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Memorandum in Support of Registration to Manufacture Marijuana

Dr. Lyle Craker, a professor in the Stockbridge School of Agriculture at the University of Massachusetts at Amherst who has more than thirty years of experience in research on medicinal plants, submits this application to the Drug Enforcement Administration (DEA) for a federal registration to manufacture (i.e., cultivate) marijuana in order to provide a new source of marijuana to DEA-licensed medical researchers seeking to conduct academic or drug development research approved by the Food and Drug Administration (FDA). Professor Craker's registration would provide researchers with an alternative source to the marijuana grown under contract to the National Institute on Drug Abuse (NIDA) by the University of Mississippi, which currently is the only facility licensed by the DEA to manufacture research-grade marijuana in the United States.

This is not Professor Craker's first such application. He submitted a similar application on June 28, 2001. On February 12, 2007, a DEA Administrative Law Judge recommended that Professor Craker's application be granted,[1] concluding that it would serve the public interest and be consistent with the United States' treaty obligations, as required by the Controlled Substances Act (CSA).[2] The DEA, however, rejected the recommendation of the Administrative Law Judge, and issued a Decision and Final Order, in January 2009, denying Professor Craker's application (Final Order).[3] Professor Craker appealed the DEA's decision to the United States Court of Appeals for the First Circuit (First Circuit).[4] Declining to address whether Professor Craker's registration would be barred by restrictions on wholesale trade in marijuana contained in the United Nations Single Convention on Narcotic Drugs (Single Convention),[5] the First Circuit deferred to the DEA's determination that Professor Craker had not shown the inadequacy of the existing supply of marijuana within the meaning of section 823(a)(1).[6]

Professor Craker submits this new application and supporting memorandum after significant changes in the relevant factual and regulatory landscape have undermined the

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[1] *See* Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge, In re Lyle E. Craker, Ph.D., No. 05-16 (Feb. 12, 2007).

[2] Pub. L. No. 91-513, tit. II, 84 Stat. 1242 (codified at 21 U.S.C. §§ 801 et seq.). Unless otherwise noted, all statutory references herein are to the CSA.

[3] 74 Fed. Reg. 2101, 2133 (Jan. 14, 2009).

[4] *See Craker v. DEA*, 714 F.3d 17, 18 (1st Cir. 2013).

[5] United Nations Single Convention on Narcotic Drugs, March 30, 1961, 18. U.S.T. 1407 [hereinafter "Single Convention"].

[6] *Craker*, 714 F.3d at 29.

rationale of the DEA's Final Order, as well as the First Circuit's decision upholding that Final Order. This memorandum sets out these changed circumstances and explains why the governing federal statutes and regulations require DEA to grant the application and register Professor Craker to manufacture marijuana for academic or drug development research.

First, the Final Order's assessment of the adequacy of the supply of marijuana within the meaning of section 823(a)(1), as well as its interpretation of the Single Convention, both relied heavily upon a Department of Health and Human Services (HHS) policy requiring research protocol review by the U.S. Public Health Service (PHS). HHS has since eliminated this requirement of PHS review of non-federally funded research protocols involving marijuana, reasoning that this additional review "is no longer necessary to support the conduct of scientifically-sound studies into the potential therapeutic uses of marijuana" given the significant overlap between PHS review and FDA's Investigational New Drug (IND) process.[7]

Second, in the three years since the First Circuit issued its decision, the University of Mississippi, the only registered manufacturer of marijuana growing under contract to NIDA, has not been able to meet the demand for FDA-approved research. Not only has NIDA's monopoly on medical research supply resulted in lengthy delays that create significant barriers to legitimate medical research, but it also has left researchers with no other option when NIDA is unable to provide the specific strain of marijuana called for in the research protocol. Under the DEA's own interpretation of section 823(a)(1), this evidence of inadequate supply "weighs heavily in favor of granting the registration" for Professor Craker.[8]

Third, distinct from his prior application, Professor Craker now also seeks authorization to extract cannabinoids to supply researchers experimenting with the isolated cannabinoids. Many recent studies in the United States and elsewhere have indicated the potential medical efficacy of cannabinoids such as Cannabidiol (CBD), thus presenting new evidence that granting Professor Craker's application would promote technical advances in the art of manufacturing controlled substances and the development of new substances.

Fourth, the Final Order was based upon an interpretation of the Single Convention recently repudiated by the State Department, which is responsible for interpreting treaties for the United States. The State Department recently made clear that the Single Convention does not prohibit more than one cultivator or bulk manufacturer being licensed by a signatory nation's licensing agency.[9] The DEA must therefore revise the interpretation of the Single Convention upon which the Final Order relied in denying Professor Craker's application.

Finally, Professor Craker seeks this registration in order to supply FDA-approved *drug development* research, a crucially important point the Final Order did not meaningfully

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[7] 80 Fed. Reg. 35,960, 35,960 (June 23, 2015).

[8] *See* 74 Fed. Reg. at 2119.

