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“Cannabidiol: Barriers to Research and Potential Medical Benefits”

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Submitted to the Senate Caucus on International Narcotics

Chairman Grassley and Co-Chair Feinstein – thank you for the opportunity to submit written testimony before your Committee for this important hearing on cannabidiol. My testimony will focus on two key areas – why cannabidiol (CBD) is not enough, and a discussion of the barriers that exist for conducting research into medical marijuana.

Let me begin by describing my background. I received my doctorate in Public Policy from Harvard’s Kennedy School of Government, where I wrote my dissertation on the regulation of the medical uses of psychedelics and marijuana. My Master’s thesis, also at the Kennedy School, was a survey of oncologists about smoked marijuana vs. the oral THC pill in nausea control for cancer patients. My undergraduate thesis at New College of Florida was a 25-year follow-up to the classic Good Friday Experiment, conducted at Harvard in 1962 in order to evaluate the potential of psilocybin to catalyze mystical experiences. I am the founder (in 1986) and executive director of the Multidisciplinary Association for Psychedelic Studies (MAPS), a non-profit research and educational organization that is sponsoring FDA-regulated research. MAPS recently received a \$2.15 million grant from the Colorado Department of Public Health and Environment, the largest marijuana research grant awarded, for our FDA-approved Phase 2 pilot study aiming to evaluate the efficacy of smoked marijuana for 76 veterans suffering from chronic, treatment-resistant PTSD. MAPS has sponsored and conducted over a dozen studies over the past three decades including a promising international series of Phase 2 pilot studies into the potential of MDMA-assisted psychotherapy for veterans and others with chronic, treatment-resistant PTSD. I currently reside in Boston with my wife and three children.

Cannabidiol, or CBD, is one of more than 70 known chemical compounds, known as cannabinoids, which are unique to the marijuana plant. Like THC, marijuana’s most well-known therapeutic compound, CBD has significant medical effects, including anti-inflammatory, anti-pain, anti-anxiety, anti-psychotic and anti-spasm properties. Unlike THC, however, it is largely non-psychoactive – meaning that it does not make people feel intoxicated. In fact, CBD can counter the psychoactivity of THC, which can help people who feel they have taken too much THC.

Emerging research on CBD is quite promising. Evidence of varying quality supports the use of CBD for a wide range of serious medical conditions, including Alzheimer’s, anorexia, anxiety, atherosclerosis, arthritis cancer, colitis/Crohn’s, depression, diabetes, epilepsy/seizure, fibromyalgia, glaucoma, irritable bowel syndrome, multiple sclerosis, neurodegeneration, obesity, osteoporosis, Parkinson’s, PTSD, schizophrenia, substance dependence/addiction, and stroke/traumatic brain injury.

Medical marijuana growers and providers in Colorado have developed a strain of marijuana with a high amount of CBD and a low amount of THC – named Charlotte’s Web – that is being used to treat children with a rare and life-threatening form of childhood epilepsy called Dravet’s syndrome. The success of this treatment for pediatric patients has attracted significant media attention, which has led families of children with epilepsy to organize around the country to advocate for access to medical marijuana. Some families have relocated to Colorado to access this novel treatment that may fundamentally improve their children’s health after other available medications have failed, and in some cases can save their lives.

There is a large body of research validating the therapeutic properties of THC, which has been more extensively studied than CBD. There are some conditions for which high THC marijuana is more effective, namely conditions usually associated with cancer and HIV. Research shows that marijuana with an equal THC/CBD ratio is the most effective at treating pain associated with cancer. Additionally, research shows that marijuana with more THC than CBD is most effective at treating nausea associated with chemotherapy. Wasting and weight loss related to HIV and anorexia were found to respond significantly to 5mg of a synthetic version of THC (Dronabinol). Multiple studies have shown that neuropathic pain, one of the most difficult conditions to treat, and a condition common among cancer and HIV patients, responds to THC.

Moreover, the most cutting-edge research shows that THC and CBD, along with other cannabinoids and terpenes in the marijuana plant, have a synergistic effect, which means that they work more effectively in unison than they do in isolation. This synergy is known as the “Entourage Effect” and is documented in several research studies. All marijuana plants have both THC and CBD, even if the THC or CBD are in trace amounts. They are both important in maximizing the benefits of the marijuana plant. As CNN’s Dr. Sanjay Gupta explains: “Eating real fruits, vegetables and other plants provides better nutrition than just taking vitamin pills with one nutrient or mineral in each. Science is showing us that we can likely say the same about cannabis.”

Due to the increased attention around CBD, many state legislatures have decided to adopt laws that only allow access to high-CBD and low-THC types of marijuana. Fifteen states have enacted such CBD-only laws. Most of these laws only permit access to a very small number of patients, and include other components that make these laws extremely difficult to implement. Therefore, these CBD-focused laws are largely symbolic. Not one of these states has implemented a state-regulated system to produce medicine and make it available to patients of their states.

These laws demonstrate several states’ recognition of the necessity to depart from federal policy on medical marijuana. They represent what most Americans know but the federal government has yet to acknowledge: marijuana has medicinal value, patients are suffering, and states need to act on their own to provide relief to patients in the face of more than four decades of federal obstruction.

