Dear Chairwoman Eshoo and Ranking Member Burgess:

I am writing on behalf of the American Psychological Association (APA) to request that you take immediate action to facilitate critically needed cannabis research by streamlining the cumbersome, redundant, and unnecessary regulatory framework for conducting that research. APA is the largest scientific and professional organization representing psychology in the United States. Our membership includes more than 118,400 researchers, educators, clinicians, consultants, and students with a mission to advance the creation, communication, and application of psychological knowledge to benefit society and improve people's lives.

We are at a critical juncture in one of the largest social experiments in the history of the United States with the proliferation of medical and recreational cannabis. Now that 33 states have approved the medical use of cannabis and 11 have approved recreational use, the majority of US adults now have state-legal access to either medical or recreational cannabis.

As with recreational alcohol use, most cannabis users are unlikely to experience significant adverse effects. However, 20-30% of regular users will meet the criteria for Cannabis Use Disorder (CUD), which accounted for approximately 138,000 treatment admissions in 2015. CUDs are often associated with dependence—in which a person feels withdrawal symptoms when not taking the drug. CUD becomes addiction when the person cannot stop using the drug even though it interferes with many aspects of their life. Estimates suggest that 9 percent of people who use cannabis regularly will become dependent on it, rising to about 17 percent in those who start using it regularly in their teens. Those seeking treatment do so for a variety of reasons: using more than they intend to, dissatisfaction with daily functioning, effects on memory, neglecting responsibilities, withdrawal effects, inability to stop using, and other health concerns. At present, treatment outcome is poor, with only a fifth of patients achieving continued abstinence.
A variety of psychological, behavioral, and pharmacologic treatment options are needed to reduce CUD withdrawal and facilitate abstinence because, with increased legalization and public acceptance, daily cannabis use and the number of adults with cannabis use disorder (including pregnant women) is rising.

Promising treatments for CUD include cognitive-behavioral therapy, contingency management, and motivational enhancement therapy but there are no FDA approved medications for CUD and additional treatment research is needed. Equally concerning from a research perspective, there is little or no scientific evidence of treatment effectiveness of medical cannabis for treatment of most of the more than fifty designated qualifying medical conditions (which vary from state to state).

**Setting the Research Agenda**

Cannabis and its constituent compounds are of significant interest to psychological scientists, who may investigate issues surrounding use, abuse, and dependence, as well as the therapeutic potential of cannabis derivatives to treat a variety of health conditions. From 2013 through 2017, approximately 25% of all National Institutes of Health (NIH) Research Project Grants (RPG) coded under the Congressionally mandated spending categories “cannabinoid” or “cannabidiol” were awarded to psychologists. Many prominent psychologists participated in a 2016 Summit convened by the NIH, which focused on the neurological and psychiatric effects of cannabis, other cannabinoids, and the endocannabinoid system. Both the adverse and the potential therapeutic effects of the cannabinoid system were discussed. The goal of the summit was to ensure that evidence-based information is available to inform practice and policy, particularly important at this time given the rapidly shifting landscape regarding the recreational and medical use of cannabis.

In 2017, the National Academies of Science released a report entitled “The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research.” The report offered four recommendations to inform a research agenda: 1) address current research gaps, highlighting the need for a national cannabis research agenda that includes clinical and observational research, health policy and health economics research, and public health and public safety research; 2) identify actionable strategies to improve research quality and promote the development of research standards and benchmarks; 3) highlight the potential for improvements in data collection efforts and the enhancement of surveillance capacity; and 4) propose strategies for addressing the current barriers to the advancement of the cannabis research agenda.

Furthermore, in 2018 the National Institute on Drug Abuse (NIDA) released a report from its Cannabis Policy Research Workgroup providing recommendations to guide NIDA’s cannabis policy research agenda. The report noted that the need for an expansion of cannabinoid research on many fronts is clear, but research with botanical cannabis and its derivatives is costly, cumbersome and limited by a sole source supply from NIDA’s Drug Supply Program. While NIDA provides a basic catalog of cannabis products and derivatives for research, it cannot keep pace with the range and variety of products
available to consumers in the 11 states that have approved recreational cannabis use or the 33 states distributing cannabis products through medical dispensaries.

