No. 09-1220

IN THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

Lyle E. Craker,
Petitioner,

v.

Drug Enforcement Administration,
Respondent.

On Petition For Review Of A Final Order
Of The Drug Enforcement Administration

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Jurisdictional Statement

Petitioner Lyle E. Craker seeks review of a Drug Enforcement Administration ("DEA") decision denying his application for registration to cultivate marijuana for medical research.

On January 14, 2009, DEA issued an order rejecting the recommendation of Administrative Law Judge Mary Ellen Bittner and denying Professor Craker's application. Lyle E. Craker; Denial of Application, 74 Fed. Reg. 2101, 2133 (Jan. 14, 2009) ("*Final Order*") (Add. 133). Professor Craker timely filed his petition for review of the order on February 13, 2009. *See* 21 U.S.C. § 877. On March 12, 2009, this Court granted Professor Craker's motion to hold the petition in abeyance pending DEA's reconsideration of its order. DEA subsequently issued an order denying reconsideration and amending the administrative record on August 18, 2011. *See* Lyle E. Craker, PhD; Order Regarding Officially Noticed Evidence and Motion for Reconsideration, 76 Fed. Reg. 51403, 51412 (Aug. 18, 2011) ("*Reconsideration Order*") (Add. 144).

DEA's adjudication of Professor Craker's application was pursuant to the Administrative Procedure Act, 5 U.S.C. § 554, and the

Controlled Substances Act, 21 U.S.C. § 824(a). Because Professor Craker's principal place of business is Massachusetts, this Court's jurisdiction is proper under 21 U.S.C. § 877, which permits a person aggrieved by a final adjudication under the Controlled Substances Act to petition for review in the circuit in which his principal place of business is located.

Statement Of The Issues

The Controlled Substances Act requires DEA to register an applicant to manufacture marijuana if the registration is consistent with the public interest and the United States' obligations under international treaties. 21 U.S.C. § 823(a). In determining the public interest, DEA must balance the need to prevent "diversion" of controlled substances to unauthorized uses against the need for competition and the adequacy of supplies for medical and scientific research. DEA is thus directed to consider as the first public interest factor:

> "(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances 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." 21 U.S.C. § 823(a)(1).

The questions presented are:

1. Whether DEA acted arbitrarily and capriciously by abandoning its longstanding interpretation of the Controlled Substances Act and construing 21 U.S.C. § 823(a)(1) to require, in order for a registration to be in the public interest, a showing that the current supply of marijuana for medical research is inadequate or is supplied under inadequately competitive conditions even in the absence of any risk of diversion.

2. Whether, in the alternative, (a) DEA acted arbitrarily and capriciously when it concluded that a single licensed supplier with a monopoly on the supply of research-grade marijuana provides the substance under "adequately competitive conditions"; or (b) DEA acted arbitrarily and capriciously when it concluded that the current supply of research-grade marijuana is adequate despite restrictions on the current supplier that prevent it from providing marijuana to all FDA-approved researchers.

3. Whether DEA incorrectly interpreted the Single Convention on Narcotic Drugs when it concluded that the Convention's "medicinal marijuana" exemption does not apply to marijuana used in legitimate medical research.

4. Whether DEA acted arbitrarily and capriciously when it premised its denial of Professor Craker's registration on an incorrect understanding of the statutory and regulatory authority of the National Institute for Drug Abuse.

Statement Of The Case

Lyle E. Craker is a professor in the Department of Plant, Soil, and Insect Sciences at the University of Massachusetts at Amherst who, for more than thirty years, has specialized in research on medicinal plants. On June 25, 2001, he applied for a federal registration to manufacture, *i.e.* cultivate, marijuana in order to provide a new source of marijuana for FDA-approved and DEA-licensed research aimed at developing a botanical marijuana prescription

medicine.[1] (App. 1).[2] Professor Craker's registration would provide researchers with an alternative, competing source to the marijuana grown by the University of Mississippi, which currently is the only facility licensed by DEA to manufacture research-grade marijuana in the United States.

A DEA Administrative Law Judge recommended that Professor Craker's application be granted, concluding that it would serve the public interest and be consistent with the United States' treaty obligations, as required by the Controlled Substances Act. Departing from the interpretation of the Act that it had advocated for more than thirty years, DEA rejected Judge Bittner's recommendation and denied Professor Craker's application on the ground that he had not shown the inadequacy of the existing supply of marijuana or that it is produced under inadequately competitive conditions. DEA also

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[1] Botanical products contain vegetable matter as ingredients. Botanical medicines provide an alternative to synthetic, semisynthetic, purified, or chemically modified drugs. *See* FDA, Guidance For Industry Botanical Drug Products, http://www.fda.gov/cder/guidance/4592fnl.htm.

