Response to Questions for the Record

Response of
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For the United States Senate
Judiciary Committee
Subcommittee on Crime and Terrorism

Researching the Potential Medical Benefits and Risks of Marijuana

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Question for the second panel (Gitlow, Barber, Piomelli)

Shouldn't we increase research on medical benefits of marijuana?

It seems safe to say that the three of you bring different perspectives, but that you each agree that further research into the potential medical benefits and risks of marijuana is merited.

What are the most important considerations that we as policymakers should take into account when confronting this issue?

Expanding research on the medical benefits of any controlled substance (including marijuana) that has a science-based prospect of being safe and effective for medical use is prudent. Based on scientific studies, we know that some molecules and compounds found in the cannabis plant have medicinal benefits. When establishing priorities for funding research or considering legislation that promotes research, science should inform those public policy decisions.

The most important considerations that policymakers should consider regarding expanding research with marijuana or the compounds found in marijuana are the following:

1. Research with controlled substances should be promoted in a manner that is consistent with public health and safety. Research with marijuana or specific compounds contained in marijuana should be conducted in light of the well-documented history of the psychoactive effect of marijuana and the abuse of marijuana.

2. Research with controlled substances should be promoted in a manner that is consistent with the benefit to the American people from such research. For example, consideration should be given to whether research with isolated compounds found in the marijuana plant versus research with the marijuana plant

is most likely to lead to medical benefits for the American people. Consideration should be give to whether research with compounds that are consistent and pure versus research with the marijuana plant which has variability in the strength of the active compounds and various impurities is most likely to lead to medical benefits for the American people. This is an issue for scientists, not lawyers, to determine. One of the purposes of the Controlled Substances Act is allow the American people to benefit from controlled substances that have a medical purpose. This underlying purpose of the Act should lead to public policy that is aimed at promoting the research that is most likely to produce medical benefits for the American people within the proven system for research and drug approvals.

3. Research with marijuana should not become entangled in the political discourse about the recreational issue of marijuana. Research aimed at developing medicines that will benefit the American people has been and should be dictated by science.

Question for D. Linden Barber, Director, DEA Compliance and Litigation Practice, Quarles & Brady, LLP

What changes or reforms should be made to DEA security practices going forward?

Mr. Barber, in your testimony you indicate that although the regulatory requirements DEA puts in place can be significant, the agency has been open to considering exceptions and flexibility where merited.

Do you believe that any of the individual exceptions you have seen granted to researchers should be codified in DEA policy in order to facilitate access to other researchers?

The DEA's regulations that are in place have proven to be effective in providing security of and accountability for controlled substances used in research. These regulations have been applied in numerous contexts involving a variety of controlled substances. When regulations are unduly burdensome and security and accountability can be achieved without strict compliance with the regulations, the DEA should consider approving other forms of security or grant waivers to the application of certain regulations. As I discussed in my testimony, the DEA has recently exercised its discretion to waive certain provisions in the regulations that were deemed to hinder research without compromising security and accountability. While a waiver may be appropriate in some circumstances, applying such a waiver to every conceivable circumstance through codification of the waiver should only be done if there is clear evidence that the regulation serves no purpose in any context. I am not aware of any waiver or exception that the DEA has granted that should be codified so that it applies to all researchers since research involves a variety of controlled substances in varying quantities and in varying research settings.

Are there other changes or reforms you believe DEA could institute to better enable research to occur?

Regulations should be proactively updated to permit the advancements in modern science without requiring registrants to petition for changes. For example, the scheduling of Dronabinol (i.e., delta-9-THC), is very restrictive. It requires that the THC be synthetic, be compounded with sesame oil, and encapsulated in a soft gelatin capsule in an FDA-approved product. However, scientific advances indicate that this particular THC may be produced by means other than chemical synthesis. Additionally, formulations other than in a compound with sesame oil in a soft gelatin capsule could be developed, but the restrictions of this regulation create an additional regulatory hurdle that could easily be removed without jeopardizing public health or creating a risk of diversion. The DEA could make delta-9-THC and other THCs schedule III substances when in an FDA-approved product. This would encourage research with a variety of THCs. This type of scheduling action would not remove THCs from schedule I unless the THC was in an FDA-approved product. It would not move marijuana from schedule I. This would permit the continued control of the production of THCs and marijuana while removing a regulatory barrier that discourages research and adds significant hurdles for entry of new THC products to the market in the event that they obtain FDA approval.

The DEA and FDA should be encouraged to evaluate for scheduling actions the specific compounds that are found in the cannabis plant. These compounds, whether obtained through extraction from the cannabis plant or produced through chemical synthesis or other scientific processes, have their own characteristics and effects on the human brain. Not all compounds in the cannabis plant are psychoactive and, among those that are psychoactive, it is likely that they do not

all present the same potential for abuse. By proactively considering the appropriate schedule for these compounds in the event that research leads to an accepted medical use in the United States, the DEA and FDA would encourage research and remove a time-consuming regulatory hurdle involving rescheduling after discovery of a medical use for a compound that is currently controlled under the broad scheduling of all THCs other than Dronabinol in Schedule I.

Additionally, this approach to evaluating the compounds that are contained in the cannabis plant may lead to the complete de-scheduling of certain non-psychoactive compounds. This would not reduce the DEA's control over the production of and research with marijuana. However, it could remove significant barriers to research with specific, isolated compounds that occur naturally in the marijuana plant (as well as in other plants and the human body). The fact that a compound naturally occurs in the cannabis plant does not necessarily warrant the scheduling of that compound when it occurs outside of the cannabis plant.

While these types of changes would promote research and remove regulatory barriers, they should not be taken precipitously. Scientific findings should dictate the scheduling and potential de-scheduling of individual compounds that occur naturally in the cannabis plant. As with all scheduling actions, it is imperative that public health and safety be protected. Scientific research and scheduling actions take time, often significant time. These processes should be allowed to run their course as rigorous deliberation by the DEA and FDA have produced the availability of controlled substances that are safe and effective when properly used while protecting public health and safety.