[9] *See* E-mail from Bureau of Int'l Narcotics & Law Enforcement Affairs, U.S. Dept. of State, to Sen. Kirsten Gillibrand (Apr. 29 2016), *available at* https://american-safe-access.s3.amazonaws.com/documents/state_dept_response_on_single_convention.pdf [hereinafter "State Dept. E-mail"].

address.[10] Physicians' ability to prescribe, and patients' corresponding ability to obtain, an FDA-approved medicine is the obvious end-goal of any drug development research. The FDA requires Phase III drug development studies to be conducted with the same supply that will eventually be sold by prescription. But the NIDA Drug Supply Program[11] is simply not designed, nor authorized, to commercially sell its marijuana as a prescription medicine. NIDA marijuana is therefore inadequate for privately-funded, FDA-regulated Phase III drug development studies.

In light of the above, and as demonstrated in further detail below, the DEA should grant Professor Craker's application for registration to manufacture marijuana. Such registration is consistent with the public interest, as determined under the six statutory factors set forth at section 823(a), and with United States obligations under the Single Convention.

I. Legal and Factual Background

The CSA establishes a comprehensive regulatory system that controls the manufacture, distribution, and use of controlled substances.[12] A primary purpose of the CSA is "to prevent the diversion of drugs" having legitimate uses "from legitimate to illicit channels."[13] A defining feature of the CSA is thus its "closed system" of distribution in which all persons in the "legitimate distribution chain" of a controlled substance must register with the Attorney General whereas "transactions outside the legitimate distribution chain [are] illegal."[14]

The CSA creates three classes of registration, for "manufacturers," "distributors," and "practitioners," each with its own requirements.[15] Professor Craker is applying for manufacturer registration under section 823(a), which provides that "[t]he Attorney General *shall* register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols."[16]

A. The Public Interest

In determining whether the registration of a manufacturer is consistent with the public interest, the DEA must consider six factors.[17] First, section 823(a)(1) requires the DEA to maintain effective controls against diversion by considering limiting the number of registered

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[10] *See* 74 Fed. Reg. at 2111-13.

[11] *See* NIDA, *NIDA Drug Supply Program*, DRUGABUSE.GOV, https://www.drugabuse.gov/researchers/research-resources/nida-drug-supply-program (last visited July 6, 2016).

[12] *MD Pharm. v. DEA*, 133 F.3d 8, 10 (D.C. Cir. 1998).

[13] *Gonzales v. Raich*, 545 U.S. 1, 12-13 & n.21 (2005); *United States v. Moore*, 423 U.S. 122, 135 (1975).

[14] *See* H.R. Rep. No. 91-1444 (1970), reprinted in 1970 U.S.C.C.A.N. 4566, 4569.

[15] *See* 21 U.S.C. §§ 822-823.

[16] 21 U.S.C. § 823(a) (emphasis added).

[17] 21 U.S.C. § 823(a).

bulk manufacturers of a particular schedule I or II controlled substance to "a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research and industrial purposes."[18] Under the DEA's own interpretation of this statutory factor, if the applicant "can demonstrate by a preponderance of the evidence that *either* supply or competition is inadequate within the meaning of paragraph 823(a)(1), this weighs heavily in favor of granting the registration."[19]

The remaining public interest factors are:

- The applicant's compliance with State and local law (§ 823(a)(2));
- The promotion of technological advances in manufacturing controlled substances (§ 823(a)(3));
- The applicant's criminal history, if any, related to the manufacture, distribution, or use of controlled substances (§ 823(a)(4));
- The applicant's past experience manufacturing controlled substances, including "the existence in the establishment of effective control against diversion" (§ 823(a)(5)); and
- Any other factor that may be relevant to the public health and safety (§ 823(a)(6)).

While the DEA *must* register treaty-compliant applicants who satisfy all of these statutory criteria,[20] it *may* register such an applicant even if it determines that not all of the statutory factors support the registration.[21]

B. The United States' International Obligations

The CSA implements the Single Convention, which ensures that the international movement of narcotics is limited to legitimate medical and scientific needs.[22] Article 28 of the Single Convention addresses the cultivation of marijuana. The treaty does not set out marijuana-specific controls, but instead incorporates by reference the Single Convention's provisions

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[18] 21 U.S.C. § 823(a)(1).

[19] 74 Fed. Reg. at 2119 (emphasis added).

[20] Section 823(a) provides that the Attorney General "shall register" an applicant to manufacture marijuana if registration is "consistent with the public interest" and treaty obligations, and sets forth six factors that "shall be considered" in determining the public interest. It therefore follows that the DEA (to whom the Attorney General delegated this authority) must register treaty-compliant applicants who satisfy all six statutory criteria.

[21] *See Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487, 36,497 (July 3, 2007).

[22] *See* 21 U.S.C. § 801(7); Single Convention, Art. 4.

governing opium poppies (article 23).[23] Under article 23, any signatory nation permitting the cultivation of opium poppy must designate an agency to (1) license cultivators; (2) designate where the plant may be grown; (3) "purchase and take physical possession" of each year's crops of opium, and (4) exercise the exclusive right to import, export, trade in, or maintain stocks of opium.[24] These "exclusive rights" requirements, however, do not apply to "medicinal opium," defined in the treaty as "opium that has undergone the processes necessary to adapt it for medicinal use."[25]

C. The Supply Of Marijuana For Medical Research

Marijuana for federally-sanctioned medical research in the United States is currently available only from the University of Mississippi. The University was first granted a license to manufacture marijuana in 1968 by DEA's predecessor, the Bureau of Narcotics and Dangerous Drugs (BNDD), and has continued ever since to be the only DEA-licensed manufacturer of research-grade marijuana.[26] The University thus maintains a DEA-protected monopoly on producing marijuana for medical research.

