...working to legalize responsible adult use...

National Organization for the Reform of Marijuana Laws

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Food and Drug Administration
5630 Fishers Ln, Rm 1061
Rockville MD 20582

Re: Docket # 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_THC

To whom it may concern:

The National Organization for the Reform of Marijuana Laws (NORML) hereby submits evidence why the cannabis plant and its resin, extracts and tinctures, etc. should be removed from Schedules I and IV of the 1961 International Single Convention Treaty.

Our organization has represented cannabis consumers for 47 years. Our constituents include countless adults who use cannabis non-problematically as a social intoxicant like alcohol, as well as innumerable patients who find cannabis uniquely valuable for medical purposes. Their experiences are born out by a growing body of scientific evidence, which fails to support the current scheduling.

Recommendation (1): Cannabis should be removed from Schedule IV.

Schedule IV was defined by the treaty framers to include substances "(a) Having strong addiction-producing properties or a liability to abuse not offset by therapeutic advantages which cannot be afforded by some other drug; and/or (b) For which the deletion from general medical practice is desirable because of the risk to public health."[1] These conditions do not apply to cannabis.

First, cannabis does not share the strong addictive properties of other Schedule IV substances, such as heroin, fentanyl derivatives, and krokodil. According to a comprehensive review by the National Academy of Sciences[2] cannabis' dependence liability (9%) is the same as that of anxiolytics, and substantially lower than other drugs including heroin (23%), cocaine (17%), alcohol (15%) and tobacco (32%). Withdrawal

[1] WHO, "Cannabis and Cannabis Resin: Information Document Agenda Item 8.2, Expert Committee on Drug Dependence, 36th Meeting, Geneva 16-20 Jun 2014.
http://www.who.int/medicines/areas/quality_safety/8_2_Cannabis.pdf

[2] NAS, "Marijuana and Medicine: Assessing the Science Basis (1999) p. 95: Table 3.4],

symptoms from cannabis dependency, when they occur, are mild and subtle compared to the profound physical effects of alcohol and heroin withdrawal.[3]

Secondly, cannabis is in no way "dangerous" like other Schedule IV substances, which pose high rates of lethal overdose. To the contrary, cannabis has an unusually low toxicity compared to other pharmaceuticals in that it poses zero risk of lethal overdose.[4] According to the U.S. DEA, "no death from overdose of marijuana has been reported."[5]

Finally, cannabis has established therapeutic value in medical practice. Cannabis has a long history of safe medical use dating from millennia. It was wrongly misplaced in Schedule IV when the International Single Convention was adopted, at a time when it had fallen into disuse in mainstream medicine and the pharmacological activity of cannabinoids was not yet scientifically understood. Since then, cannabis has become legally recognized as a pharmaceutical drug in over twenty countries, including the Netherlands, Canada, Jamaica, Austria and Israel, as well as 30 U.S. states. It is now estimated that over 1.2 million Americans are using cannabis as a legal medicine under state law.[6].

Over 100 human studies have found cannabis and THC to be therapeutically effective for a wide range of medical conditions, including nausea, appetite loss, chronic pain and neuropathy, multiple sclerosis, spinal cord injury, epilepsy, glaucoma, Crohn's disease, Tourette's syndrome, et al.[7] In an exhaustive review of existing studies, the National Academy of Sciences determined there is "substantial" or "conclusive" evidence that cannabis is effective in treatment of chronic pain, nausea, and MS.[8] A growing body or recent studies have found that many patients find cannabis to be a safer, more effective harm reduction for opiates in the treatment of chronic pain, reducing opiate abuse, deaths, and health care expenditures.[9] Numerous FDA-approved controlled trials have assessed the safety and efficacy of cannabis in various patient populations. A scientific review of several of them concludes: "Based on evidence currently available the [U.S.] Schedule I classification is not tenable. It is not accurate that cannabis has no medical value, or that information on safety is lacking."[10]

Recommendation (2): Cannabis should be removed from Schedule I.

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[3] NAS, ibid, pp. 89-91.

[4] Hall, Degenhardt, and Lynskey. The Health and Psychological Effects of Cannabis Use, 2nd edition. National Drug and Alcohol Research Centre, University of South Wales, 2001.

[5] US DEA Drug Fact Sheet: Marijuana (April 2018) https://www.dea.gov/druginfo/drug_data_sheets/Marijuana.pdf

[6] ProCon.org estimate as of Mar 1, 2016: https://medicalmarijuana.procon.org/view.resource.php?resourceID=005889

[7] Grotenhermen, F and Muller-Vahl, K, "Medicinal Uses of Marijuana and Cannabinoids," *Critical Reviews in Plant Sciences*, 35:5-6, 378-405 (2016).

[8] Report of the National Academy of Sciences, "The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research." National Academies Press, Wash. DC (2017).

[9] California NORML Research Report, "Studies show medical cannabis reduces opioid use," http://www.canorml.org/OpioidStudies2.pdf (Apr 2018).

