirements, and apply for a DEA license.

The continued classification of cannabis as a Schedule I substance has been justified based on a lack of research. Yet at the same time the federal
government has effectively blocked the standard FDA development process that would allow for the marijuana plant to be brought to market as a prescription medicine. Cannabis is the only Schedule I substance that the DEA prohibits from being produced by private laboratories for scientific research. Although the DEA has licensed multiple, privately-funded manufacturers of all other Schedule I drugs (such as heroin and LSD), it permits just one facility at the University of Mississippi to produce cannabis for federally-approved research. This facility, under contract with the National Institute on Drug Abuse (NIDA), holds a monopoly on the supply of cannabis available to scientists, including researchers seeking to conduct FDA-approved studies of the plant's medical properties.8

In 2016, the DEA announced a new policy designed to increase the number of entities registered to grow cannabis for research purposes. However, despite receiving 26 applications from producers in 2016, no further progress has been made toward ending the NIDA monopoly by licensing privately-funded, federally-approved research-grade marijuana production facilities, as the Department of Justice has effectively blocked the DEA from taking any action on the applications.9

The Schedule I status of cannabis also shapes the type of research conducted by impacting funding streams. For example, the mission of NIDA – a member institute of the National Institutes of Health, which is the primary funder of research across health domains – is to study factors related to “substance abuse”. Accordingly, NIDA conducts research disproportionately focusing on the negative health effects, with only 16.5% of NIDA’s spending on therapeutic properties of cannabis.10 The cost of large-scale clinical research can dissuade many researchers from pursuing studies on cannabis when prohibition restricts federal funding to studies that do not align with agency priorities.

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3) **Cannabis should ultimately be descheduled.** Rescheduling cannabis would be a step in the right direction, because it would allow doctors to prescribe it as a medicine and open the door for more research. However, patient access to vital medicines and the full protection of state medical cannabis programs require completely removing cannabis from Schedule of Controlled Substances and the Controlled Substances Act of 1970.

The public has supported medical cannabis for over two decades. A recent poll shows that nine out of ten (93%) Americans now support medical cannabis. In addition, elected officials from both parties have introduced several bills at the federal level with the aim of descheduling cannabis and/or removing some of the barriers inherent in its current Schedule I status. In June, Senator Chuck Schumer introduced legislation which would remove cannabis from the Schedule of Controlled Substances under the Controlled Substances Act.

For these reasons, cannabis does not meet the criteria for a Schedule I Substance as defined by the Controlled Substances Act of 1970. Thus, we urge you to reschedule, and ultimately deschedule, cannabis both domestically and within the international drug treaties to which the U.S. is a party.

Thank you for considering our comments. Please do not hesitate to reach out to me with any questions or comments: (347) 276-0669; srajagopalan@drugpolicy.org.

Respectfully Submitted,

Suchitra Rajagopalan,  
Research Coordinator, Drug Policy Alliance

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