COMMENT:
CANNABIS IS A GENERALLY SAFE DRUG WITH NUMEROUS MEDICAL BENEFITS

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.

April 23, 2018

NATIONAL CANNABIS INDUSTRY ASSOCIATION
SCIENTIFIC ADVISORY COMMITTEE
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The purpose of this comment, provided by the National Cannabis Industry Association's Scientific Advisory Committee, is to describe the unequivocal scientific evidence that supports the removal of cannabis (marijuana) as a Schedule 1 (Class 1) drug. The Controlled Substances Act of 1972 defines a Schedule 1 (Class 1) drug as being federally illegal with no currently accepted medical use, a high potential for abuse, and severe safety concerns. There is now compelling scientific evidence from rigorous Food and Drug Administration (FDA)-approved clinical studies which clearly document that cannabis and its chemical components have numerous accepted medical uses, a low potential for abuse, and minimal safety concerns. Cannabis is currently scheduled together in Class 1 with drugs like heroin and LSD; while cocaine and methamphetamine are classified as a Schedule 2 drugs. Moreover, alcohol and tobacco, the dangers of which have been widely recognized by science and medicine, are not included in the drug schedule at all. There is no scientific justification for the inclusion of cannabis in the drug schedule. The FDA should call for the removal of cannabis from any form of scheduling and provide similar recommendations in preparing its response to the World Health Organization (WHO) regarding the abuse liability of cannabis.

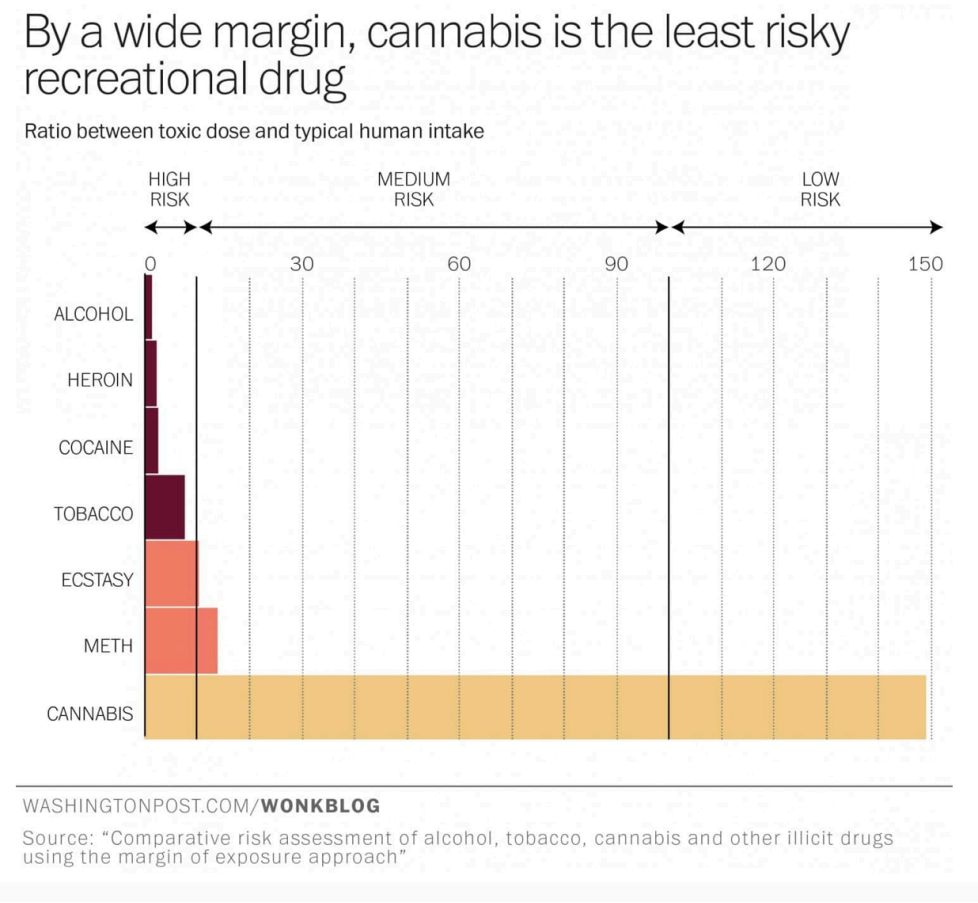
The current scheduling of cannabis as a Class 1 drug by definition requires that it have no medical use, but numerous scientific studies and other governmental agencies in the United States [the FDA, the National Institutes of Health (NIH), and the National Academy of Sciences (NAS)] contradict this assertion. A recent report published by the NAS concluded that there was *conclusive* evidence that cannabis or cannabinoids are effective for the treatment of pain in adults; chemotherapy-induced nausea and vomiting; and spasticity associated with multiple sclerosis. (NAS, Engineering and Medicine. The Health Effects of *Cannabis* and Cannabinoids: The Current State of Evidence and Recommendations for Research. Washington, DC: National Academies Press; 2017.) The report further concluded that there was moderate clinical evidence that cannabinoids improve outcomes in individuals with sleep disturbances. These conclusions were made by evaluating all of the published research and clinical trials on cannabis or its chemical constituents. Numerous clinical trials to evaluate the potential benefits of cannabis, cannabis extracts, or components of cannabis for other indications are ongoing and have shown promising results. For example, Epidiolex, an extract from cannabis with high levels of the cannabinoid cannabidiol (CBD), has shown clear and striking benefits in childhood forms of epilepsy and was recently recommended for FDA final approval by an FDA advisory panel. Additional US government sponsored research studies have shown recently that cannabis may be used as a safe alternative to opiates for managing pain

