



...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 No. FDA-2019-N-0767 for “International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization; Scheduling Recommendations; Cannabis and Cannabis Resin; Dronabinol (*delta-9*-tetrahydrocannabinol); Tetrahydrocannabinol (Isomers of *delta-9*-tetrahydrocannabinol); Extracts and Tinctures of Cannabis; Cannabidiol Preparations; Preparations Produced Either by Chemical Synthesis or as Preparation of Cannabis; Request for Comments.”

To whom it may concern,

I am writing on behalf of the National Organization for the Reform of Marijuana Laws (NORML) to urge the US Food and Drug Administration to consider recommendations proposed by the World Health Organization Expert Committee on Drug Dependence which seek to ease international restrictions that presently limit access to cannabis and certain cannabis-derived products, as well as potential drug development.

Specifically, the Expert Committee has called for rescheduling the cannabis plant from the most restrictive category available under the 1961 Single Convention treaty to a lesser restrictive schedule. It has further recommended descheduling certain CBD-dominant products entirely.

In recent years, nations such as Canada and Uruguay have amended their federal laws to regulate the adult use of cannabis. Many US states have taken similar action. The use of medical cannabis products has also become widely accepted throughout the world. The WHO should take these political changes into consideration when reviewing the plant’s status.

Abuse Potential

Cannabis clearly does not share the high abuse potential associated with most other controlled substances, such as heroin or cocaine, or even other legal intoxicants like alcohol or tobacco. According to a comprehensive review by the United States National Academy of Sciences¹,

¹ National Academy of Sciences. *Marijuana and Medicine: Assessing the Science Base*, 1999. Page 95: Table 3.4: Prevalence of Drug Use and Dependence in the General Population

cannabis' dependence liability is similar to that of caffeine (7 percent) or anxiolytics (9 percent), and is far lower than the dependence liability associated with other substances like alcohol (15 percent) and tobacco (32 percent).

In the United States, state jurisdictions permitting cannabis access experience a decrease in subjects' willingness to use other controlled substances, particularly opioids, but also alcohol, tobacco, and benzodiazepines, among others.² Further, rates of cannabis use disorder and other measures of problematic use have declined over the past decades, at the same time that numerous US states have liberalized their cannabis laws. Among adolescents, "Past year prevalence of marijuana use disorders declined by an estimated 24 percent over the 2002 to 2013 period," according to data published in the *Journal of the American Academy of Child & Adolescent Psychiatry*.³ Between 2002 and 2016, rates of marijuana dependence fell nearly 40 percent among regular adult users, according to data published in the journal *Drug and Alcohol Dependence*.⁴

Therapeutic Potential

There exist numerous FDA-approved controlled trials assessing the safety and efficacy of cannabis in various patient populations.⁵ A scientific review of several of these trials concludes: "Based on evidence currently available the Schedule I classification is not tenable. It is not accurate that cannabis has no medical value, or that information on safety is lacking."⁶

Cannabis' medical efficacy is most well established in the treatment of chronic pain. According to an exhaustive review published in 2017 by the US National Academy of Sciences, "There is conclusive or substantial evidence that cannabis ... [is] effective for the treatment for chronic pain in adults."⁷ Cannabis and its compounds are also well-established to be safe and effective in the treatment of nausea, seizures, multiple sclerosis, and as an appetite stimulant.

Several countries – such as Canada, Jamaica, and the Netherlands – as well as the majority of US states recognize the therapeutic use of cannabis by statute. It is now estimated that over 1.2 million Americans are using cannabis as a legal medicine under state law. Many others are consuming CBD-dominant products for therapeutic purposes, and many states recognize this compound's utility via state statute. According to the opinion of Dr. Nora Volkow, Director of the US National Institute on Drug Abuse, cannabidiol is "a safe drug with no addictive effects."⁸

² Summaries and citations of relevant studies can be found at: <http://norml.org/marijuana/factsheets/item/relationship-between-marijuana-and-opioids>.

³ Gruzca et al., 2016. Declining prevalence of marijuana use disorders among adolescents in the United States, 2002 to 2013. *Journal of the American Academy of Adolescent Psychiatry*: 487-494.

⁴ Steven Davenport, 2018. Falling rates of marijuana dependence among heavy users. *Drug and Alcohol Dependence*: 52-55.

⁵ Summaries and citations of relevant studies can be found at: <http://norml.org/library/recent-research-on-medical-marijuana>.

⁶ Grant et al., 2012. Medical marijuana: Clearing away the smoke. *The Open Neurology Journal*: 18-25.

⁷ National Academy of Sciences. *The Health Effects of Cannabis and Cannabinoids*, 2017: [Conclusions for: Therapeutic Effects](#)

⁸ Nora Volkow. [The potential promise of CBD](#). Huffington Post. December 8, 2017.

In Conclusion

For these reasons, NORML opines in favor of the Expert Committee's recommendation to remove CBD from the international drug conventions. We also favor easing the existing schedule of the cannabis plant, though ultimately NORML believes that cannabis ought to similarly be removed from the international drug conventions so that nations that wish to do so may further expand their regulations governing cannabis' use, possession, production, and dispensing for either recreational or medical use.

Sincerely,
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