

# Position on Cannabis Research



## Contextual background

- Scientific research shows that cannabis, or its constituent components, has both significant potential for abuse and valid therapeutic use in medicine.
- Legalization of cannabis by U.S. states has resulted in a proliferation of novel products for which we lack a basic scientific understanding of risk/benefit; widespread access poses a public health risk.
- Data are needed to inform standards/regulations for the cannabis/hemp industry.

## Urgent research needs that can be addressed by CPDD scientists

- What is the pharmacology, safety, and abuse liability of novel cannabis products?
- How do cannabis and its constituents affect the brain and other organs?
- What are valid methods of detecting cannabis use and impairment?
- What types of cannabis products are being used and does use vary by geographic location or demographic characteristics (e.g., gender, race, age, and socioeconomic status)?
- What regulatory policies are needed for product packaging, labeling, advertising and retail sales?
- What is the impact of cannabis legalization on other drug use, such as opioids and tobacco?
- What are the mechanisms and interactive effects of cannabis constituent components?
- How does cannabis exposure affect fetal and child development and health?
- What is the impact of cannabis legalization on public health?
- Can we develop cannabinoid medications with low abuse liability and better safety/efficacy?

## Barriers to fulfilling research needs

- The DEA review process for human research on Schedule I cannabinoids is burdensome, lengthy, and redundant with many facets of review by the FDA and institutional review boards.
- Federal and state requirements for conducting research with Schedule I drugs are often at odds with each other, and there are differences in interpretation across local DEA field offices.
- There is no regulatory pathway for a researcher with a license to study Schedule I drugs to obtain, store, or test cannabis products sold in retail stores or online in states that have legalized cannabis.
- The scheduling of cannabis and cannabinoids is confusing and often inconsistent. For example, THC currently exists in Schedules I, II, and III of the CSA and cannabidiol (CBD) derived from hemp is unscheduled via the 2018 Farm Bill, is in Schedule 5 for Epidiolex, and is a Schedule I drug if synthetically manufactured. CBD derived from the plant and synthetic CBD are chemically identical.
- Security requirements for storing small amounts of cannabis for research are excessive.
- Due to the difficulty in obtaining a Schedule I manufacturing license, there is virtually no domestic source for individual cannabinoids (e.g. THC, CBD, CBG) for human research.

## Recommendations for addressing barriers

- Streamline the regulatory process for manufacturing and conducting research on cannabis and cannabinoids, including time limits for review of new and amended applications.
- Eliminate requirement for DEA to approve new protocols and protocol amendments for Schedule I license holders; replace with a research summary submitted during annual license renewal.
- Create a regulatory pathway that allows researchers with a Schedule I license to obtain, store and conduct research on retail cannabis products.
- Fund research on cannabis to inform regulatory policy that mirrors that for tobacco and alcohol.

**The promulgation of retail cannabis products has far outpaced science and poses a substantial public health risk; we are handcuffed by regulatory restrictions and barriers. Research is needed to promote both individual and public health through science-based education and regulation.**