The University's marijuana production is governed by an exclusive contractual agreement with NIDA, which permits the University to grow, harvest, store, and ship marijuana to researchers only at NIDA's direction.[27] Once every five years, NIDA entertains new bids on the contract, but has never awarded the contract to any entity other than the University of Mississippi.

D. Elimination of the PHS Review Process for Non-Federally Funded Research Protocols Involving Marijuana

Prior to June 2015, in order to obtain marijuana from the University of Mississippi (i.e., through the NIDA Drug Supply Program), all researchers had to submit their research protocols for PHS review.[28] In June 2015, HHS announced that, effective immediately, it was eliminating the PHS review process, "in order to streamline the application and approval processes for cannabis research."[29] In particular, HHS "determined that the PHS review overlaps in several

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[23] *See* Single Convention, Art. 28 ¶ 1 (requiring parties that permit to cultivation of marijuana to "apply thereto the system of controls as provided in article 23 respecting the control of the opium poppy").

[24] Single Convention, Art. 23 ¶¶ 1-3.

[25] Single Convention, Art. 1 ¶ 1(n).

[26] 74 Fed. Reg. at 2104.

[27] 74 Fed. Reg. at 2104.

[28] *See* 80 Fed. Reg. at 35,960.

[29] 80 Fed. Reg. at 35,960.

important ways with FDA's IND process and is no longer necessary to support the conduct of scientifically-sound studies into the potential therapeutic uses of marijuana."[30]

In light of the revised policy, in order to obtain marijuana through the NIDA Drug Supply Program for use in non-federally funded human research, applicants must fulfill the following criteria:

- Demonstrate scientific validity and ethical soundness through review by the FDA's IND process. Specifically, research protocols undergo a scientific review that assures the safety and rights of subjects and the scientific quality of the clinical investigations, and assesses the likelihood that investigations will yield data capable of meeting the statutory standards for drug marketing approval; and

- Possess a DEA registration for marijuana.[31]

II. Granting Professor Craker's Application to Manufacture Marijuana Is Consistent with the Public Interest, as Determined Under the CSA

Federal law significantly restricts the DEA's discretion to grant or deny Professor Craker's application. As noted previously, section 823 mandates that the Attorney General "shall register" an applicant to manufacture marijuana if registration is "consistent with the public interest" and treaty obligations. The DEA's public interest determination is controlled by statutory factors set out in sections 823(a)(1)-(6). Notably, while the DEA *must* register treaty-compliant applicants who satisfy all of these statutory criteria, it *may* register such an applicant even if it determines that not all of the statutory factors support the registration. In other words, the regulatory structure grants the DEA broader discretion to *grant* registration than to *deny* it. Here, each of the six statutory factors set forth at sections 823(a)(1)-(6) supports registering Professor Craker. Under the governing regulations, the DEA thus is statutorily required to find that Professor Craker's registration is consistent with the public interest and must, therefore, grant the application unless doing so will violate the Single Convention—which, the State Department has now made clear, it does not.

A. Professor Craker Will Have Effective Controls Against Diversion in Place and Has Demonstrated that There Is an Inadequate Supply of Marijuana for Legitimate Medical and Scientific Research

Section 823(a)(1) requires the DEA to maintain effective controls against diversion by considering limiting the number of registered bulk manufacturers of a particular schedule I or II controlled substance to "a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research and industrial purposes."[32] This factor weighs in favor of

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[30] 80 Fed. Reg. at 35,960.

[31] 80 Fed. Reg. at 35,960.

[32] 21 U.S.C. § 823(a)(1).

granting Professor Craker's application. He has established both that effective controls against diversion are in place and that the existing marijuana supply is insufficient to meet the needs of academic and drug-development researchers, including privately-funded sponsors of FDA-regulated drug development research who must be able to eventually supply patients with medicinal marijuana from the same supply used for FDA Phase III clinical studies.

1. Effective Controls Against Diversion Are in Place

There is minimal risk that marijuana Professor Craker cultivates will be diverted. The DEA has a wide range of procedures and controls to adequately protect against diversion of controlled substances manufactured for research purposes, and Professor Craker has adequately demonstrated that he will comply with all DEA requirements. Professor Craker has previously proposed to produce marijuana in a climate-controlled facility on the University of Massachusetts, Amherst campus, which the DEA determined can be made secure.[33]

Likewise, there is minimal risk that marijuana cultivated by Professor Craker would be diverted after it leaves the University of Massachusetts. Professor Craker will provide marijuana only to researchers who hold DEA registrations and are conducting FDA-approved academic or drug development research. In other words, Professor Craker will send marijuana only to qualified and competent researchers who are conducting legitimate medical or scientific research with procedures in place to adequately protect against diversion of the marijuana.[34] Accordingly, the DEA must conclude that Professor Craker has demonstrated that effective controls against diversion can be put in place.