[2] Citations to the Addendum are denoted by "Add." Citations to the Appendix are denoted by "App."

concluded that Professor Craker's registration is barred by restrictions on wholesale trade in marijuana contained in the United Nations Single Convention on Narcotic Drugs ("Single Convention"), March 30, 1961, 18. U.S.T. 1407.

This case thus turns on three core disputes: the correct interpretation of the Controlled Substances Act's provision regarding the registration of Schedule I drug manufactures, the inadequacy of both the current supply of marijuana and competition among marijuana suppliers, and the correct interpretation of the Single Convention.

A. Registration Of Schedule I Drug Manufacturers.

The Controlled Substances Act establishes a comprehensive regulatory system that controls the manufacture, distribution, and use of controlled substances. *MD Pharm. v. DEA*, 133 F.3d 8, 10 (D.C. Cir. 1998). A primary purpose of the Act is "to prevent the diversion of drugs" having legitimate uses "from legitimate to illicit channels." *Gonzales v. Raich,* 545 U.S. 1, 12-13 & n.21 (2005); *United States v. Moore*, 423 U.S. 122, 135 (1975). A defining feature of the Act 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,[3] whereas "transactions outside the legitimate distribution chain [are] illegal." *See* H.R. Rep. No. 91–1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4569.

The Act creates three classes of registration, for "manufacturers," "distributors," and "practitioners," each with its own requirements. *See* 21 U.S.C. §§ 822-823. This case involves manufacturer registration under § 823(a) of Title 21, which provides that "[t]he Attorney General *shall register* an applicant to manufacture controlled substances in schedule I or II[4] if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols." *Id.* § 823(a) (emphasis added).

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[3] The Attorney General has delegated the responsibility for registering manufacturers of Schedule I and II drugs to DEA. 28 C.F.R. § 0.100(b).

[4] The Act assigns controlled substances to one of five schedules based on factors including addictiveness, safety, and use in accepted medical treatment. 21 U.S.C. § 812. Marijuana and its primary psychoactive ingredient, tetrahydrocannabinols ("THC"), are contained in Schedule I, the most restrictive classification. *Id.* § 812(c); *Raich*, 545 U.S. at 14.

1. The Public Interest.

In determining whether the registration of a manufacturer is consistent with the public interest, DEA must consider six factors. 21 U.S.C. § 823(a). DEA must first consider whether the "maintenance of effective controls against diversion" of controlled substances into illicit channels requires limiting the number of licensed importers and bulk manufacturers "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." *Id.* § 823(a)(1).

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)).

2. The United States' International Obligations.

The Controlled Substances Act implements the Single Convention, which ensures that the international movement of narcotics is limited to legitimate medical and scientific needs. *See* 21 U.S.C. § 801(7); Single Convention, Art. 4 (Add. 10).[5]

Article 28 of the Single Convention addresses the cultivation of marijuana.[6] Rather than specifically detailing a set of controls for marijuana, however, the treaty instead requires that parties "shall apply" to marijuana "the system of controls as prescribed in article 23 respecting the control of the opium poppy." *Id.* Art. 28 ¶ 1 (Add. 12). Under Article 23, any signatory nation permitting the cultivation of opium poppy must designate an agency to (i) license cultivators and designate where the plant may be grown; (ii) "purchase and take physical possession" of each year's crops of opium, and (iii) exercise the exclusive right to import, export, trade in, or maintain stocks of opium.

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[5] The Single Convention is reprinted in excerpted form in the Addendum (Add. 7-12), and in full in the Appendix (App. 49-92). For the Court's convenience, references in this brief are cited to the Addendum.

[6] The Single Convention refers to marijuana as "cannabis." *See* Single Convention, Art. 1 (Add. 7).

Id. Art. 23 ¶¶ 1-3 (Add. 11). These exclusive rights do not apply to "medicinal opium," defined in the treaty as "opium that has undergone the processes necessary to adapt it for medicinal use." *Id.* Art. 1 ¶ 1(n) (Add. 7).

B. The Supply Of Marijuana For Medical Research.

Marijuana for medical research in the United States is currently available only from the University of Mississippi. The University was first granted a license by DEA to manufacture marijuana in 1968, and has been the only licensed manufacturer of research-grade marijuana ever since. *Final Order*, 74 Fed. Reg. at 2104 (Add. 104). The University thus maintains a monopoly on producing marijuana for medical research.

