VIA ELECTRONIC SUBMISSION—REGULATIONS.GOV

Document Management Staff, Drug Enforcement Administration
Re: Docket No. DEA-506
RIN 1117-AB54
Request for Information on Controls to Enhance the Cultivation of Marijuana for Research in the United States

Multidisciplinary Association for Psychedelic Studies -- *Comment for the public record, revised after formal submission to DEA 05/22/20*

VIA ELECTRONIC SUBMISSION—REGULATIONS.GOV
Attn: Drug Enforcement Agency (DEA)
Re: *"Request for Information on "Controls to Enhance the Cultivation of Marihuana for Research"*

I. INTRODUCTION AND OVERVIEW OF COMMENT

The Multidisciplinary Association for Psychedelic Studies ("MAPS") is an IRS-approved 501(c)(3) research and educational organization whose mission includes developing FDA-approved medical uses of MDMA-assisted psychotherapy, marijuana[1] and other Schedule I substances. For nearly 20 years, MAPS has been working in association with Professor Lyle Craker, Professor Emeritus of Botany and Plant Sciences at University of Massachusetts, Amherst's Stockbridge School of Agriculture. With MAPS' assistance, Professor Craker has twice submitted applications for Drug Enforcement Administration ("DEA") registration as a bulk manufacturer of marijuana ("DEA Registration"),[2] seeking a legal pathway to produce a MAPS-owned (but still DEA-regulated) uninterrupted and consistent supply of marijuana for our privately-funded commercial medicinal cannabis botanical product FDA drug development efforts, a central component of MAPS' institutional mission. DEA denied Professor Craker's first application, filed in 2001, and has yet to act on his second, filed in early 2017.[3]

The DEA Final Order denying Professor Craker's 2001 application ("Craker Final Order")

[1] Throughout this Comment we use the terms cannabis and marijuana interchangeably.
[2] This application and registration process is governed by 21 U.S.C 823(a), which applies to the application and registration process for anyone seeking a DEA license to bulk manufacture any Schedule I or II controlled substance. For sake of brevity, throughout this comment we use the term "DEA Registration" to refer to registration as a bulk manufacturer of marijuana.
[3] MAPS also assisted Professor Craker in administrative review proceedings and litigation before the Federal Court of Appeals for the First Circuit challenging the DEA's denial of the 2001 application.

published in the Federal Register in January, 2009,[4] was at that time the most extensive public statement DEA had ever made regarding its interpretations and analyses of the statutory and regulatory scheme governing the DEA Registration process,[5] including DEA's interpretation of the relevant U.S. treaty obligations under the United Nations' Single Convention on Narcotic Drugs, 1961 (''Single Convention''), 18 U.S.T.1407,[6] as well as DEA's interpretation of the statutory requirement that DEA register no more than the total number of bulk marijuana manufacturers necessary to produce an "adequate and uninterrupted supply produced under adequately competitive conditions.''[7] Thus, the Craker Final Order is widely regarded, and often cited by DEA and others, as DEA's definitive articulation of its interpretation of this regulatory scheme, including restrictions imposed by the Single Convention. Indeed, on the first page of the NPRM, in a section with the heading "Background and Purpose of This Proposed Rule," the NPRM cites the Craker Final Order.[8]

It is this very same regulatory scheme the March 23, 2020 Notice of Proposed Rulemaking ("NPRM") addresses; DEA now proposes to amend and supplement existing regulations governing applications for DEA Registration and to add new procedures governing the purchase, sale and distribution of the cannabis such manufacturers will produce once registered. ("Proposed Rules")(85 FR 16292).

MAPS welcomes the opportunity to provide these Comments in response because the Proposed Rules are centrally important to our work and our continuing efforts to obtain DEA Registration for Professor Craker--as noted above, his second application for DEA Registration is still awaiting DEA's review and determination, and will be evaluated under the Proposed Rules if they are adopted.

The NPRM explains that the Proposed Rules are an outgrowth of a Department of Justice ("DOJ") review of DEA's 2016 policy statement setting forth a new policy DEA was then-adopting intended to "increase the number of entities registered under the … CSA to grow …

[4] 74 FR 2101.
[5] *See*, e.g., 74 FR 2127, "This section of the discussion contains a far more extensive analysis of 21 U.S.C. 823(a)(1) … than DEA has previously published."
[6] 21 U.S.C 823(a) requires that DEA Registrations must be consistent with U.S. obligations under the Single Convention.
[7] 21 U.S.C. 823(a)(1).
[8] 85 FR 16292. See also, e.g., DOJ Office of Legal Counsel ("OLC") Memorandum Opinion for the Acting Chief Counsel Drug Enforcement Administration, entitled "Licensing Marijuana Cultivation in Compliance with the Single Convention on Narcotic Drugs." (Slip Opinion posted on the OLC website April 29, 2020, avail. at: https://www.justice.gov/olc/file/1272131/download ("OLC Opinion") at fn. 1; fn. 10; pp. 5, 8, 24.