2. The University of Mississippi (i.e., the NIDA Drug Supply Program) Cannot Produce an Adequate Supply of Marijuana for Legitimate Medical, Scientific, Research, and Industrial Purposes

The University of Mississippi, the only registered manufacturer of marijuana and party to an exclusive contractual agreement with NIDA, has not been able to meet the demand for FDA-approved research.[35] Not only does NIDA's monopoly on medical research supply result in lengthy delays that create significant barriers to legitimate medical research, but it also leaves researchers with no other option when NIDA is unable to provide the specific strain of marijuana called for in the research protocol. Under the DEA's own interpretation of section

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[33] DEA personnel previously concluded that the facility Professor Craker proposed was adequately protected against diversion after conducting an on-site inspection. *See* 74 Fed. Reg. at 2125 (noting Professor Craker's testimony regarding the DEA on-site inspection).

[34] *Cf.* 21 U.S.C. § 823(f).

[35] Although the First Circuit expressed doubt about whether the adequacy of supply should be measured against FDA-approved research, this was informed by the former HHS policy that required protocol review by PHS. As noted above, HHS has since eliminated the requirement of PHS review of non-federally funded research protocols involving marijuana. 80 Fed. Reg. at 35,960. Thus, there is no reason that the adequacy of supply cannot be measured against FDA-approved research.

823(a)(1), this evidence of inadequate supply "weighs heavily in favor of granting the registration" for Professor Craker.[36]

Despite repeated requests, NIDA has been unable to supply the Multidisciplinary Association for Psychedelic Studies (MAPS) with the strain of marijuana MAPS requested for DEA-registered researchers at the University of Pennsylvania Perelman School of Medicine to conduct DEA- and FDA-approved medical research.[37] This randomized, double-blind, placebo-controlled Phase II study, funded by a $2.15 million grant to MAPS from the Colorado Department of Public Health and Environment, will test the safety and efficacy of marijuana in reducing the symptoms of posttraumatic stress disorder (PTSD), a debilitating disorder experienced by a subset of individuals following trauma.[38]

One of the study's key objectives is to evaluate the effect different contents of THC and CBD have upon the efficacy and safety of the marijuana in reducing PTSD symptoms.[39] To this end, the research protocol calls for study participants (76 military veterans with treatment-resistant PTSD) to be randomly assigned to receive one of four different strains of marijuana that vary based on THC and CBD potency: (1) high-THC marijuana; (2) high-CBD marijuana; (3) high-THC/high-CBD marijuana; and (4) placebo marijuana (i.e., low levels of THC and CBD).[40] With respect to the first category, the researchers sought to study a 12% THC/<1% CBD variety, which the researchers requested from NIDA. However, NIDA was unable to provide a strain with the requested potency. Instead, NIDA informed the researchers that, because it did not have this strain, the best it could do was provide 10.6% THC/<1% CBD variety. Likewise, with respect to the third category, the researchers sought to study a 12% THC/12% CBD variety, which the researchers requested from NIDA. However, NIDA was unable to provide a strain with the requested potency. Instead, NIDA informed the researchers that, because it did not have this strain, the best it could do was provide a 8.9% THC/9.3% CBD variety.[41] Thus, despite holding the requisite DEA registration and receiving approval from both the DEA and FDA, and despite having constructed a protocol specifically designed to work within the limitations of

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[36] Specifically, in the DEA's 2009 order regarding Professor Craker's prior application, the DEA stated, "[i]f [Professor Craker] can demonstrate by a preponderance of the evidence that either supply or competition is inadequate within the meaning of paragraph 823(a)(1), this weighs heavily in favor of granting the registration." 74 Fed. Reg. at 2119. It likewise follows that, under the DEA's own interpretation of section 823(a)(1), Professor Craker need only present evidence of either inadequate supply or inadequate competition. He need not prove both.

[37] *See Marijuana for Symptoms of PTSD in U.S. Veterans*, MAPS, http://www.maps.org/research/mmj/marijuana-us (last visited July 6, 2016).

[38] *Study of Four Different Potencies of Smoked Marijuana in 76 Veterans with Chronic, Treatment-Resistant PTSD*, CLINICALTRIALS.GOV, https://clinicaltrials.gov/ct2/show/NCT02759185?term=marijuana+and+ptsd&rank=1 (last visited July 6, 2016).

[39] *Id.*

[40] *Id.*

[41] *See* E-mail from Richard "Rik" Kline, Ph.D., Program Director, NIDA Drug Supply, to Rebecca Matthews, Clinical Trial Leader, MAPS Public Benefit Corporation (June 9, 2016).