**Scientists Need to Study a Broad Range of Cannabinoid Products**

On July 7, 2016, NIDA published a Request for Information in order to gather information on several related topics from the research community, including: the specific marijuana varieties, strains, or constituent chemotypes that are of research interest; the marijuana constituents, products and/or preparations that are of research interest; and the particular research questions that could or would be addressed with such products.

The most consistent recommendation was to provide marijuana strains and products that reflect the diversity of products available in state medical marijuana dispensaries. That would include cannabis strains and hybrids with higher tetrahydrocannabinol (THC) content, more reflective of what is found in state programs (up to about 30% THC), as well as increasing the number and variety of cannabis chemotypes to include not only a range of THC concentrations, but also other cannabinoids: cannabidiol, cannabigerol, cannabiol, cannabichromere, tetrahydrocannabinvarin, terpenes (e.g., linalool, terpinolene, nerolidiol, myrcene), and flavonoids, with varying concentrations of each to better isolate and characterize their constituent pharmacological effects.

In addition to botanical cannabis, scientists reported a need for an expanded range of formulations designed for varied routes of administration to reflect what is available in state dispensaries. These formulations include those for oral, sublingual, respiratory, rectal, and dermal delivery of purified and whole plant extracts (e.g., edibles, hash oil, budder, wax, and shatter) along with matching placebo formulations. Regarding placebos, there is increasing demand to improve the quality of placebo cannabis because the current process for its manufacture removes not only THC but many other compounds, including other cannabinoids as well as volatile compounds (terpenes) that contribute to the product’s color and olfactory characteristics. A more effective placebo would better mimic the taste, smell, and appearance of active botanical cannabis.

The scientific community is eager to advance cannabis research on both the harmful and therapeutic effects of cannabis and its derivatives. Without access to an expanded range of cannabis products engineered under the Food and Drug Administration’s (FDA) Good Manufacturing Practices, scientific research cannot hope to keep pace with the ever-expanding recreational and medicinal cannabis marketplace. We are pleased that the Drug Enforcement Administration (DEA) is finally responding to multiple requests from both the House and Senate as well as our own request to process grower applications it began receiving in 2016. However, it is unclear whether those growers will produce a range of cannabinoids comparable to those available in state dispensaries. Providing scientists with access to the range of products available through state-dispensaries will be critical to understanding the effects of real-world use of cannabinoids.
Reducing Harm and Recognizing Therapeutic Potential

As outlined above, psychologists are interested in studying a wide range of scientific questions that require a broader supply of cannabis products, including how the route of administration and potency influences abuse-liability, risk for cannabis use disorder, cognitive abilities, risk for psychosis, and motor vehicle operation, as well as the potential therapeutic indications for cannabis derivatives.

There is no longer any doubt that at least some of the chemical constituents of cannabis have therapeutic benefit, and cannabinoids have been approved by the FDA for the treatment of various medical conditions. Synthetic THC (dronabinol) and a structurally similar analogue (nabilone) have been approved for use in treating anorexia associated with weight loss for patients with AIDS, and nausea and vomiting associated with cancer chemotherapy for patients who have failed to respond adequately to conventional antiemetic treatments. More recently, the FDA approved the first plant-derived (i.e., natural product, not synthesized) formulation of cannabidiol for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, for patients two years of age and older.

A Rational Approach to Decreasing Regulatory Burden

Scientists are responsible stewards of pharmaceutical compounds scheduled under the Controlled Substances Act (CSA) as evidenced by the lack of DEA enforcement actions against registrants with PhD degrees. In the publicly available data on the DEA’s Diversion Control Division website, a detailed list of criminal cases against hundreds of individuals with doctoral level degrees (who also include physicians, veterinarians, osteopaths, nurse practitioners, pharmacists, and other allied health professionals) spanning twenty years indicates only one action was filed against an individual with a PhD, a plant biologist. The majority of criminal actions prosecuted by DEA appear to involve physicians and allied health professionals who have diverted Schedule II-V drugs that they had access to in their everyday professional lives. Scientists receive special training in the ethical and responsible conduct of research and invest extraordinary time, effort, and expense to gain credibility within the research community. Even an unintentional violation of DEA protocols could easily damage their careers.