The University's marijuana production is governed by an exclusive contractual agreement with the National Institute on Drug Abuse ("NIDA"), which permits the University to grow, harvest, store, and ship marijuana to researchers only at NIDA's direction.[7] *Id.* In

[7] NIDA is one of the National Institutes of Health, which, in turn, is a component of the Public Health Service of the Department of Health and Human Services.

order to obtain marijuana from the University, researchers must submit their research protocols to NIDA for approval. The contract prohibits the University from providing marijuana to researchers whose protocols NIDA has not approved. (App. 141). Once every five years,[8] NIDA entertains new bids on the contract, but it has never awarded the contract to anyone other than the University of Mississippi.

C. Professor Craker's Application.

Professor Craker submitted his application to manufacture marijuana to DEA on June 25, 2001, seeking to supply a well-characterized (*i.e.* grown to specifications) source of marijuana for clinical research involving either smoked or vaporized marijuana. He told DEA that "[a] second source of plant material is needed to facilitate privately-funded, FDA-approved research into medical uses of marijuana, ensuring a choice of sources and an adequate supply of quality, research-grade marijuana for medicinal applications." *Final Order*, 74 Fed. Reg. at 2107 (Add. 107). He testified that NIDA's

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[8] Since 1999, the contract term has been five years. In prior years, the contract term had been three years. (Add. 26).

monopoly has impeded, and sometimes precluded, legitimate medical research through delays, low-quality product, and even refusals to supply marijuana to government-approved researchers.

Professor Craker's proposed cultivation operation would be funded by a grant from the Multidisciplinary Association for Psychedelic Studies ("MAPS"). MAPS is a tax-exempt, non-profit research and education organization. Its mission is to develop FDA-approved prescription drugs from Schedule I controlled substances. (Add. 37).

In order for MAPS to develop a prescription marijuana product, it must demonstrate marijuana's safety and effectiveness through an adequate number of controlled studies published in scientific literature. *See* 21 C.F.R. § 314.126. MAPS is currently one of the only organizations in the United States working to demonstrate the safety and efficacy of smoked and or vaporized marijuana, rather than extracts or synthetic cannabinoids.[9] The Director of MAPS, Dr. Richard

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[9] Although much clinical research continues to use smoked botanical marijuana, NIDA encourages researchers to develop "a dosage form alternative to smoking," (continued…)

Doblin, testified to his belief that the efficacy and safety of vaporized botanical marijuana "will be similar" to drugs containing cannabinoid extracts, but that NIDA's monopoly has obstructed the necessary research. *Final Order*, 74 Fed. Reg. at 2106 (Add. 106).

Dr. Doblin testified that a reliable supply of marijuana is necessary to support the research to gain approval of marijuana as a prescription medicine. (Add. 51). To this end, MAPS has obtained an orphan drug designation from the FDA's Office of Orphan Products for the use of marijuana in response to AIDS wasting syndrome. (Add. 57). This designation will permit MAPS to develop a product faster once the appropriate research is underway.

Following Professor Craker's application, DEA investigators visited the University of Massachusetts, inspected the indoor facility where Professor Craker proposes to cultivate marijuana, and determined that the facility "could be made secure with no problems." *Final Order*, 74 Fed. Reg. at 2125 (Add. 125).

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and has adopted the view that the future of medicinal marijuana lies in "isolated components, the cannabinoids and their synthetic derivatives." (App. 133-34).

On December 10, 2004, DEA issued an order—phrased as a direction for Professor Craker to show cause why his application for registration should not be denied—all but finding the application to be inconsistent with the public interest and with the United States' international obligations. With regard to the first public interest factor—"maintenance of effective controls against diversion"—DEA stated, contrary to how it had interpreted the factor in the past, that it "must limit the number of producers of research-grade marijuana to that which can provide an adequate and uninterrupted supply under adequately competitive conditions" without regard to whether there is a potential for diversion. (App. 14). With regard to the United States' international obligations, the order stated, "In accordance with the Single Convention, the federal Government must limit marijuana available for clinical research to one source." (App. 13). Professor Craker requested a hearing and the matter was assigned to Judge Bittner. *See generally* 21 C.F.R. § 1301.43(a).

D. Proceedings Before Judge Bittner.

Judge Bittner presided over nine days of evidentiary hearings between August and December 2005. The parties called

numerous witnesses and presented hundreds of documentary exhibits. On February 12, 2007, Judge Bittner issued an eighty-seven-page opinion concluding that Professor Craker's application was consistent with the public interest and with the United States' international obligations, and recommending that his registration be granted.