THC- and CBD-potency available from NIDA, these researchers were unable to obtain the strains of marijuana called for by their FDA-approved research protocols. Professor Craker would be able to create these strains, if the DEA grants his application.[42]

Moreover, even when NIDA does not flatly deny a researcher's request for a particular strain of marijuana, its monopoly on medical research supply often results in arbitrary, lengthy delays, thereby creating significant barriers to legitimate medical research. For example, Chemic Laboratories, Inc. (Chemic), a DEA-licensed laboratory, had to wait over two years for a response to its initial request to purchase 10 grams of marijuana for privately-sponsored research into the chemical constituents produced by vaporizers, a non-smoking delivery system that the Institute of Medicine (IOM) recommended be developed.[43] After more than five years of effort, Chemic was unable to purchase 10 grams of marijuana from NIDA,[44] and eventually gave up without conducting the study.

Even NIDA recognizes that its monopoly creates a barrier to legitimate research. In June 2015, NIDA Director Dr. Nora Volkow testified before Congress that, without this monopoly, "efficiency, effectiveness, availability for research would be better."[45]

There is evidence that the NIDA monopoly is dissuading researchers from conducting medical research on marijuana in the first instance. Despite the widespread desire for additional data on the potential medical uses of marijuana,[46] in 2015, only two researchers in the United

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[42] NIDA's inability to provide high-potency marijuana has also prompted action at the state level. Indeed, "multiple states have set up their own marijuana grow operations because of a purported need for marijuana rich in certain components, like CBD." *Drug Caucus Hearing on Barriers to Cannabidiol Research Before the S. Comm. on Int'l Narcotics Control*, 114th Cong. (June 24, 2015) (statement of Kevin A. Sabet, Ph.D., President, SAM, Inc.).

[43] *See Drug Caucus Hearing on Barriers to Cannabidiol Research Before the S. Comm. on Int'l Narcotics Control*, 114th Cong. (June 24, 2015) (statement of Sen. Cory Booker).

[44] *See Health and Human Services and National Institute on Drug Abuse Place Another Hurdle in Front of Marijuana Vaporizer Research*, MAPS (Feb. 9, 2009), http://www.maps.org/research/mmj/vaporizer-research-news-timeline.

[45] *Drug Caucus Hearing on Barriers to Cannabidiol Research Before the S. Comm. on Int'l Narcotics Control*, 114th Cong. (June 24, 2015) (statement of Dr. Nora Volkow, Director, NIDA). Specifically, Dr. Volkow stated that she would support the licensing of additional marijuana manufacturers because it would "make[] research much more efficient." *Id.* When Senator Cory Booker asked Dr. Volkow to confirm that "efficiency, effectiveness, availability for research would be better if there was not a monopoly," Dr. Volkow replied, "Correct." *Id.*

[46] In March 2016, NIDA and a number of other Institutes and Centers at the National Institutes of Health (NIH) convened a two-day summit, titled "Marijuana and Cannabinoids: A Neuroscience Research Summit." The goal of the summit was "to ensure evidence-based information is available to inform practice and policy, particularly important at this time given the rapidly shifting landscape regarding the recreational and medicinal use of marijuana." National Institute on Alcohol Abuse and Alcoholism, *Marijuana and Cannabinoids: A Neuroscience Research Summit*, NIAAA.NIH.GOV, http://www.niaaa.nih.gov/news-events/meetings-events-exhibits/marijuana-and-cannabinoids-neuroscience-research-summit (last visited July 6, 2016).

States received a supply of marijuana from NIDA for medical research in humans.[47] At the recent National Institutes of Health (NIH) neuroscience summit on cannabinoids, several researchers reported that the federal government's current administrative barriers dissuade qualified scientists and doctors from even applying to research cannabis.[48]

Finally, NIDA's inability to meet "reasonably anticipated demand" for FDA-approved marijuana research projects in the "foreseeable future" provides additional support for granting Professor Craker's registration.[49] FDA has approved Phase II studies investigating the efficacy and safety of marijuana in reducing symptoms of PTSD.[50] The next phase of research (Phase III research), however, cannot source its marijuana from NIDA. The NIDA Drug Supply Program is not designed for or authorized to commercially sell its marijuana as a prescription medicine should FDA-approved prescription use be granted.[51] NIDA marijuana is therefore inadequate for privately-funded, FDA-regulated Phase III drug development studies—which FDA requires be conducted with the same supply that would be sold by prescription. DEA licensing of private producers is required, as a practical matter, to enable privately-funded FDA-regulated Phase III drug development studies.

In sum, NIDA's inability to meet both the current demand and reasonably anticipated future demand for legitimate medical research "weighs heavily in favor" of granting Professor Craker's application.

B. Professor Craker Has Complied, and Will Continue to Comply, with Applicable State and Local Law

As in the review of his prior application, there is "no evidence" that Professor Craker has not complied with applicable state or local laws.[52] The DEA thus should again find that this factor weighs in favor of granting Professor Craker's application.[53]

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[47] *See* Letter from Sen. Kirsten Gillibrand et al. to President Barack Obama (Apr. 15, 2016), *available at* https://www.gillibrand.senate.gov/newsroom/press/release/senator-gillibrand-joined-by-bipartisan-group-of-26-senators-and-representatives-urges-president-obama-to-remove-barriers-to-research-on-medical-marijuana [hereinafter "Gillibrand Letter"].

[48] Gillibrand Letter.

[49] *See* 74 Fed. Reg. at 2119.

