Statement of
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# Researching the Potential Medical Benefits and Risks of Marijuana

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Chairman Graham, Ranking Member Whitehouse, and Members of the Judiciary Committee's Subcommittee on Crime and Terrorism, thank you for the opportunity to testify about the regulatory issues involved in conducting research with marijuana. My name is Linden Barber and I am a Partner in the law firm of Quarles & Brady and have served as the Director of the firm's DEA Compliance and Litigation Practice for nearly five years. From 1999 to 2011, I was an attorney for the Drug Enforcement Administration and served in a variety of roles including as the Associate Chief Counsel for Diversion Litigation.

The Controlled Substances Act enacted in 1970 contains two findings that are particular germane to the issue of researching the potential medical benefits and risks of marijuana: 1) Many of the controlled substances have a useful and legitimate medical purpose and are necessary to maintain the health of the American people; and 2) the improper use of controlled substances have a substantial and detrimental effect on the health of the American people. These findings have been borne out over the last 46 years. Controlled substances are used in thousands of surgeries every day, surgeries that make peoples lives better. The misuse of controlled substances and the harm that accompanies that misuse is a tragic reality in our society.

The regulatory system established in the DEA's regulations allows for research with controlled substances, including marijuana, while requiring researchers to establish and maintain protocols and systems to prevent the improper use of controlled substances and the diversion of those substances to other than legitimate research channels.

***DEA Requirements for Research with Controlled Substances***

The DEA regulations, consistent with the Controlled Substances Act, require researchers who conduct research with any controlled substance to be registered with the Agency. This requirement applies to research with any controlled substance regardless of the schedule in which the drug is placed. The application form to obtain a registration for research with a Schedule I substance is the same form used to apply for a registration to conduct research with a substance in Schedules II-V.

The DEA regulations impose an additional requirement when seeking to register to conduct research with a Schedule I substance. The researcher must submit a protocol for the research. The protocol must contain information about the researcher/investigator, the research project, and the authority (e.g., institutional authority, approved Notice of Claimed Investigational Exemption for a New Drug). When the research is a clinical

investigation, the researcher must obtain approval from the Food and Drug Administration as required under 21 U.S.C § 355(i).

In my experience both at DEA and representing registrants, some of whom are engaged in research, DEA takes prompt action on applications to register to conduct research with Schedule I drugs including approval of applications to conduct clinical research that is approved by FDA. Recently, applications to conduct research with Schedule I substances have typically been approved by DEA in less than five weeks after FDA approval was received.

Conducting research with marijuana requires that a supply of marijuana be readily available to researchers. Currently the University of Mississippi is registered as a manufacturer to cultivate marijuana. Pursuant to 21 U.S.C. § 826, DEA establishes annual production quotas for all substances in Schedule I and II. It is important to note that there is no difference between how DEA establishes quotas for Schedule I versus Schedule II substances. DEA considers the same factors and performs the same analysis when establishing aggregate production quotas regardless of whether the substance is in Schedule I or Schedule II. The proposed aggregate production quota is published every year in the Federal Register and nay interested person is entitled to submit comments or objections and

DEA must consider those. This process has worked well for members of industry, the public, and researchers in establishing the production quotas across the broad spectrum of Schedule I and II controlled substances. This process also provides interested persons with an opportunity to comment on or object to the proposed aggregate quota.

Although there is currently only one entity registered with DEA to cultivate marijuana, the DEA regulations have long permitted a researcher in Schedule I drugs to manufacture substance for which the registration was granted if manufacturing, to include cultivating, is set forth in the protocol submitted to DEA with the application. Thus, researchers have an avenue by which they may cultivate marijuana within the boundaries of their approved research protocol.

Recordkeeping requirements under DEA's regulations are an important mechanism that allows DEA to account for the production and use of controlled substances. In the research setting, the recordkeeping requirement relating to Schedule I substances are no more onerous than the recordkeeping requirements for Schedule II controlled substances.

The security requirements for conducting research with Schedule I drugs are no different than the requirements for conducting research with other controlled substances. The physical security requirement is that

controlled substances of all schedules be stored in a securely locked, substantially constructed cabinet. DEA's regulations provide that "substantial compliance" with the security requirements may be deemed sufficient after evaluation of the overall security system and needs of the applicant.

The substantial compliance provision is particularly applicable if a researcher desires to cultivate marijuana for research. Storing growing plants in a securely locked, substantially constructed cabinet is not feasible. But the DEA regulations were not drafted with cultivating marijuana in mind. Nevertheless, DEA used its discretion when reviewing and approving the security at the University of Mississippi to ensure that the marijuana growing in the fields was secure even though they were not located within the type of secure building that is required of pharmaceutical manufacturers. This, in my opinion, is evidence that DEA is willing to consider alternatives for security when appropriate to do so.

Furthermore, DEA's regulations contain a provision that permits any person to apply for an exception to the application of any provision of the regulations. In other words, if a regulation is impracticable for a researcher, the researcher has recourse to apply for an exception.

While there are substantial regulatory requirements for those conducting research with Schedule I controlled substances, these regulations are crafted to permit research while preventing the substances being researched from being diverted or misused. This protects the public while permitting research. Additionally, DEA has provided a regulatory mechanism to seek an exception to any regulation.

***DEA's History with Researchers***

DEA has registered hundreds of individuals to conduct research with marijuana, marijuana extracts and THC. It also has shown a flexibility, particularly recently, by easing regulatory requirements involving research with cannabidiol (CBD), an extract of the marijuana plant. DEA's regulations require a researcher who requires more of a Schedule I substance than approved based on the researcher's application and protocol to submit a request for approval to use additional amounts to DEA and FDA. For CBD research, DEA has granted nearly 40 waivers to this regulatory requirement since late December 2015.

While some have interpreted DEA's enforcement role and it historical enforcement actions involving marijuana as an indication that DEA has an institutional bias against marijuana that has not been my experience. While historically some individuals in the Agency may have been skeptical about

research with marijuana, Administrator Rosenberg and Deputy Assistant Administrator Milione have been very supportive of research. From the perspective of one who represents registrants before the Agency, it appears that DEA's leadership is working with researchers to reduce barriers to research and is coordinating with the Department of Health and Human Services to improve the process for approving research with marijuana.