April 23, 2018

Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA–2018–N–1072 International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Cannabis Plant and Resin; Extracts and Tinctures of Cannabis; Delta-9-Tetrahydrocannabinol (THC); Stereoisomers of THC; Cannabidiol; Request for Comments.

Thank you for this opportunity to provide public input on the international scheduling of cannabis and its chemical constituents.

Given the variety of approaches that individual states in the United States have taken towards the regulated intra-state distribution of cannabis, the Food and Drug Administration (FDA) may want to consider receiving input from all states that have accepted the medical and/or recreational use of cannabis in some form, in order to better inform its own understanding of the impact that state use has upon the federal regulation of cannabis and to guide potential future recommendations on this subject to the World Health Organization and the United Nations.

Because Hawaii's Department of Health (DOH), the state agency responsible for administering our Medical Use of Cannabis Program, has decided not to submit input at this time, this author has taken it upon himself to provide the following information as a private resident and as a state-licensed medical doctor with an interest in protecting the state-accepted medical use of cannabis in Hawaii.

Background

Following adoption of the federal Controlled Substances Act (CSA) in 1970, the State of Hawaii, along with the other states in the Union, decided that a complimentary system was necessary at the state level in order to coordinate the state and federal regulation of controlled substances.

However, in keeping with its own authority under federalism, Hawaii did not adopt

the version of the Uniform Controlled Substances Act (UCSA) that was recommended by the Uniform Law Commission. Instead, Hawaii created its own version of the UCSA that contains a completely different set of scheduling criteria that have nothing to do with "accepted medical use".

Furthermore, unlike the federal CSA, where administration and enforcement of the act is based upon separate federal regulations, Hawaii's UCSA places scheduling criteria and scheduling classifications both within the statute itself.

In addition, Hawaii's UCSA also contains a legislative process that allows for the annual matching of state and federal scheduling changes. This process has been used to create the impression that the state and federal scheduling of controlled substances must always be the same, even though Hawaii's scheduling criteria are completely different from the federal criteria, and even though Hawaii's UCSA allows the Department of Public Safety (DPS) to make annual scheduling recommendations to the Legislature based on changes in state law, and authorizes the Legislature to adjust the state scheduling of controlled substances independent of federal changes.

In 2000, without consulting with the U.S. Department of Justice (DOJ), Hawaii exercised its authority to accept the medical use of controlled substances, and created, via the legislative process, a state-regulated program that accepted the medical use of cannabis in Hawaii for the first time.

Despite the original intent of our lawmakers to have Hawaii's Medical Use of Cannabis Program housed within DOH, administration of the program was instead given to the Narcotics Enforcement Division (NED), a branch of DPS, which created a direct conflict of interests with NED's federal counterpart. It took fifteen years for Hawaii's Medical Use of Cannabis Program to be moved to DOH.

Hawaii's program, as it was originally implemented, restricted the production of cannabis to patients and caregivers who met certain eligibility criteria set by the state, and required ongoing medical supervision by a certifying physician. Because patients are the ultimate user of a controlled substance in this case, they are not required to obtain separate state controlled substances registration from NED.

Given the non-uniformity of its own UCSA, Hawaii was also able to leave cannabis in state Schedule I because Hawaii's scheduling criteria do not require a consideration

of accepted medical use. This inconsistency with the federal CSA offered a convenient way to continue the annual matching of state and federal scheduling without addressing the state scheduling of cannabis, and encouraged a tradition of ignoring the fact that substances in Hawaii's Schedule I must have the "highest degree of danger".

For fifteen years the program remained under the administration of NED, until DOH finally took over the program in the beginning of 2015. Then, later that same year, a state-regulated dispensary system that allowed for the commercial production and distribution of cannabis for medical use was adopted under state law. Eight dispensary applicants spread throughout the Hawaiian Islands (3 on Oahu, 2 on Hawaii, 2 on Maui, and 1 on Kauai) were subsequently selected for state licensing in April of 2016 using a merit-based application process. Nearly a year and a half later, a dispensary on Maui was the first to open its doors to patients in August of 2017. Since that time, three other dispensaries have also started serving patients, all doing so under the assumption that they are in direct violation of federal law.

Current Situation

As noted above, there are currently four dispensaries (3 on Oahu and 1 on Maui) that are selling cannabis for medical use to patients under state licensing and NED registration to produce and dispense a state Schedule I controlled substance. All dispensaries are operating under the assumption that they are violating federal law, which puts them at unnecessary risk for federal intervention and prohibits them from interacting with banking institutions and our state University system.

Our state Legislature still hasn't found a way to recognize that the state-accepted medical use of cannabis in Hawaii is currently accepted medical use in treatment in the United States, which prevents any discussion with DOJ regarding the impact that state-accepted medical use has upon the federal CSA.

Certain inconsistencies also exist within Hawaii's Medical Use of Cannabis Act itself, such as prohibiting the inter-island transportation of cannabis for medical use by patients, while at the same time authorizing dispensaries to transport material between islands for testing purposes. Such irregularities continue to blur the lines between the state and federal regulation of this substance, and perpetuate the misconception that Hawaii's program is violating federal law.

Conclusions

Decisions about the international scheduling of cannabis cannot be made in a vacuum. Given the varied ways in which individual states have approached this issue, it would make sense for the FDA to solicit input on this subject from all states that have already accepted the medical and/or recreational use of cannabis under state law.

Ultimately, it is our patients who are losing out under the current climate of dis-regulation. In Hawaii, thousands of registered patients live in fear of what could happen if the federal government were to escalate its war on cannabis, and thousands more are being deprived of the potential beneficial uses of this substance because of an aversion to violating federal law.

In the meantime, the current situation encourages an attitude of "staying below the radar", which attracts individuals and business that have no compunction about operating a commercial enterprise that they believe is violating federal law, and which continues to undermine any remaining respect for the general rule of law. Add to this an attitude on the part of our state Legislature that any changes in this area must first occur at the federal level, and we have a perfect storm for ignoring the impact that the state-accepted medical use of cannabis in Hawaii has upon the federal regulation of this substance, while missing out on possible solutions that would come to light if this connection were being recognized.

It is the hope of this author that a better understanding of this relationship between the state medical use of cannabis and its federal scheduling will allow for a more productive discussion on the impact of potential changes to the international scheduling of this substance.

Thank you for taking the time to consider this information.

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