Comments to the DEA regarding regulations implementing rescheduling of marijuana to Schedule III of the Controlled Substances Act

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A.G. Order No. 5931-2024

Thank you for the opportunity to comment on this crucial issue. This NPRM does not address several important issues related to conducting research on marijuana and its constituents. Many questions remain about the health effects of marijuana both positive and negative, and it is critically important to gather new information and knowledge in order to clarify the answers to these questions. We hope that a change from Schedule I to Schedule III will lead to more research, but this cannot happen without regulatory changes that address current barriers to research directly related to the drug's schedule.

We would like to emphasize specific areas of concern that must be addressed in order to increase and improve feasibility of research on marijuana and its effects. These concerns are summarized below in three sections: regulatory requirements for conducting research; access to marijuana and marijuana-derived products; and scientific issues.

Regulatory requirements.

Of key importance will be how rescheduling will impact the registration requirements and processes for marijuana researchers. The current Schedule I status of marijuana has historically resulted in time consuming, costly, and complicated processes for researchers studying marijuana and its constituents (see CPDD Congressional Testimony). We appreciate recent steps taken by the Department to decrease some of these process burdens, and we think that a change to Schedule III could reduce these barriers further. To help clarify this possibility, specific questions that should be addressed in the final rule include:

1. Will research registrations for marijuana be simplified and streamlined and if so, how?
2. Will marijuana be subjected to the same requirements as other Schedule II-IV registrations or will there be marijuana-specific requirements?
3. What will the specific security requirements be for marijuana and marijuana-derived products?
4. Will DEA approval of protocols be required as part of research registrations or will protocol approvals obtained from HHS (eg FDA, NIH) suffice?
5. Will subsequent protocols/revisions need to be provided to DEA at all?
6. Will a physician/researcher need a research registration if only University-associated research pharmacies possess/distribute marijuana and marijuana products (eg THC)?

7. If marijuana-derived products are produced and used entirely within a State, what if any DEA and FDA requirements will no longer be enforced (e.g. INDs, DEA registrations)?
8. Will researchers be permitted to make some changes to marijuana-derived products, such as simple formulations, without obtaining a manufacturers registration?
9. Will administrative changes be made for marijuana research that will eliminate the use of DEA 222 forms?
10. Will other administrative changes that reflect differences between Schedule I and Schedule III substances – such as fewer inventory reporting requirements, multiple research sites and multiple investigators allowed under a single principal investigator registration, and elimination of security safes – apply to marijuana?
11. Will there be guarantees that regulatory changes implemented when the final rule becomes effective will not cause delays or new registration requirements for researchers already conducting marijuana research under a Schedule I registration?

Access to marijuana and marijuana-derived products

1. From a scientific perspective it is critically important to conduct research on the marijuana and marijuana-derived products actually being used by the public (ie. State-legal). Will mechanisms be permitted, such as through the HIDTA program or NIDA Drug Supply Program or other sources, to allow research on marijuana from State dispensaries in a manner consistent with current Federal law?
2. Will any State-approved marijuana be obtainable? If so, how?
3. Will University-associated or other research pharmacies be able to order marijuana from Federally-approved growers? State-approved growers?
4. Will University-associated or other research pharmacies be allowed to stock and distribute marijuana and marijuana-derived products to patients in a research protocol?
5. How will physicians be able to recommend or prescribe marijuana-derived products under an IND application from the FDA that are not FDA-approved products in research? Might there be some use of a traditional prescription form or something similar?
6. If barriers to researcher registrations are lowered, will there be adequate increases in legal sources of marijuana to handle the increase in demand for products from the NIDA Drug Supply Program? From other growers?
7. To further improve feasibility of research and to be in agreement with the changing schedule of marijuana from Schedule I to Schedule III, will synthetically-derived phytocannabinoids (eg delta-9-THC (dronabinol API)) which are chemically identical to cannabinoids found in the marijuana plant also be moved from Schedule I to Schedule III? What about other synthetic cannabinoids that have similar pharmacology to phytocannabinoids?

Scientific and legal issues

1. Will “hemp” and “marijuana” be explicitly defined in terms of which products will be scheduled or not scheduled in order to provide clarity for the research community?
2. Will any accommodations be made to eliminate the scientifically unsound distinction between hemp-derived and non-hemp-derived compounds?
3. Will assurances be provided in the regulations that marijuana research in compliance with the published regulations will not put a University or other research facility at risk of violating the Drug Free Schools Act or Drug Free Workplace Act?

The bottom line: better information and improved knowledge generated through high quality research should be of paramount interest to everyone – law enforcement, regulators, scientists, and practitioners – as it will guide the development of policies to best protect and improve public health. Making marijuana research more feasible by eliminating administrative barriers – such as by explicitly stating that individual protocol reviews will no longer be required for new or revised research studies- will be extremely helpful. As marijuana researchers and allied organizations, we feel that it is important that you are aware of the research community’s concerns. We hope you can address these issues, as appropriate, in the final rule, and will look forward to reviewing that information.

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International Cannabinoid Research Society