marijuana to supply legitimate researchers in the United States."[9] The DOJ determined that changes to the 2016 Policy Statement were necessary in order to comply with 21 U.S.C 823(a)'s requirement that DEA Registrations must be consistent with U.S. obligations under the Single Convention (*See* NPRM, 85 FR 16292 at FN 3 and accompanying text).[10]
As discussed further, below, the Proposed Rules add and/or change some important details concerning the process by which DEA will take "physical possession" and handle distribution of cannabis cultivated by those whose applications for DEA registration are approved. The Proposed Rules also provide new definitions for key terms (e.g. "medicinal cannabis" and "cannabis preparation"). The definitions have important ramifications for which of various specific distribution rules and restrictions will apply, and for the applicability of exemptions to some of the Single Convention restrictions that present the most significant obstacles to commercial cannabis drug development efforts.

The NPRM states that "the proposed rule, if adopted, would supersede the 2016 policy statement." 85 F.R. 16294. The Proposed Rules, however, clearly do not change, nor indicate any DEA retreat from, the Policy Statement's primary goal of increasing the number of DEA Registrations in order to enhance, improve, and facilitate research, including privately-funded commercial cannabis drug development, that could result in the development of FDA-approved marijuana-based medicines. 85 F.R. 16292 at pp. 16292, 16293.

The Proposed Rules are a significant and encouraging step that continues the evolution of DEA's stance towards commercial medicinal cannabis drug development. DEA's dramatic policy shift was first evident in the 2016 Policy Statement and is also manifest in the Proposed Rules. Together these represent a 180 degree about-face from DEA's previous policies concerning these same matters and constitute a complete reversal of key legal arguments DEA asserted as bases for denying Professor Craker's 2001 application for DEA Registration, including DEA's ruling that the Single Convention required DEA to maintain the "very government monopoly...that Respondent seeks to defeat through obtaining a DEA registration,"[11] and DEA's ruling that a legal pathway existed for commercial medicinal marijuana drug development within the NIDA-

[9] "Applications to Become Registered under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States," 81 FR 53846 (Aug. 12, 2016) ("2016 Policy Statement.")
[10] The DOJ Office of Legal Counsel ("OLC") issued on June 6, 2018 a Memorandum Opinion for the Acting Chief Counsel Drug Enforcement Administration, entitled "Licensing Marijuana Cultivation in Compliance with the Single Convention on Narcotic Drugs." (Slip Opinion posted on the OLC website April 29, 2020, avail. at: https://www.justice.gov/olc/file/1272131/download ("OLC Opinion"). The NPRM does not cite or refer to the OLC Opinion, perhaps because though dated June 6, 2018, the OLC Opinion was not publicly available until posted on the OLC website on April 29, 2020--more than a month after the NPRM was published. There can be no doubt, however, that the OLC Opinion articulates the DOJ determination that changes were necessary to bring DEA's 2016 Policy Statement into compliance with Single Convention obligations.
[11] 74 FR 2101 at p. 2155

controlled system.[12] (Both discussed in greater detail, below).

We strongly support and commend DEA for its Proposed Rules' commitment to ending the NIDA monopoly system, and to grant additional DEA Registrations in order to facilitate and enhance privately funded commercial medicinal cannabis drug development. However, we also have significant concerns regarding whether DEA will follow through with effective and consistent implementation that actually enhances and facilitates the opportunities for commercial medicinal cannabis drug product development, including the whole-plant botanical drug development that MAPS has long sought to accomplish. Our concerns are based upon nearly two decades of bureaucratic delay in the Craker matter and reliance therein on legal arguments and interpretations of law completely at odds with those DEA now asserts in the NPRM.