[50] *See Study of Four Different Potencies of Smoked Marijuana in 76 Veterans with Chronic, Treatment-Resistant PTSD*, CLINICALTRIALS.GOV, https://clinicaltrials.gov/ct2/show/NCT02759185?term=marijuana+and+ptsd&rank=1 (last visited July 6, 2016).

[51] *See* NIDA, *NIDA Drug Supply Program*, DRUGABUSE.GOV, https://www.drugabuse.gov/researchers/research-resources/nida-drug-supply-program (last visited July 6, 2016) (describing the kinds of marijuana available through the NIDA Drug Supply Program).

[52] *See* 74 Fed. Reg. at 2113.

[53] *See Craker*, 714 F.3d at 23.

C. Professor Craker Will Promote Technical Advances in the Art of Manufacturing Controlled Substances and the Development of New Substances

Granting Professor Craker's application would promote technical advances in the art of manufacturing controlled substances and the development of new substances. Distinct from his former application, Professor Craker now seeks authorization to extract cannabinoids to supply researchers experimenting with isolated cannabinoids.[54] This factor thus weighs in favor of granting Professor Craker's application.

D. Professor Craker Has Never Been Convicted of Any Violation of Any Law Pertaining to Controlled Substances

Professor Craker has never been convicted of any controlled-substance related offense. The DEA thus should again find that this factor weighs in favor of granting Professor Craker's application.[55]

E. Professor Craker Will Implement Effective Controls Against Diversion

Professor Craker will have satisfactory diversion control in place. As noted above, if his application is approved, Professor Craker will grow marijuana in a climate-controlled room that can be made secure, as DEA personnel concluded after conducting an on-site inspection of the University of Massachusetts facility that Prof. Craker first proposed in 2001.[56] Further, Professor Craker has extensive experience with sensitive research and research on medicinal plants. As a Captain in the U.S. Army Chemical Corps, Professor Craker worked in secret, secure research environments at Fort Detrick, Maryland.[57] For more than thirty years, Professor Craker has specialized in research on medicinal plants. In light of the above, the DEA should again find that this factor weighs in favor of granting Professor Craker's application.[58]

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[54] Many recent studies in the U.S. and elsewhere have indicated the potential medical efficacy of cannabinoids such as CBD. *See*, *e.g.*, GW Pharmaceuticals, *GW Pharmaceuticals Announces Positive Phase 3 Pivotal Study Results for Epidiolex (cannabidiol)*, GWPHARM.COM (Mar. 14, 2016), http://www.gwpharm.com/GW%20Pharmaceuticals%20Announces%20Positive%20Phase%203%20Pivotal%20Study%20Results%20for%20Epidiolex%20cannabidiol.aspx (announcing the positive results of its pivotal Phase III study of its investigational drug Epidiolex® (cannabidiol or CBD) for the treatment of Dravet syndrome, a rare and debilitating type of epilepsy for which there are currently no approved treatments in the United States).

[55] *See Craker*, 714 F.3d at 23; 74 Fed. Reg. at 2113.

[56] *See* 74 Fed. Reg. at 2125 (noting Professor Craker's testimony regarding the DEA on-site inspection).

[57] Hearing at 16, lines 1-7, In re: Lyle E. Craker, Ph.D., No. 05-16 (Aug. 22, 2005) (testimony of Lyle E. Craker, Ph.D.), *available at* http://www.maps.org/research-archive/mmj/legal/craker-dea/transcript0822.html.

[58] *See Craker*, 714 F.3d at 23.

F. Other Factors Relevant to Public Health and Safety Likewise Weigh in Favor of Granting Professor Craker's Application

Professor Craker's application likewise is supported by consideration of other factors relevant to public health and safety. When the DEA denied Professor Craker's previous application, the agency contended that granting Professor Craker's application would amount to circumventing HHS's policy with respect to providing marijuana to researchers. As noted above, HHS has since eliminated this policy,[59] and thus this former policy cannot be a reason to deny Professor Craker's application.

III. Granting Professor Craker's Application is Consistent with the Single Convention

Professor Craker's registration would not contravene the Single Convention's restrictions on wholesale trade in marijuana, for two reasons. First, Professor Craker seeks to manufacture exclusively medical marijuana, which the plain language of the treaty exempts from its provisions requiring signatory countries to designate an agency to have the "exclusive" right to import, export, trade in, or maintain stocks. Second, even if Professor Craker were not manufacturing "medical" marijuana as that term is used in the treaty, Professor Craker's compliance with the system of DEA registration and FDA review established by the CSA would satisfy the requirements of the Single Convention. The DEA's prior interpretation of the Single Convention is not correct, nor is it controlling, as the First Circuit elected "not [to] review the arguments relative to the Single Convention."[60]

A. Professor Craker's Distribution is Exempt From the Single Convention's Requirement of Exclusive Governmental Controls Under the Treaty's "Medical" Marijuana Exemption

Recognizing that "the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes,"[61] article 23 of the Single Convention provides a broad exemption from the government's exclusive rights for opium used for medical purposes. This exemption applies to "medicinal opium," "opium alkaloids," and "opium preparations."[62]

The Single Convention applies an equivalent exemption to marijuana. Specifically, article 28 provides that if a party permits the cultivation of cannabis, "it shall apply thereto the system of controls as provided in article 23 respecting the opium poppy."[63] When article 23 is applied to

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[59] The former HHS policy required protocol review by the PHS. HHS eliminated this requirement with respect to non-federally funded research protocols involving marijuana, finding it unnecessary given the overlap with FDA's IND process. 80 Fed. Reg. at 35,960.