(https://www.drugabuse.gov/publications/marijuana/marijuana-safe-effective-medicine). The data is unambiguous: numerous independent research studies have shown that cannabis, or components of cannabis, have benefits for numerous medical indications.

Should cannabis be listed as a Schedule 1 drug because it has a high potential for abuse? Here again the science is crystal clear. Unlike narcotics, cannabis does not cause strong forms of chemical dependency and has relatively minor withdrawal symptoms. Indeed, only a small percentage (7%) of people who use cannabis will become dependent on it, while the percentages for alcohol (15%) and tobacco (33%) are much higher (Anthony *et al.*, *Experimental and Clinical Psychopharmacology* 1994; 2:244). A 2015 study sponsored by National Institute on Drug Abuse (NIDA) found that 4 million people in the United States have marijuana use disorder, while the corresponding number for alcohol is 15 million. Relative to alcohol and tobacco, cannabis has a much lower potential for abuse.

Should cannabis be listed as a Schedule 1 Drug because of severe safety concerns? Once again, the science tells us otherwise. A study published in *Lancet* (Nutt *et al.*, *Lancet* 2010; 376:1558) used scientific and medical criteria to determine the relative harm of drugs and established that alcohol, heroin, cocaine, and methamphetamine are far more harmful to individuals and society than cannabis. To date, there are still no reported deaths due to the intoxicating effects of cannabis, while the annual number for prescription opiates may be as high as 63,000 [Center for Disease Control (CDC)]. Alcohol-related deaths total approximately 88,000 annually (National Institute on Alcohol Abuse and Alcoholism) and the figure for tobacco is 480,000 (CDC and NIDA). Another research study that compared the relative risk assessment of alcohol, tobacco, cannabis and other illicit drugs using the margin of exposure approach showed that cannabis, by a wide margin, is the least risky of these recreational drugs (see Figure 1; Lachenmeier and Rehm 2015; Scientific Reports 5:8126). Interestingly, beyond cannabis having limited safety concerns, NIDA-sponsored studies indicate opiate-related adverse events and deaths are significantly lower in states with cannabis regulation. Presumably, these results are attributable to the fact that cannabis is an effective pain medicine and people are likely replacing opiates with cannabis as a safe and effective alternative.

Figure 1



In 1972, the US government formed a commission (the "Shafer Commission," formally known as The National Commission on Marijuana and Drug Abuse) to investigate and analyze the harmful effects of cannabis. This commission, which was composed of scientists and clinicians, concluded that no significant physical, biochemical, or mental abnormalities could be attributed solely to cannabis smoking, and called for its decriminalization. The authors of the report went on to argue that "in the long run marijuana legalization appears to hold the greatest promise for effective and intelligent control of marijuana use." Cannabis has numerous accepted medical uses, has low abuse potential, and is generally safe for consumption. From a scientific standpoint, it is abundantly clear that cannabis should be removed from the Drug Schedule completely and should instead be treated similarly to alcohol. While President Nixon rejected the conclusions of the Shafer report, the FDA is now in a position to rectify this mistake and join the NAS and the NIH in accepting cannabis for what it is… a generally safe drug with numerous medical benefits. The FDA should recommend to the Drug Enforcement Agency (DEA) and to the WHO that cannabis should be removed from any form of drug scheduling.