It is striking that the Single Convention interpretations DEA now asserts completely contradict DEA's interpretations of the very same provisions of the Single Convention that DEA asserted required denial of Professor Craker's application for DEA registration and required "the very government monopoly...that Respondent seeks to defeat through obtaining a DEA registration." 74 FR 2101 at p. 2155. Clearly the treaty provisions themselves have not changed, which indicates that the Single Convention itself is so ambiguous that DEA and other government agencies can render facially reasonable interpretations (having the force of law) that support whichever policy choices the agency prefers. While we acknowledge that amendment of, or withdrawal from, the Single Convention is beyond DEA's authority, we agree completely with Senator Brian Schatz's following comments:

> "As the OLC memo outlines DOJ's reinterpretation of the federal government's obligations under the Single Convention, it begs the question of whether marijuana's status in the Single Convention impedes the ability to research its potential therapeutic effects, thereby preventing any change to its current schedule—which requires a medically-accepted use. **It may be an appropriate time to consider initiating the process under Article 3 of the Single Convention to modify the treaty to accomplish its intention of allowing robust research to be conducted.**"

Relatedly, we note that the OLC Opinion states that the State Department's Office of the Legal Adviser identifies Australia, Canada, Israel, and the United Kingdom as countries with similar licensing practices as the United States, in which the government agency does not purchase or take physical possession of marijuana grown for medical research and commercial drug development, but rather allows private licensed growers to distribute it to appropriately licensed

[12] Throughout this Comment we use the following terms interchangeably to refer to the pre-2016 policy Statement regulatory scheme governing DEA Registrations: the NIDA-controlled system; the NIDA monopoly system; the existing NIDA monopoly; the NIDA single source system; the NIDA monopoly over the supply of marijuana for research; the NIDA system, and; the NIDA single grower contract system.

researchers and drug developers.[13]
In the next section of these Comments, we provide further details about Professor Craker's two applications for DEA registration as a bulk manufacturer to provide marijuana for MAPS-sponsored FDA-approved clinical studies, along with DEA's responses in opposition including repeated and significant delays as well as legal arguments and treaty interpretations completely contradictory to those expressed in DEA's 2016 Policy Statement and the current NPRM and Proposed Rules.

We then present our Recommendations, which are informed by the historical context discussed above and in the next Section, and aim to resolve several ambiguities and omissions in key provisions of the Proposed Rules by adding language to clarify and resolve these ambiguities and supply omitted details in order to require DEA to: Act swiftly and equitably on applications that were submitted under the guidance of and encouraged by the 2016 Policy Statement without the benefit of this NPRM; refrain from overly-restrictive interpretations of the Single Convention and the obligations it imposes upon DEA and reduce the opportunities for DEA to improperly mask policy choices as legal mandates. Specifically, our Recommendations address the lack of specific timelines or procedures describing when and how DEA will take action on the currently pending applications; the lack of clarity regarding how the DEA will apply the Proposed Rules, especially the provisions to implement the Single Convention's "actual possession" requirements and the exception for ''medicinal cannabis or cannabis preparations'' including how "medicinal cannabis" is defined. We also address DEA examples presented in its commentary to the Proposed Rules suggesting that DEA may impose arbitrary and unnecessary numerical limits on the number of DEA Registrations it will approve rather than leaving the marketplace unimpeded.

II. DEA'S HISTORY OF DELAYS AND RELIANCE UPON LEGAL ARGUMENTS AND TREATY INTERPRETATIONS COMPLETELY CONTRADICTORY TO THOSE EXPRESSED IN THE 2016 POLICY STATEMENT, THE NPRM AND THE PROPOSED RULES.

As noted above, MAPS has supported and assisted Professor Craker in twice applying for DEA Registration. DEA has responded with repeated and extensive delay--DEA took nearly eight years to issue its Final Order denying the first application; DEA took more than 30 months to even publish the Notice of Professor Craker's second application having been filed, and has taken no other "action" on the application since then. Until the 180 degree reversal represented by the 2016 Policy Statement, DEA steadfastly defended the NIDA monopoly supply system as required by the Single Convention and completely adequate, including with regard to providing

[13] OLC Opinion, Slip. Op. at p. 20; *see also* the OLC Opinion's further discussion of the widely varying ways in which other parties to the treaty interpret and implement the Single Convention's provisions restricting cultivation and distribution of marijuana, Slip. Op. at pp. 20-22.

marijuana for clinical research aimed toward commercial drug development and, if approved by FDA, for supply to patients, and justified its denial of Professor Craker's 2001 application with reliance upon legal arguments and treaty interpretations that completely contradict DEA's position regarding the very same legal issues and Single Convention obligations espoused in the 2016 Policy Statement, the NPRM and the Proposed Rules.