[60] *Craker*, 714 F.3d at 26.

[61] Single Convention, Preamble.

[62] Single Convention, Art. 23 ¶ 2(e).

[63] Single Convention, Art. 28, ¶ 1.

marijuana, the exemption for "medicinal opium" translates into an exception for "medicinal cannabis" (and "medicinal cannabis resin"). The treaty defines "medicinal opium" as opium "which has undergone the processes necessary to adapt it for medicinal use."[64] It thus follows that "medicinal cannabis" means marijuana which has undergone the processes necessary to adapt it for medicinal use.

Clinical research and observational studies have shown that marijuana has a number of medicinal uses. For instance, "medical marijuana can make chemotherapy more tolerable, boost appetite, reduce the eye pressure of glaucoma, relieve pain, stop muscle spasms, treat depression or anxiety, [and] alleviate PTSD."[65] Indeed, forty states have recognized the medicinal use of marijuana: 23 have passed laws establishing medical cannabis programs, while an additional 17 have passed laws regarding the medical use of the cannabis-derived compound CBD.[66]

Professor Craker is applying to the DEA to cultivate marijuana exclusively for DEA-registered medical researchers seeking to conduct FDA-approved medical research. Marijuana used for bona fide, FDA-approved, medical research is necessarily being used "medicinally."[67] Accordingly, because Professor Craker seeks to cultivate exclusively "medicinal marijuana," his registration would not contravene the Single Convention, which exempts medicinal marijuana from the government's exclusive right of wholesale trading.

B. The DEA May Register Another Marijuana Manufacturer, as DEA Registration and FDA Approval Satisfy the Single Convention's Requirement of Governmental Controls Over Marijuana Distribution

Even if the Single Convention's "medical" marijuana exemption does not apply here, Professor Craker's proposed registration nonetheless would be consistent with the Single

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[64] Single Convention, Art. 1 ¶ 1(o).

[65] John Hudak, *The Medical Marijuana Mess*, THE BROOKINGS INSTITUTION (Mar. 22, 2016), http://www.brookings.edu/research/essays/2016/the-medical-marijuana-mess?cid=00900024020017601US0001; *see also* Center for Medicinal Cannabis Research, Completed Studies, http://www.cmcr.ucsd.edu/index.php/2015-11-20-20-52-15/completed-studies (last visited July 6, 2016) (presenting the results of clinical studies examining the effectiveness of cannabis in treating a number of medical conditions).

[66] Gillibrand Letter.

[67] The DEA has previously asserted that "there is currently no such thing in the United States as 'medicinal cannabis,'" because marijuana is classified as a Schedule I controlled substance and has not been approved for medical use by FDA. Brief for the Drug Enforcement Administration at 56, *Craker*, 714 F.3d 17 (No. 09-1220). The inclusion of marijuana in Schedule I—without any scientific evaluation of its medical use—cannot preclude the existence of medicinal marijuana, as this would read the "medicinal marijuana" exemption out of the Single Convention altogether. The canon against superfluity counsels against any interpretation that renders one provision superfluous; that is to say, a law should be read so that all of its provisions are given effect and none is superfluous. *E.g.*, *Alaska Dept. of Envtl. Conservation v. EPA*, 540 U.S. 461, 489 n.13 (2004).

Convention because such registration complies with governmental controls restricting the wholesale trade in marijuana.

Nothing in the text of the Single Convention suggests that there is a limitation on the number of marijuana manufacturer licenses that each signatory nation may issue. The Single Convention prescribes five governmental controls over the cultivation of marijuana. The first three controls relate to the licensing of cultivators.[68] Congress, through the CSA, assigned this function to the Attorney General, who delegated that authority to the DEA.[69]

The fourth control requires a national agency to purchase and take physical possession of the crops.[70] In interpreting treaties, the United States Supreme Court has "traditionally" taken into consideration "the postratification understanding of the contracting parties."[71] The postratification conduct of the parties to the Single Convention demonstrates that parties "are free to construe the term 'physical possession' as they see fit."[72] Thus, the government agency need not actually take physical possession of the marijuana crop, but instead may satisfy the "physical possession" requirement by detailed government regulation of persons possessing the substance and through forms of "constructive possession."[73]

The final control is the government's exercise of an "exclusive right" over "importing, exporting, wholesale trading and maintaining stocks."[74] The Single Convention clearly contemplates that more than one cultivator or bulk manufacturer may be licensed by the signatory nation's licensing agency. Specifically, paragraph 2 of article 23 sets forth the controls that *each* signatory nation's licensing agency must apply.[75] Several of these controls contemplate that a government licensing agency may grant more than one marijuana manufacturer license. The second and fourth controls use the term "cultivators," recognizing that the government agency may license more than one cultivator.[76] The third control recognizes the same by setting

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[68] Single Convention, Art. 23 ¶¶ 2(a)-(c).