After considering each of the statutory public interest factors, Judge Bittner found that the public interest favored registering Professor Craker because another source of marijuana for medical research is needed. With respect to the "maintenance of effective controls against diversion," § 823(a)(1), she found "minimal risk" that Professor Craker's marijuana would be diverted into unlawful channels. (Add. 97).

Judge Bittner went on to find that the current supply of research-grade marijuana is inadequate and is produced under inadequately competitive conditions. Based on largely undisputed evidence, she found that NIDA's contract with the University of Mississippi has impeded the supply of marijuana for legitimate scientific and medical research: "NIDA's system for evaluating requests for marijuana for research has resulted in some researchers who hold

DEA registrations and requisite approval from the Department of Health and Human Services being unable to conduct their research because NIDA has refused to supply them with marijuana." (Add. 97). Judge Bittner then held that "[t]he question is not . . . whether the NIDA process addresses that agency's needs, but whether marijuana is made available to all researchers who have a legitimate need for it in their research." (Add. 98). She also rejected DEA's argument that bidding process for the NIDA contract rendered competition adequate, and concluded that the inadequacies in supply and competition weighed in favor of granting Professor Craker's registration.

With respect to the United States' international obligations, Judge Bittner found that marijuana grown for medical research purposes would qualify as "medicinal" marijuana under the Single Convention and thus Professor Craker's registration would be consistent with the treaty.[10] (Add. 95).

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[10] Judge Bittner also stated that the Professor Craker's proposed cultivation would likely fall within an exception in the Single Convention's definition of "stocks." Professor Craker does not pursue this argument on appeal.

E. DEA's Denial Of Professor Craker's Application.

On review, DEA rejected Judge Bittner's recommendation and denied Professor Craker's application. In examining the public interest, DEA applied the interpretation of the Controlled Substances Act first articulated in its order to show cause: *i.e.*, that—even in the absence of any risk of diversion—Professor Craker was not entitled to his registration unless the current supply of research-grade marijuana is either inadequate or is produced under conditions that are inadequately competitive. *Final Order*, 74 Fed. Reg. at 2119 (Add. 119). DEA concluded that, despite the University of Mississippi's monopoly, the current conditions are adequately competitive and the existing manufacturer is capable of producing an adequate and uninterrupted supply.

1. The Public Interest.

Although DEA found that most of the public interest factors identified by 21 U.S.C. § 823(a) were neutral or favored granting

Professor Craker's application,[11] DEA focused most heavily on the first factor, "maintenance of effective controls against diversion." Without finding any risk of diversion, DEA applied its new interpretation of that factor, relying on subordinate language to conclude that the current supply of marijuana is adequate because the amount produced by the University of Mississippi is sufficient to meet "current and foreseeable research needs." *Id.* DEA dismissed Professor Craker's argument that NIDA's history of denying marijuana to legitimate research rendered the supply inadequate under the statute. *Id.* at 2119-20 (Add. 119-20).

DEA also concluded that marijuana is currently supplied under "adequately competitive conditions" even though the University of Mississippi holds a monopoly on the manufacture of marijuana for medical research. DEA interpreted "competitive conditions" to refer exclusively to conditions that might impact the price paid by researchers, and it concluded that there was no evidence that the price

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[11] Like Judge Bittner, DEA found that Professor Craker would comply with State and local law, had never been convicted of any violation of law relating to controlled substances, would establish effective controls against diversion, but had not previously cultivated marijuana. It also noted that Professor Craker had not shown that he was likely to promote technological advances in the art of manufacturing.

of marijuana would decrease if Professor Craker were registered. *Id.* at 2121 (Add. 121). DEA also asserted that adequate competition exists through periodic bidding on NIDA's contract.[12] *Id.* at 2121-22 (Add. 121-22).

2. The United States' International Obligations.

DEA interpreted the Single Convention as precluding Professor Craker's registration. It concluded that the Single Convention's "medicinal opium" exemption does not extend to marijuana because, "in the United States, marijuana has no currently accepted medical use and there are no FDA-approved medical products consisting of marijuana." *Id.* at 2116 (Add. 116). Although the Single Convention defines "medicinal opium" as "opium that has undergone the processes necessary to adapt it for medicinal use," DEA adopted a highly technical definition of the term found in earlier treaties and

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[12] Additionally, in considering "any other factor that may be relevant to the public health and safety," DEA cited testimony by the Director of MAPS indicating that he routinely used marijuana illegally, and considered this evidence to be "a sufficient independent basis upon which the DEA may deny the application." *Final Order*, 74 Fed. Reg. at 2127 (Add. 127). On reconsideration, DEA conceded that any concerns over Dr. Doblin's marijuana use could be mitigated. *Reconsideration Order*, 76 Fed. Reg. at 51412 (Add. 144).