In order to facilitate more research, it would not be necessary to broadly reschedule cannabis, which falls under CSA Schedule I. Rather, providing a Schedule II-like exemption for cannabis used in research settings would markedly decrease the regulatory burden imposed on scientists dedicated to studying cannabis (Appendix). DEA should be asked to provide data on the incidence of enforcement actions brought against scientists registered to use Schedule II substances in research settings. Assuming that those numbers would be extremely small, it would be reasonable to treat cannabis acquisition, scientific protocol review, and protocol amendments in the same way that these are handled for Schedule II substances.

The Role of DEA in Context: Diversion, Science, and Safety

As outlined above, there are no data to suggest that scientists registered to investigate substances under the CSA are responsible for the diversion of cannabis. Still, it might be argued that strict security requirements for cannabis are necessary to prevent theft. However, even if 100% of the 2019 DEA Aggregate Production Quota of cannabis allowed to be grown for research (5,400 lbs.) were to be stolen, that would make up only 0.022% of the estimated illicit domestically produced cannabis available on the US black market.
market (24,400,000 lbs.) in 2019. For context, NIDA only distributed, in total, 16 lbs. of cannabis for research (personal communication, Dr. Richard Kline, Chemical and Pharmaceutical Branch Chief at NIDA) so all the infrastructure, security, and byzantine protocol review (see Appendix) was in place to safeguard just 16 lbs. of cannabis.

Further, there is little rationale for DEA to be involved in scientific protocol review for cannabis research, which is adequately and, arguably, better handled by Institutional Review Boards and the FDA. Further it lies outside of the scope of DEA’s role as an arm of the Department of Justice and adds significant delays for scientists seeking to initiate cannabis research. This is particularly troubling for junior scientists who must demonstrate significant progress early in their careers in order to receive those first RPG’s and the time it takes for registration and approval of Schedule I protocols serve as a strong disincentive for early career scientists to initiate research on cannabinoids.

Cannabis has proved to be a relatively safe drug to administer in research laboratories and the toxic effects of high dose cannabis administration resolve with time as the active constituents are metabolized. Although withdrawal from long term cannabis use can result in anxiety, irritability, cannabis craving, restlessness, sleep disturbances and appetite suppression, those effects manifest within 24 hours and typically resolve within 1 to 2 weeks. There has never been a recorded case of cannabis overdose resulting in death (By comparison, alcohol, another pharmacologically active substance used recreationally by millions across the US (and which has no approved medicinal use), is lethal when used at high doses acutely, is increasingly implicated in chronic morbidity and mortality, and can cause life threatening seizures upon withdrawal in alcohol dependent individuals).

In closing, thank you for holding this critically important hearing and for the opportunity to provide written testimony for the record. It is critical that cannabinoid research catch up with the real-world use of this class of compounds to better understand their harms and to develop effective treatment for those who develop CUD, as well as to unlock their potential therapeutic efficacy in treating a variety of medical conditions. If you have any questions or need additional information, please contact Dr. Geoff Mumford, APA’s Senior Director for Science Policy, at gmumford@apa.org or 202.336.6067.

Russ Shilling
Chief Scientific Officer
References:


9. Compton WM, Han B, Jones CM, Blanco C Cannabis use disorders among adults in the United States during a time of increasing use of cannabis. Drug Alcohol Depend. 2019 Nov 1;204

APPENDIX
Flow charts depicting the complexity of the current regulatory framework for conducting research with cannabinoids.
CONDUCTING BASIC RESEARCH ON MARIJUANA

Develop Research Proposal [2-3 months]

IACUC Review & Approval [1-2 months]

**Review Scientific Protocol**
- Federally Funded
  - Federal Grant Review/Funding
    - Grant Submission
    - Peer Review
    - Advisory Council Review
    - Director Approval [~9 months]
- Non-Federally Funded
  - Protocol Review
    - By external scientific experts
      (Coordinated by NIDA) [1-2 months]

**State Schedule I Registration**
- Verify Protocol
- Background Check
- Site Inspection
- Annual renewals [2-4 months]

**Federal Schedule I Registration**
- Protocol Review (DEA/FDA)
- Background Check (DEA)
- Site Inspection (DEA)
- Annual Renewals [3-6 months or more]

**NIDA Drug Supply Program**
- Confirms IACUC approval, protocol review & federal license.
  [Marijuana ships ~3-4 weeks after order submission]

**Protocol Changes**
- [Research stops while amending protocols]
  - Amend IACUC Approval
  - Revise State Registration
  - Revise Federal Registration
  - Resume Research