[69] 28 C.F.R. 0.100(b).

[70] Single Convention, Art. 23 ¶ 2(d).

[71] *See Zicherman v. Korean Air Lines Co.*, 516 U.S. 217, 226 (1996).

[72] *See* 74 Fed. Reg. at 2114 (stating the conclusions of the DEA Administrative Law Judge, which were based on the United Kingdom's regulatory scheme).

[73] The United Kingdom's protocol regarding the manufacture of marijuana provides that when marijuana is cultivated at licensed sites, "a form of constructive purchase and possession will be deemed to have taken place between the [National Cannabis] Agency and producer with actual ownership and possession of the material reverting immediately to the producer for the purposes for which the license was granted." *See* Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge at 74, In re Lyle E. Craker, Ph.D., No. 05-16 (Feb. 12, 2007).

[74] Single Convention, Art. 23 ¶ 2(e).

[75] Single Convention, Art. 23 ¶ 2.

[76] Single Convention, Art. 23 ¶¶ 2(b) & (d).

requirements that apply to "[e]ach license."[77] Indeed, the Bureau of Narcotics and Law Enforcement at the State Department made this point when it recently stated that the United States could issue multiple licenses for the cultivation of marijuana without violating the Single Convention.[78]

The postratification conduct of the parties to the Single Convention demonstrates the same. Countries such as the United Kingdom, Canada, and Israel have implemented programs that adhere to the Single Convention while allowing more than one entity to hold a license to cultivate and distribute cannabis for medical purposes. For example, Health Canada currently has more than 30 licensed producers of medical cannabis.[79] Likewise, under the protocol of the United Kingdom's National Cannabis Agency (which implements article 28 through licensing), "any import, export or wholesale dealing from a licensed [National Cannabis] Agency site will be deemed to have taken place with the explicit authority of [National Cannabis] Agency."[80]

Thus, this "exclusive right" provision is not intended to limit the number of marijuana manufacturer licenses that each signatory nation can issue. Instead, as the Commentary to the Single Convention explains, the purpose of this "exclusive right" is to ensure government supervision over the lawful trade in cannabis and opium: "If [parties] allowed the sale of crops to private traders, they would not be in a position to ascertain with reasonable exactitude the amounts which enter their controlled trade. The effectiveness of their control regime would thus be considerably weakened."[81]

Congress addressed this "exclusive right" control by structuring the CSA to require a "closed system" of distribution in which all persons in the legitimate distribution chain of a controlled substance must obtain DEA registration.[82] Thus, by ensuring the government's control over "distributors" and "practitioners" in the supply of individual research protocols, DEA registration not only satisfies the first three requirements of articles 23 and 28 relating to cultivator licensing, but it also effectuates the fifth requirement, government control over lawful trade of marijuana.

The DEA denied Professor Craker's prior application because the agency believed that NIDA reviewed individual research protocols as part of DEA's registration process under the CSA, and thus was precisely the control "over the wholesale distribution of marijuana that the Single Convention demands."[83] In particular, the DEA stated that "[t]he process HHS has

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[77] Single Convention, Art. 23 ¶¶ 2(c).

[78] *See* State Dept. E-mail.

[79] *See* Health Canada, *Authorized Licensed Producers under the* Marijuana for Medical Purposes Regulations, http://www.hc-sc.gc.ca/dhp-mps/marihuana/info/list-eng.php (last visited July 6, 2016).

[80] *See* Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge at 74, In re Lyle E. Craker, Ph.D., No. 05-16 (Feb. 12, 2007).

[81] Secretary-General of the United Nations, Commentary on the Single Convention on Narcotic Drugs, 1961 (1973).

[82] *See* 21 U.S.C. §§ 822-823.

[83] 74 Fed. Reg. at 2115.

established to assess the scientific merit of proposed research studies involving marijuana is that described in the 1999 [guidelines]," which require protocol review by PHS.[84]

Since the DEA denied Professor Craker's earlier application, HHS has eliminated the requirement of PHS review of non-federally funded research protocols involving marijuana. HHS announced the revision of its policy in June 2015, stating, "the PHS review overlaps in several important ways with FDA's IND process and is no longer necessary to support the conduct of scientifically-sound studies into the potential therapeutic uses of marijuana."[85] Thus, HHS has expressly recognized that FDA will in fact conduct the very review that the DEA believed NIDA must perform.

Professor Craker will distribute the marijuana he grows exclusively to researchers holding DEA registrations and with the concomitant FDA approval. Accordingly, Professor Craker's proposed registration, if granted, will comply with governmental controls restricting the wholesale trade in marijuana, and therefore would be consistent with the Single Convention.

IV. Conclusion and Requested Action

For the reasons set forth above, the DEA should grant Professor Craker's application for registration to manufacture marijuana under section 823(a) of the CSA. Such registration is consistent with the public interest and with United States obligations under the Single Convention.

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[84] 74 Fed. Reg. at 2120.

[85] 80 Fed. Reg. at 35,960.