pharmacopoeia. *Id.* Applying that definition, rather than the one contained in the Single Convention, DEA concluded that, "by any plausible application of the term 'medicinal opium' to cannabis, as a factual matter, there is currently no such thing in the United States as 'medicinal cannabis.'" *Id.*

DEA also concluded that Professor Craker's proposal to make marijuana available only to DEA-licensed and FDA-approved medical research did not satisfy the Single Convention's requirement that national agencies control the domestic trade in marijuana. *See id.* at 2114-15 (Add. 114-15). Instead, DEA held that the Single Convention mandates NIDA review of marijuana research protocols. *Id.*

F. Professor Craker's Motion For Reconsideration.

Professor Craker moved DEA to reconsider its order, challenging, *inter alia*, DEA's interpretation of the Controlled Substances Act and its conclusion that NIDA review of medical research is required by the Single Convention. DEA denied the motion, repeatedly stating its view that NIDA's review is "the process by which the Department of Health and Human Services (HHS) carries out its

statutory duty to review proposed research involving marijuana," and thus is a necessary component of the Controlled Substances Act's implementation of the Single Convention. *See Reconsideration Order*, 76 Fed. Reg. at 51405 (Add. 137).

Statement Of The Facts

A. The Inability Of Researchers To Obtain Marijuana From NIDA.

The undisputed record evidence in this case demonstrates that NIDA's monopoly over the supply of research-grade marijuana has blocked legitimate medical research by qualified medical researchers. Using NIH grants, NIDA funds research "on the causes, consequences, prevention, and treatment of drug abuse and drug addiction." (Add. 32). NIDA selects research for funding through a review committee comprised of members drawn from the Public Health Service ("PHS"), various specialty institutes of NIH, and from the Substance Abuse and Mental Health Services Administration. *Final Order*, 74 Fed. Reg. at 2105 (Add. 105). For twenty-five years, NIDA exclusively provided the marijuana grown under its contract with the University of Mississippi to those researchers who NIDA had selected to receive NIH funding.

In 1999, NIDA changed its procedures for supplying marijuana to researchers. Whereas researchers previously could obtain marijuana only if their research was funded by NIH grants, the new procedures permit privately funded researchers to obtain marijuana directly from the University of Mississippi on a cost-reimbursable basis. (App. 134). However, NIDA continues to subject privately funded research to its review process. Among the factors that NIDA considers in determining whether to authorize access to marijuana from the University is the "objectives of the proposed research," including "[t]he extent to which the protocol describes a biopharmaceutical study designed to support the development of a dosage form alternative to smoking." *Id.* NIDA guidelines state that, "if there is any future for marijuana as a medicine, it lies in its isolated components, the cannabinoids and their synthetic derivatives." (App. 133). NIDA thus believes that any marijuana-based prescription medicine will use "a purified constituent" and a non-smokable delivery system. (Add. 61). NIDA's representative testified that it is not NIDA's mission to study medicinal uses of marijuana or to advocate for medicinal marijuana research. (Add. 32).

Dr. Doblin testified that MAPS had been unable to procure marijuana from NIDA, blocking the progress of his organization's botanical marijuana research. Judge Bittner found that, on at least three occasions, MAPS-affiliated researchers interested in studying the beneficial effects of marijuana were unable to obtain marijuana from NIDA.

1. Dr. Donald Abrams' Application To Study The Effects Of Marijuana On AIDS Wasting Syndrome.

In 1995, Dr. Doblin worked with Dr. Donald Abrams, M.D., to develop an FDA-approved research protocol studying whether marijuana had beneficial effects when smoked by patients suffering from AIDS wasting syndrome. (Add. 54). Dr. Abrams submitted the protocol, along with a request for marijuana, to NIDA. After providing no communication for nine months, NIDA denied Dr. Abrams the marijuana "based on issues of design, scientific merit, and rationale." *Final Order*, 74 Fed. Reg. at 2108 & n.24 (Add. 108). In 1996, NIDA contacted Dr. Abrams and offered to provide marijuana and one million dollars in funding if he would agree to change the study to assess the

risks—rather than the benefits—of smoked marijuana. *Id.* at 2108 n.25 (Add. 108).