[10] Grant et al. 2012. Medical marijuana: clearing away the smoke. *The Open Journal of Neurology*, 2012: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3358713/

Schedule I is the mainline schedule for medically useful drugs deemed to have a high liability for abuse or addiction. Aside from cannabis, Schedule I consists of cocaine, opium and related substances.

Cannabis does not belong in this schedule because it lacks a similar degree of toxicity and high liability for addiction. As noted above, cannabis has an unusually low dependency potential. It also has relatively mild withdrawal symptoms, unusually low toxicity, and zero risk of lethal overdoses.

The WHO Expert Committee on Drug Dependence has never conducted a Critical Review of cannabis to justify its present scheduling. Cannabis was originally placed in Schedule 1 because of its inclusion in the 1925 Opium Convention. This was done at the behest of the delegation from Egypt, which had prohibited its use and sought to suppress the resulting illegal smuggling into the country. A review by the League of Nations Health Committee in 1935 recommended that cannabis extracts and tinctures be placed under control of the Second Opium Convention. No further scientific reviews were conducted when cannabis was carried over to Schedules I and IV in the Single Convention Treaty.[11]

Since that now-distant era, a growing body of expert reviews have concluded that cannabis does not present extraordinary health risks, and that criminal penalties against its use are unwarranted: the New York LaGuardia Report (1944), U.S. National Commission on Marihuana and Drug Abuse (1972), the Canadian Le Dain Commission (1973), the National Academy of Science (1982), the California Research Advisory Panel (1989), and the Jamaican National Commission on Ganja (2001).

In the meantime, the social use of cannabis – unlike other Schedule I substances -- has come to be legally accepted in a growing number of countries. Cannabis is legally available for adult social use in the Netherlands, Uruguay, Spain, and the U.S. states of Colorado, California, Oregon, Washington, Alaska, Massachusetts and Maine. Canada has announced its intention to follow suit. Cannabis is also allowed for religious use in India and Jamaica.

In view of this evidence, NORML contends that cannabis should be withdrawn from both Schedules I and IV.

Further Recommendations: Treaty Changes Needed

In general, the safety, dependence, and usage profile of cannabis compares favorably to alcohol, tobacco and other unscheduled substances. For this reason, NORML believes that cannabis should be withdrawn from the treaty framework entirely. However, further treaty changes are required to do so.

In particular, Article 28 of the Single Convention Treaty requires cannabis to be controlled in the same manner as the opium poppy. Article 23 goes on to stipulate that production be controlled by one or more government agencies, otherwise referred to as the Agency. Article 23 further mandates that all cultivators must be licensed by the Agency, their total crop delivered to and purchased by the Agency, and the Agency given exclusive right to import, export, and wholesale stocks of the drug.

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[11] WHO, op. cit. 2014.

This policy is inconsistent with the practice for alcohol, tobacco and other legal substances. NORML strongly questions the wisdom of a government cannabis monopoly. In the U.S., where medical cannabis remains illegal, the DEA has assumed to the role of the national Agency. The DEA has abused its monopoly powers by restricting all cultivation to a single licensee, NIDA's contractor at the University of Mississippi, which is the sole legal source of cannabis for researchers in the U.S. The quality of NIDA's cannabis is notably poor; access by researchers has been unduly restricted; and the facility produces just a couple of the hundreds of varieties of cannabis and cannabis products now available on the market. Although the DEA announced in 2016 that it would license a limited number of additional research farms, it has so far failed to do so.

Experience and economic theory teach that state monopolies are inefficient, unresponsive, corruptible, anti-competitive, and encourage black market alternatives. NORML accordingly recommends that cannabis, like alcohol and tobacco, should not be a national monopoly but should be produced, processed, distributed, developed, and marketed by independent, competing producers, subject to regulations like other agricultural and pharmaceutical products.

Further control measures on cannabis are mandated pursuant to Article 2 (7) of the treaty as specified in Article 19, paragraph 1, subparagraph *(e),* Article 20, paragraph 1, subparagraph *(g)*, Article 21 *bis* and in Articles 22 to 24; 22, 26 and 27; 22 and 28; 25. These require reporting of the total area under cultivation; calculation of the quantities consumed for medical and scientific purposes, quantities imported and exported; annual production limits based on projected demand; limits on production for international trade, etc. These provisions don't provide for non-medical use, and are unnecessarily over-prescriptive with regards to medical production.

Interim Alternative: Scheduling in II and III

Recognizing that current treaty provisions are not up for review by WHO, and that controls on cannabis are mandated by the treaty, the most appropriate place for cannabis and cannabis resin in the existing scheduling framework would appear to be Schedule II, which is for drugs with lesser abuse potential. Countries can allow Schedule II drugs to be dispensed without a medical prescription, which corresponds to current practice in jurisdictions where adult use is legal. Schedule II would likewise seem to be a logical place for potent cannabis extracts and tinctures, which are currently in Schedule I but not IV.

However, low-potency cannabis extracts and tinctures would more appropriately be placed in Schedule III, which is for pharmaceuticals that contain low amounts of drugs and are unlikely to be abused. Cannabis products in this category would include topical preparations; CBD-predominant extracts, which have low psychoactivity; and microdose products with low levels of THC.

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