These CBD-focused laws are extremely limited and exclude the vast majority of patients who need THC and other cannabinoids in the plant (or the whole plant) to treat or alleviate their medical conditions. Research continues to show that therapeutic benefits are maximized by

utilizing the whole plant, not individual compounds in isolation. As some conditions respond better to a THC-rich strain of marijuana, the adoption of high-CBD/low-THC programs denies access to patients who can benefit from marijuana strains higher in THC.

Arbitrarily restricting medical marijuana access to certain therapeutic compounds hurts sick and dying people. Restricting options for the most effective medical treatment limits relief, and potential healing, for patients suffering from serious, and sometimes fatal, medical conditions. States should adopt comprehensive medical marijuana laws, which allow patients to access the full spectrum of marijuana's medically beneficial qualities.

On the issue of research barriers, it has been well-documented that the federal government continues to place obstacles in the way of marijuana research. I was pleased this week when HHS announced the elimination of the Public Health Service (PHS) review of privately-funded medical marijuana protocols – something that has significantly slowed or completely blocked the ability of my colleagues and me to perform FDA-regulated medical marijuana research. However, more must be done. The federal government must also end the so-called “NIDA monopoly”. Federal law (the Controlled Substances Act) requires the manufacture of Schedule I and II substances to be conducted in a manner that provides “an adequate and uninterrupted supply produced under adequately competitive conditions.” Yet, since 1968, the National Institute on Drug Abuse (NIDA) has maintained an unjustified monopoly on the production of marijuana for legitimate medical and research purposes in the US. The DEA helps to protect NIDA's monopoly by refusing to grant competitive licenses for marijuana production. MAPS supported the efforts of Prof. Lyle Craker, UMass Amherst, in his 2001 application to DEA for a license to produce marijuana exclusively for federally regulated research. DEA rejected the application. In 2007, Prof. Craker won a DEA Administrative Law Judge (ALJ) hearing when Judge Bittner found that it would be in the public interest for DEA to license Prof. Craker. DEA subsequently rejected the ALJ recommendation.

Currently, there is no path for marijuana to become a federally approved medicine. Privately-funded sponsors must conduct FDA-approved Phase 3 multi-site clinical trials to demonstrate that marijuana meets the necessary standards to become a medicine under federal law. However, NIDA's marijuana can only be used for research but not for prescription sale should FDA approve such a use. The key problem is that FDA requires multi-site Phase 3 studies to be conducted with the exact same product the sponsor seeks to market. As a result, NIDA's marijuana is fundamentally inadequate for privately-funded Phase 3 drug-development research. No such Phase 3 research is currently being conducted in the US or anywhere else in the world, despite strong public interest. The NIDA monopoly exists only for marijuana, not for any other Schedule 1 drug, and needs to be ended through DEA licensing of private producers.

Several months ago, NIDA awarded a five-year, \$68 million contract (an average of \$13.6 million a year for 5 years) to Prof. ElSohly at the University of Mississippi to grow marijuana for research under contract to NIDA. That is an outrageous amount of money for marijuana that is inadequate for Phase 3 research. Ending the NIDA monopoly would save a great deal of taxpayer money.

The NIDA monopoly is also an inadequate supply for research prior to Phase 3. For example, NIDA cannot currently supply the 12% THC, 12% CBD marijuana variety that we requested in August 2014, for our study in veterans with chronic, treatment-resistant PTSD, offering us 9% THC, 9% CBD instead. NIDA indicated that we would need to wait for another growing season before it could provide the variety we requested. This is not surprising since it is not NIDA's mission to study the medicinal uses of marijuana or to advocate for such research. Prior to the end of the PHS protocol review several days ago, NIDA's monopoly on the supply of cannabis available for research resulted in arbitrary and lengthy delays. For its part, the DEA wants to have it both ways, denying that marijuana is a medicine because the FDA has not approved it, while simultaneously blocking privately-funded production which is essential for FDA Phase 3 clinical trials.

From 2003 to 2010, Chemic Labs, a DEA-licensed analytical lab, sought to purchase 10 grams from NIDA for MAPS-sponsored research into vaporizers, a non-smoking delivery system which the Institute of Medicine report recommended be developed. Chemic had to wait for more than two years for a reply to its initial request, requiring MAPS to sue NIDA for unreasonable delay. In the end, Chemic gave up without ever receiving the marijuana. In the 1990s, NIDA had also refused to provide marijuana to two other MAPS-sponsored, FDA and IRB-approved protocols that sought to evaluate marijuana for AIDS wasting syndrome (IND #43-542) and for migraines (IND #58-177).

Finally, while research and development of FDA-approved medication is the preferred path, we must recognize that it will be many years before privately-funded sponsors of research have gathered the necessary Phase 3 data to submit to the FDA for prescription approval. In the meantime, many patients will suffer greatly as a result of the waiting time and lack of access. While reducing and removing barriers to research is essential, patients should also have access to medical marijuana right now through their state programs. Thirty-nine states currently have some form of medical marijuana, so Congress and the Administration must find a way to allow these programs to proceed, while simultaneously enabling research to move forward so that the medical uses of marijuana can be properly evaluated by privately-sponsored research evaluated by the FDA.

Many thanks for your time.