2. Dr. Ethan Russo's Application To Study The Effects Of Marijuana On Migraines.

Between 1996 and 1999, MAPS worked with neurologist Dr. Ethan Russo, M.D., on research involving migraine headaches. (Add. 56). Dr. Russo held a DEA registration for his research protocol, which had been approved by FDA and two independent institutional review boards. (App. 191). Over the course of nearly four years, Dr. Russo sought marijuana from NIDA for his research. NIDA repeatedly refused to supply him with marijuana, even after the 1999 change in guidelines permitted Dr. Russo to fund his research privately. *Reconsideration Order*, 76 Fed. Reg. at 51407 (Add. 142). Dr. Russo stated that due to NIDA's involvement he has not completed his clinical study of migraines. (App. 191).

3. Chemic Laboratories' Application To Study A Vaporizer Delivery Device.

In 2003, MAPS began working with Chemic Laboratories to develop a device that would allow research subjects to inhale heated, vaporized marijuana, rather than marijuana smoke. (Add. 57). In June 2003, Chemic applied to NIDA for ten grams of marijuana that would

be used to test the consistency of the device's performance. (Add. 58.) The proposed tests were mechanical only and would not have involved human consumption of marijuana. Because no human use was involved, FDA approval of the research was not required. (Add. 59). After failing to act for over a year, NIDA denied the request. (Add. 58). NIDA rejected the request based on its view that the project would not add significantly to the scientific knowledge base. *Id.*

4. MAPS's 2011 Application To Research Post-Traumatic Stress Disorder.

In April 2011, FDA approved a first-of-its-kind study to test whether marijuana can ease symptoms of post-traumatic stress disorder in combat veterans, including nightmares, insomnia, flashbacks, and anxiety. Brian Vastag, *Marijuana Study for Veterans with Trauma Faces Hurdle*, Wash. Post, October 2, 2011, at A8. The study was to be fully funded by MAPS; no federal funds were involved. On September 14, 2011, NIDA rejected MAPS' research protocol, offering contradictory explanations for the study's purported

drawbacks. (App. 195).[13] For example, one reviewer said that the study should only include experienced marijuana smokers as subjects, to minimize anxiety reactions. (App. 207). Another reviewer said the study should only include marijuana-naïve subjects to enhance the likelihood of an effective double-blind. (App. 202-03). Moreover, a spokesperson for HHS told the Washington Post that all five reviewers would need to come to an unanimous agreement before NIDA would approve marijuana for the study. Vastag, *supra*.

Standard Of Review

This is a direct appeal from a final decision of DEA, arising under provisions of the Administrative Procedures Act, 5 U.S.C. § 706(2)(A), and the Controlled Substances Act, 21 U.S.C. § 877.

Under the Administrative Procedures Act, DEA's denial of a license to Dr. Craker must be set aside if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C.

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[13] Letter from Sarah A. Wattenberg to Dr. Rick Doblin (Sept. 14, 2011), *available at* http://www.maps.org/mmj/OASH_MAPS_Coverletter_Doblin.pdf. Given its timing, this incident was not before Judge Bittner or DEA. However, judicial notice of NIDA's denial is appropriate in these circumstances. *See* Fed. R. Evid. 201(b)(2) (stating that judicially noticeable facts are those that "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned").

§ 706(2)(A). An agency's ruling is arbitrary and capricious "if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). A reviewing court "should not attempt itself to make up for such deficiencies," nor "supply a reasoned basis for the agency's action that the agency itself has not given." *Id.* Thus, "[i]t is well established that an agency's action must be upheld, if at all, on the basis articulated by the agency itself." *Id.* at 50.

DEA's interpretation of the Controlled Substances Act is subject to the two-step review articulated by the Supreme Court in *Chevron U.S.A., Inc. v. National Resources Defense Council*, 467 U.S. 837 (1984). Under the first step of this review, the court determines whether Congress has unambiguously indicated its intent. If so, that intent controls. *Id.* 842-43. If not, *Chevron*'s second step requires

deference to the agency's interpretation of the statute if it is "based on a permissible construction of the statute." *Id.* at 843.

DEA's interpretation of the Single Convention subject to *de novo* review. "'Treaty interpretation . . . is a purely legal exercise.'" *Acevedo-Reinoso v. Iberia Lineas Aereas de Espana S.A.*, 449 F.3d 7, 11-12 (1st Cir. 2006) (quoting *McCarthy v. Nw. Airlines, Inc.*, 56 F.3d 313, 316 (1st Cir. 1995)). "'Pure' legal errors require no deference to agency expertise, and are reviewed *de novo*." *L.S. Starrett Co. v. FERC*, 650 F.3d 19, 23 (1st Cir. 2011) (quoting *Knott v. FERC*, 386 F.3d 368, 372 (1st Cir. 2004)); *see also Providence Hosp. v. NLRB*, 93 F.3d 1012, 1016 (1st Cir. 1996) ("As to matters of law, appellate review is plenary.").