A. DEA DELAY

Repeated DEA delays also served to protect the existing NIDA monopoly and obstruct efforts to create a legal pathway for privately-funded medicinal cannabis botanical drug development, including MAPS's plans to have Professor Craker provide to MAPS an alternative non-NIDA-controlled source of marijuana for FDA clinical trials aimed at gaining FDA approval for whole-plant smoked or vaped medicinal cannabis. Examples of DEA's delay include the following:

On June 24, 2001, Professor Craker submitted his application to DEA. Several months later, DEA claimed the application could not be found. Professor Craker then submitted a photocopy, which after a few months DEA refused to accept since the photocopies didn't have original signatures. Then, in an envelope without a cover letter or specific return address other than DEA headquarters, someone in DEA sent back to Professor Craker his original, date-stamped application showing it had been received when initially mailed. Professor Craker then mailed back his original application which DEA finally accepted and then DEA was unresponsive for the next three years. Professor Craker eventually filed a lawsuit in federal court alleging unreasonable delay. Only after the court ordered the agency to file responsive pleading explaining the delay did DEA finally issue an order to show cause indicating its intention to deny the application, triggering Professor Craker's right to Administrative review under the Administrative Procedure Act (APA), including the right to an evidentiary hearing.

After the conclusion of that hearing, in February 2007, DEA Administrative Law Judge (ALJ) Mary Ellen Bittner issued an 80-page opinion recommending that DEA grant Dr. Craker's application. Again, the agency delayed, waiting almost two years before issuing the Craker Final Order rejecting ALJ Bittner's recommendation on the basis that the NIDA monopoly served satisfactorily to meet domestic research demand and was required by federal law and the Single Convention treaty. 74 FR 2101.

As discussed further, below, DEA ruled that Professor Craker's application was precluded as a matter of law and that it had no authority to grant DEA Registrations allowing research or drug development outside of the NIDA single source system because the Single Convention required the "very government monopoly...that Respondent seeks to defeat through obtaining a DEA registration." 74 FR 2101 at p. 2155. With the assistance of MAPS and pro bono legal

representation by the Washington, D.C., law firm Covington & Burling LLP and the American Civil Liberties Union, Professor Craker appealed the DEA's Final Order to the Federal Court of Appeal for the First Circuit. On April 15, 2013, the Court of Appeal upheld the Final Order. Under the applicable standard of review, the Court was required to extend great deference to DEA's statutory interpretation, and was required to uphold it as long as it is "based on a permissible construction of the statute." Under that standard of review, the Court ruled it was required to accept the DEA's arguments that the NIDA monopoly supply system provided "an adequate supply produced under adequately competitive conditions" and that U.S. obligations under the United Nations Single Convention prohibited the DEA from licensing Professor Craker.

MAPS also assisted Professor Craker in preparing a new application for DEA Registration pursuant to the 2016 Policy Statement. Professor Craker submitted the application on February 22, 2017, and then waited for DEA's response. He is still waiting. DEA is required, generally, to promptly publish in the Federal Register notice of applications filed for DEA Registration; moreover, for applications seeking to supply marijuana for only clinical research purposes, 21 U.S.C. §823(i)(2) requires DEA to either grant registration or serve an order to show cause within 90 days. DEA did not publish notice in the Federal Register of any applications that were submitted in response to the 2016 Policy Statement, nor take any other action, until more than 2 ½ years after accepting Professor Craker's application for filing.[14]

In August 2019, more than three years after DEA encouraged the new applications, another pending applicant, Scottsdale Research Institute, filed a lawsuit in federal court alleging unreasonable delay and urging DEA to process its application. On August 27, 2019, DEA finally published a single "collective" notice in the federal Register listing 33 pending applications DEA had received after issuing the 2016 Policy Statement. More than six months later, on March 23, 2020, DEA published the proposed rule at hand. 81 FR 53846.

Even the United States Congress has taken note of DEA's delays processing applications for DEA Registration, as evidenced by its 2015 enactment of 21 U.S.C. §823(i)(2), as noted above. HR639, the "Improving Regulatory Transparency for New Medical Therapies Act," which amended the Food, Drug, and Cosmetic Act; the Public Health Service Act; and the Controlled Substance Act (CSA). HR639 became Public Law No. 114-89 on November 25, 2015.

The relevant section (HR639 Sec. 3: Enhancing New Drug Development, amending Controlled Substances Act (CSA) §303 (21 U.S.C. §823(i)(2)) establishes timelines for the Attorney

[14] Professor Craker was informed, albeit indirectly, that DEA had received his second application. DEA acknowledged, in a response to an August 2017 inquiry from Senator Elizabeth Warren, that the agency had indeed received Professor Craker's application and was processing it.

General to either register an applicant to manufacture a controlled substance for a clinical trial or serve an order to show cause upon the applicant. The relevant text is as follows:

> For purposes of registration to manufacture a controlled substance under subsection (a) for use only in a clinical trial, the Attorney General shall, in accordance with the regulations issued by the Attorney General, issue a notice of application not later than 90 days after the application is accepted for filing. Not later than 90 days after the date on which the period for comment pursuant to such notice ends, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 304(c), unless the Attorney General has granted a hearing on the application under section 1008(i) of the Controlled Substances Import and Export Act."