Moreover, in interpreting a treaty, "[t]he clear import of treaty language controls unless 'application of the words of the treaty according to their obvious meaning effects a result inconsistent with the intent or expectations of its signatories.'" *United States v. Stuart*, 489 U.S. 353, 365-66 (1989) (quoting *Sumitomo Shoji Am., Inc. v. Avagliano*, 457 U.S. 176, 180 (1982)). The interpretation of a treaty by the government agency charged with its enforcement is entitled to great

weight only as evidence of the intent or expectations of the United States as a signatory. *See Sumitomo*, 457 U.S. at 183-84.

Summary Of The Argument

Professor Craker's proposed registration to manufacture marijuana for medical research is consistent with both the public interest and the United States' international obligations. DEA's contrary conclusion was arbitrary and capricious because it relied on an interpretation of the Controlled Substances Act that is flatly inconsistent with the statute's plain language and DEA's own longstanding interpretation of the statute. DEA also misconstrued the Single Convention and relied on a fundamental misunderstanding of the United States' implementation of and compliance with the treaty. Because DEA's interpretation of the Single Convention is so transparently in error and is not a matter of agency discretion, we first address DEA's arbitrary and capricious application of the Controlled Substances Act.

1. DEA acted arbitrarily and capriciously in holding that Professor Craker's application is not consistent with the public interest. The text of the first statutory public interest factor directs DEA to

consider "maintenance of effective controls against diversion." 21 U.S.C. § 823(a)(1). Under the statute's plain meaning and DEA's longstanding interpretation, DEA may consider those factors only insofar as they are necessary to maintain effective diversion controls. *See Noramco of Delaware, Inc. v. DEA*, 375 F.3d 1148, 1153 (D.C. Cir. 2004). Although DEA did not find any risk of diversion, it not only considered those factors, it required Professor Craker to affirmatively prove that the current supply of marijuana for medical research is inadequate or that it is provided under inadequately competitive conditions.

Because Congress has directly spoken to the issue, DEA's new construction is not entitled to deference. Indeed, DEA's new interpretation is not even a "permissible construction of the statute" under *Chevron*. *See* 467 U.S. at 843. DEA's proffered explanations are unpersuasive, contravene the text of the statute, and were rejected by the D.C. Circuit in *Noramco*. Moreover, DEA has engaged in arbitrary and capricious decisionmaking by applying its new interpretation *only* to Professor Craker while shifting back to its longstanding and correct standard in applications involving other controlled substances.

Even under its incorrect standard, DEA acted arbitrarily and capriciously in concluding that the University of Mississippi's monopoly over marijuana cultivation fosters "adequately competitive conditions" and provides an "adequate and uninterrupted supply" of marijuana. With respect to competition, DEA's narrow focus on the price paid by researchers overlooks the non-price benefits of competition, and its reliance on the contractual bidding process employed by NIDA is at odds with the text and structure of the Controlled Substances Act. With respect to "supply," DEA improperly excluded from its consideration evidence that NIDA's review process obstructs access to marijuana for research projects approved by FDA.

2. DEA incorrectly interpreted the United States' international obligations when it concluded that the "medicinal" marijuana exemption in the Single Convention does not apply to bona fide medical research, and that, absent that exemption, Professor Craker's registration is prohibited by the Single Convention. The text, structure, and purpose of the Single Convention make plain that the "medicinal" marijuana exemption is broad, and that medical research is precisely the sort of beneficent purpose for which it was intended.

DEA's conclusions to the contrary rely on a hypertechnical definition of the term "medicinal opium" that was drawn from outdated pharmacopeia and from prior treaties, rather than from the Convention itself.

In any event, DEA's conclusion that Professor Craker's registration would contravene the Single Convention's restrictions on wholesale trade in marijuana is erroneous. DEA mistakenly believed that NIDA's scientific review of marijuana research is conducted under the Controlled Substances Act, and thus is an inescapable element of the United States' implementation of the Single Convention's restrictions. However, the scientific review of research protocols is expressly delegated to FDA, not NIDA. *See* FDA Staff Manual Guides Vol. II 1410.10(1)(A)(8). NIDA's review is required only by its contract with the University of Mississippi—not any statute or regulation. Accordingly, Professor Craker's proposed registration is consistent with the Single Convention by virtue of the fact that he will be supplying marijuana exclusively to FDA-approved and DEA-registered research; NIDA's approval is not required.