Whether any, all or none of these and other examples of DEA delay was maliciously intentional, the pattern of delay over the past 20 years has undeniably had significant detrimental impact upon the efforts of MAPS and others seeking to further the marijuana drug research and commercial drug product development objectives DEA now espouses (and has formally adopted via the 2016 Policy Statement, the NPRM and the Proposed Rules). It is worth noting that even now, four years after the remarkable change in DEA policy objectives announced in the 2016 Policy statement, the agency has not approved a single additional DEA Registration. As of the date these Comments were prepared, the only legal source of marijuana in the U.S. for medical research remains NIDA via its single contract supplier at the University of Mississippi. As DEA now explicitly acknowledged, NIDA marijuana is available for research but not potential commercial sales, making it inadequate for FDA Phase 3 research which must be conducted with the exact same drug proposed for marketing as a prescription medication.[15]

Moreover, the combination of this pattern of delay with the specific DEA legal arguments and interpretations of the Single Convention DEA asserted throughout the proceedings related to Professor Craker's application, discussed in more detail in the next Section, certainly lends to the not unreasonable perception of intentional delay employed by DEA to oppose and obstruct efforts to end the NIDA monopoly supply system.

B. DEA RELIANCE UPON LEGAL ARGUMENTS AND TREATY INTERPRETATIONS COMPLETELY CONTRADICTORY TO THOSE EXPRESSED IN THE 2016 POLICY STATEMENT, THE NPRM AND THE PROPOSED RULES.

The 2016 Policy Statement and the Proposed Rules are premised upon DEA's very-much-revised

[15] As discussed further at p.10 of this Comment, below, DEA stated in the 2016 Policy Statement that the NIDA single grower contract system, "was designed primarily to supply marijuana for use in federally funded research—not for commercial product development. Thus… there was no clear legal pathway for commercial enterprises to produce marijuana for product development." 2016 Policy Statement, 81 FR at p. 53846.

interpretation of the very same Single Convention provisions and obligations it ruled required denial of Craker's application ""as a matter of law." Completely contradicting the DEA's justification under the Single Convention for denying Craker's 2001 application, DEA has now announced that it intends to register new applicants for licenses to manufacture marijuana. The agency explicitly announced it was ending the NIDA monopoly over the supply of marijuana for research. The 2016 Policy Statement discusses the changed circumstances that led to DEA's new policy choices--e.g., increased "researcher demand for a variety of strains of marijuana and cannabinoid extracts"--but completely lacks any explanation of how the same treaty that DEA ruled precluded registering Processor Craker because it *required* the NIDA monopoly system now accommodates DEA's "new approach":

> "Based on discussions with NIDA and FDA, DEA has concluded that the best way to satisfy the current researcher demand for a variety of strains of marijuana and cannabinoid extracts is to increase the number of federally authorized marijuana growers. To achieve this result, DEA, in consultation with NIDA and FDA, has developed a new approach to allow additional marijuana growers to apply to become registered with DEA, while upholding U.S. treaty obligations and the CSA." 81 FR 53846

The 2016 Policy Statement also includes a similar 180 degree reversal from DEA's legal arguments concerning the viability of commercial cannabis drug development under the NIDA monopoly supply system. Throughout the ALJ proceedings discussed above and in the Craker Final Order DEA took the position, and ruled, that we had misconstrued the NIDA system when we argued that the current supply of marijuana for research purposes was inadequate because there was no legal pathway for commercial drug development with NIDA-supplied marijuana (much less any capability to provide patients with medicinal cannabis if we eventually obtained FDA approval for a prescription medical product). The Craker Final Order stated:

> "...[no provision of the National Center's contract with NIDA imposes any prohibition on the use of the marijuana produced under the contract for the purposes of the development of a commercial product. Indeed, the language of the contract with NIDA suggests otherwise.New procedures that HHS announced in 1999 for providing marijuana for medical research contain no restriction on using NIDA-supplied marijuana for the development of commercial products. To the contrary...HHS made it possible starting in 1999 for a commercially sponsored researcher to develop a drug product using NIDA-supplied marijuana. Finally, Respondent cites no provision of law that prohibits NIDA from serving as a supply source for a prescription drug approval process." 74 FR 2101 at 2113

We therefore felt somewhat vindicated when the 2016 Policy Statement included the following

DEA acknowledgment of the inadequacy of the NIDA system for commercial medicinal marijuana drug product development--a complete reversal of the DEA's argument justifying the denial of Professor Craker's DEA Registration:

> The historical system, under which NIDA relied on one grower to supply marijuana on a contract basis, was designed primarily to supply marijuana for use in federally funded research— not for commercial product development. Thus, under the historical system, there was no clear legal pathway for commercial enterprises to produce marijuana for product development. In contrast, under the new approach explained in this policy statement, persons may become registered with DEA to grow marijuana not only to supply federally funded or other academic researchers, but also for strictly commercial endeavors funded by the private sector and aimed at drug product development. Likewise, under the new approach, should the state of scientific knowledge advance in the future such that a marijuana-derived drug is shown to be safe and effective for medical use, pharmaceutical firms will have a legal means of producing such drugs in the United States— independent of the NIDA contract process.[16]

We recognize that governments and their policies change and evolve over time, and we are encouraged by the fact that the 2016 Policy Statement and the Proposed Rules articulate a dramatic change in DEA policies and objectives that brings them into alignment with our work. Despite the decades of DEA opposition and delay, MAPS continues to pursue commercial medical botanical cannabis drug development. MAPS recently completed a state-of-Colorado-funded FDA and DEA-regulated Phase 2 clinical trial with NIDA research material in 76 US veterans with PTSD.[17] MAPS is currently designing a protocol to expand on that study in a larger number of participants, to submit to the State of Michigan for funding. MAPS taking a botanical product through the rigors of the FDA drug approval process necessitates a close working relationship with the manufacturer. To that end, MAPS continues to endeavor to partner with Professor Craker as a DEA-licensed manufacturer. Given MAPS' long relationship with Professor Craker, as well as our now-extensive experience with clinical trials utilizing Schedule 1 substances including marijuana, MAPS remains optimistic and committed to eventually undertaking research with an optimized plant product capable of meeting the quality and consistency standards of an FDA-approved medicine.

The problem here is that DEA did not only significantly change its discretionary policy choices regarding the DEA Registration Process, but rather bases its new policies upon legal conclusions

[16] 2016 Policy Statement, 81 FR at p. 53846.

[17] From 2016 to 2018, MAPS conducted a randomized, double-blind, placebo-controlled Phase 2 clinical trial to evaluate the safety and efficacy of four different potencies of smoked NIDA marijuana to manage symptoms of chronic, treatment-resistant posttraumatic stress disorder (PTSD) in 76 veterans. This study was funded by a $2.156 million grant from the Colorado Department of Public Health and Environment (CDPHE).

and interpretations of the statutory framework (including 21 U.S.C. 823(a)(1)) and Single Convention restrictions that are completely opposite from the legal conclusions and interpretations DEA claimed required denial of Professor Craker's 2001 application for DEA Registration. If it legal under the governing statutes and the Single Convention for DEA to end the NIDA monopoly and grant additional DEA Registrations today--and we agree that it is legal--then it was just as legal for DEA to do this back in 2001 when Professor Craker submitted his first application, and back in 2009 when DEA issued ther Craker Final Order. DEA's dramatically changed positions regarding its interpretation of Single Convention obligations and the legal pathways for commercial drug development under the NIDA monopoly system therefore suggest that DEA misrepresented its discretionary policy decisions as being mandated by law when denying Professor Craker's 2001 application.

It is one thing for a government agency to pursue --and change--policies that may not align with ours; such is the nature of representative democracy. It is quite another, however, for an agency to enforce and implement its policy choices through legal positions and statutory interpretations manipulated to justify any position the agency chooses, or flip 180 degrees if the agency's policy objectives change for whatever reason.

Even if that is indeed what occurred, it is obviously too late now to "undo" DEA's denial of Professor Craker's 2001 application. But to paraphrase philosopher George Santayana, those who cannot learn from history are doomed to repeat it. Our interactions with DEA over the past 20 years informs our analysis of the risk resulting from ambiguities and omissions we perceive in the Proposed Rules. With that history and analysis in mind, we respectfully submit the following specific recommendations in hopes of making it less likely under the Proposed Rules that the DEA Registration process can be politicized, manipulated and misrepresented to deny DEA Registration to applicants pursuing research or drug development goals with which DEA may not agree.

CONCERNS & RECOMMENDATIONS

1) LACK OF AGENCY DEADLINES, INSUFFICIENT ACCOUNTABILITY PROCEDURES, AND NO PATH TO AMEND APPLICATIONS

CONCERNS: The Proposed Rules provide no timeline or deadlines for DEA to take action on currently pending applications or applications submitted after the rules are final and promulgated, and there are no procedures (other than federal court intervention to compel agency action unreasonably withheld) for applicants to compel timely agency action. Further, the proposed rule presents no opportunity for applicants who submitted applications prior to promulgation of these new rules to amend their applications in light of

the new rules.

REASONS FOR CONCERNS:

Given DEA's past history of delay in processing applications for registration, both generally and specifically with regard to Dr. Craker's applications, and given DEA's long-standing explicit opposition to the MAPS goal of privately-funded medicinal cannabis botanical drug development, we are concerned that DEA may not act in as timely fashion on the pending applications for registration under the Proposed Rules.

In this context, the APA's rule against unreasonable delay (*see* 5 U.S.C. 706) is an insufficient accountability mechanism. The current rules (21 CFR 1301 *et seq.*) and these proposed changes provide strong incentives for applicants to establish business relationships and incur significant expenses prior to being granted a registration. This not only favors applicants with deeper pockets or higher risk tolerance over those who hope to do research in a cost-effective and risk-averse manner, but it also makes adversarial proceedings to compel DEA action on any one application an unappealing accountability mechanism.

For these reasons, DEA's evaluation of the previously-submitted applications under the new framework of the Proposed Rules may detrimentally impact those applications if DEA's review occurs side-by-side with competing applications submitted with the benefit of having seen the Proposed Rules before submission.

RECOMMENDATIONS:

- DEA action on all pending applications, by way of issuance of registration or issuance of an order to show cause, should occur in the order in which the applications were filed, beginning with the oldest application. DEA should be required to act upon each of the thirty-five applications noticed on August 27, 2019 (84 FR 44290) no later than 30 days following final promulgation of the new rules. DEA should not delay internal review of these applications awaiting final promulgation of the new rules, but rather should undertake such review and reach preliminary decisions as to each based upon the proposed new rules and be prepared to formally act on each application immediately upon final promulgation of the rules. If DEA determines that even with this preliminary review process 30 days is an unrealistic deadline, the final rules should include a specific timeline for DEA to act upon pending applications, or additional provisions for applicants to compel timely agency action.

- If the final content of the new rules changes through the public comment and remaining administrative process, DEA can conduct a post-promulgation expedited final review of each application to determine whether any preliminary decision should be altered.

2) NUMBER OF LICENSES, EXTENT OF RESTRICTIONS, AND TYPE OF PRODUCTS

CONCERNS: The anticipated number of licenses and additional controls may prevent satisfaction of §823(a)(1). DEA's stated belief that "a range of 3 to 15 growers is a reasonable estimate for purposes of this economic analysis" implies that it is comfortable with a range that may woefully underestimate the amount of research that would happen under authentically competitive conditions. Based on the OLC interpretation of the Single Convention requirements, the proposed rule imposes additional security requirements and grants DEA significant additional discretion in allowing or disallowing physical possession through secure on-site storage.

REASONS FOR CONCERNS:
The CSA requires DEA to limit the total number of registered bulk manufacturers of marijuana to the number necessary to produce an adequate and uninterrupted supply under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes. §823(a)(1). The hypothetical scenarios that DEA uses to predict potential economic impact on growers use an arbitrarily selected number of applicants (3-15). 85 FR 16292 at 16299. While the total number of potential applicants is not explicitly set by the proposed rule, this range suggests that DEA could set improper numerical limits on the number of registrations it will approve.

Excessive artificial limiting of the number of registrations may result in inefficient production, less innovation, higher prices to consumers, reduced competitiveness in the international market, and potential for corruption. Normally, US antitrust laws ensure that the private sector remains innovative, competitive, and efficient; though this new private market will be thoroughly controlled by DEA to comply with treaty obligations, it should not flout the fundamental economic principles of the country. We have confidence in DEA's ability to successfully monitor a sufficient, even if large, number of production facilities to eliminate diversion while enhancing the research landscape.

The myriad cannabinoids in cannabis and their complex interaction with the human body further complicate the statutorily required supply analysis under 21 U.S.C. §823(a)(1). Harvested cannabis to be utilized in research, in whatever form, is complex; widening the supply and demand analysis would allow the domestic market to engage in more complex, unique, and potentially groundbreaking research and development. Limits on registrations are a vestige of international opium control mechanisms; the Single Convention recognizes that "conditions under which the cannabis plant is cultivated for the production of drugs are very different from

those under which the opium poppy is grown for opium," yet the authors nonetheless chose to require the same control regime for both plants. OLC Opinion at 22. However, the US Office of the Legal Adviser also notes the different properties of the two plants giving rise to "significantly different" diversion risks. *Id.*

The 2018 OLC Opinion does not rule out private drug development of medicinal cannabis drug products, but rather articulates requirements imposed by the Single Convention with which the DEA must comply in promulgating these new rules. MAPS construes the proposed changes provided as §1318.04(a) to imply that where registrants comply with security requirements in part 1301, including for any proposed secure storage area for post-harvest bulk material to be delivered to the agency, no additional, new security requirements should apply. Further, it seems that so long as those requirements in 1301 can be complied with in storing harvested material, possession by way of delivery into this on-site secure area will be allowed. This nonetheless requires the agency's possession and control over the U.S. supply of bulk manufactured marijuana, permissively allowing for physical possession to occur at the grow location in an agency-designated, secured area. Only when a suitably secure on location storage area cannot be identified will off-site delivery to the agency need to occur. This section also states that registrants must comply with the security requirements in part 1301. Once stored, the proposed rule states that the agency will "control access."

Further, MAPS understands the definition of medicinal marijuana provided as §1318.02(b)[18] to turn on FDA determination of what constitutes a marketable drug product. Because FDA permits development of botanical drugs,[19] including those consisting of plant material, MAPS construes the proposed definition of medicinal marijuana in this proposed rule to include any botanical marijuana drug product approved by FDA in the future. Under this definition, agency exclusive economic rights provided for in §1318.04(b) would not extend to the importation, exportation, whole trade, and maintenance of stocks of an FDA-approved botanical cannabis drug product. To resolve any potential ambiguity, we recommend adding the language below to the Proposed Rules definition medicinal cannabis.

RECOMMENDATIONS:

- Amend the Proposed Rules' definition of "medicinal cannabis" appearing at 85 FR 16295 as follows:

  "Medicinal cannabis means a drug product made from the cannabis plant,

[18] "Except as provided in paragraph (e) of this section, the term *medicinal cannabis* means a drug product made from the cannabis plant, or derivatives thereof, that can be marketed under the Federal Food, Drug, and Cosmetic Act."
[19] See Botanical Drug Development Guidance for Industry, FDA CDER, December 2016, available at https://www.fda.gov/media/93113/download

or derivatives thereof, including whole plant material itself, that can be legally marketed under the Federal Food, Drug, and Cosmetic Act. …"

- The agency's determination of "the number of establishments which can produce an adequate and uninterrupted supply" for applicable purposes is based on an analysis assuming a homogenous and interchangeable cannabis product with competition based on quantity and price. DEA needs to permit the medical researchers to differentiate by studying different strains and/or drug delivery methods. DEA should simply request applicants to explain the market need and present supply of the market, without assuming homogeneity of the product. The number of registrations should thus be determined by the size and scope of the research and development interests in federally legal marijuana for applicable indications. This could be based on the existence of a drug development plan or a contract with a researcher or partner organization.

- Security mechanisms already used for manufacturing Schedule I substances, including entire site security, secure areas, safes, access logs, or other lock-and-key secured mechanisms are appropriate, with the least restrictive additional means.

CONCLUSION

The continual and non-transparent evolution of informal agency policy and the inertia of actual change in outcomes creates doubt about the prospect of speedy, impactful implementation of these rules.

Both this proposed rule and the 2016 policy change are interpretations of *how* DEA might exert its discretionary powers over the licensure of bulk marijuana manufacturers, but never has the agency provided details about *when* it may do so. Regrettably, this rule also imposes additional obligations and considerations on applicants who have already gone through an extended process relying on DEA's previous policies.

We note that GW Pharmaceuticals, with its marijuana product grown in England under a Home Office regulatory approach of constructive possession established in 1998, without a single objection in any annual report of the International Narcotic Control Board, and a current NASDAQ stock market cap of about $4 Billion, is not recommending any changes to DEA's proposed rules to be imposed on domestic growers. Rather, GW Pharmaceuticals wonders about importing into the US its cannabis extract (e.g. a Botanical Drug Substance) that can be used in the manufacture of a prescription medicine, and sold to US consumers.

MAPS has an immediate need for DEA licensing of Professor Craker to produce marijuana for

an FDA-regulated study of veterans with PTSD. Other applicants have immediate needs of their own. U.S. businesses and jobs will be created by federal licensing of additional domestic marijuana producers for research and development into potential medical, commercial and industrial applications. Given the time and resources put into preparing federally-compliant cultivation plans, the applications that were submitted according to the original policy change should immediately be issued licenses or denied with cause.

We also support Sen. Brian Schatz' suggestion, noted in the Introduction and Overview section, above, that it's time for the US to consider initiating the process under Article 3 of the Single Convention to modify the treaty to accomplish its intention of allowing robust research to be conducted. We suggest eliminating Article 28 Control of Cannabis which imposes on the production of cannabis the same controls as the production of opium. We are confident that DEA could successfully control diversion from cannabis production facilities without having to purchase and take possession of the crops.

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