Argument

I. DEA's Conclusion That Professor Craker's Registration Is Not In The Public Interest Was Arbitrary And Capricious.

The Controlled Substances Act requires that DEA "shall register" an applicant to manufacture Schedule I substances if it finds that the application is consistent with the public interest and the United States' treaty obligations. 21 U.S.C. § 823(a). Of the six statutory public interest factors, the vast majority of DEA's discussion concerned § 823(a)(1), "maintenance of effective controls against diversion." *See Final Order*, 74 Fed. Reg. at 2123 (Add. 123). Yet DEA did not find any appreciable risk of diversion in Professor Craker's application.[14] Instead, DEA abandoned its longstanding interpretation of § 823(a)(1) and, relying on a subordinate clause of that provision, stated that it must limit the number of registrants unless Professor Craker could affirmatively show either that the current supply of marijuana is inadequate or that it is provided under inadequately

[14] In light of its interpretation of § 823(a)(1), DEA assessed the risk of diversion under the fifth public interest factor, which relates to the applicant's past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion. *See* 21 U.S.C. § 823(a)(5).

competitive conditions. DEA concluded that Professor Craker had not met that standard even though NIDA's exclusive control over the supply of marijuana has made it unavailable for some legitimate research.

A. Section 823(a)(1) Does Not Require Inadequate Supply Or Competition If There Is No Risk Of Diversion.

DEA's consideration of the adequacy of supply or competition in the absence of a risk of diversion is at war with the plain language of the Controlled Substances Act. Indeed, DEA applied the *opposite* interpretation—that it need not even consider supply or competition unless it found that registration posed a risk of diversion—for thirty years before Professor Craker's application. DEA crafted its new interpretation to deny Professor Craker's application *even while applying its traditional interpretation in other cases*. Because Professor Craker's application presents no significant risk of diversion, DEA should have found that § 823(a)(1) and the public interest weighed in his favor.

1. The Plain Language Of § 823(a)(1) Requires That Supply And Competition May Be Considered Only As A Means To Control Against Diversion.

The Court's "first step in interpreting a statute is to determine whether the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the case." *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997); *see also Chevron*, 467 U.S. at 842-43. Here, the language of the Controlled Substances Act directs DEA to consider, in determining the public interest:

> "(1) maintenance of effective controls against diversion . . . into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances 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." 21 U.S.C. § 823(a)(1).

Thus, the public interest factor that DEA is directed to consider is the "maintenance of effective controls against diversion." *Id.* DEA may limit registrations to the number of manufacturers of a drug that can provide an adequate supply under adequately competitive conditions, but only where that is necessary to "maintain[] . . . effective controls against diversion." *Id.* Even then, any such limitation must still foster

competition to supply the drug and preserve an adequate supply for legitimate purposes. *See id.*

Until Professor Craker's application, the DEA had itself applied this reading for more than thirty years. In 1974, DEA issued proposed regulations stating that "[DEA] presently interprets the statute as *requiring the registration* of otherwise qualified applicants to manufacture any controlled substance as long as the total number of registrants remains within the effective control by the Administration." Bulk Manufacture of Schedule I and II Substances, 39 Fed. Reg. 12138, 12138 (proposed April 3, 1974) ("*Bulk Manufacture*") (emphasis added). DEA stated further, "We believe that [this section of the statute] permits the Drug Enforcement Administration to restrict entry to a number of registrants constituting adequate competition *only when actually necessary to maintain effective controls against diversion*." *Id.*

DEA applied that plain language interpretation in 2002, stating that it "is '*required* to register an applicant who meets all the other statutory requirements, without regard to the adequacy of competition, if the Administration determines that registering another manufacturer will not increase the difficulty of maintaining effective

controls against diversion.'" Johnson Matthey, Inc., 67 Fed. Reg. 39041, 39043-44 (June 6, 2002) ("*Johnson Matthey*") (quoting *Bulk Manufacture*, 39 Fed. Reg. at 12138) (emphasis added). Thus "even if . . . competition in the market for [a controlled substance] was adequate," DEA "would still find it appropriate to register" an additional source of the controlled substance, where "each of the other factors to be considered in determining the public interest weigh in [the applicant's] favor." *Id.* at 39044 n.2.

This plain meaning interpretation of § 823(a)(1) has likewise been upheld by D.C. Circuit. In *Noramco*, the D.C. Circuit stated that "[t]he stated purpose of section 823(a)(1) is to effectively control against diversion." 375 F.3d at 1153. The court thus held that the section "*expressly directs* the DEA to limit competition *only as a means to achieve 'maintenance' of such control*." *Id.* (emphasis added).

Accordingly, if there is no risk of diversion, DEA must find that registration is consistent with the public interest factor of maintaining controls against diversion. Nothing in the text of the statute suggests that DEA may refuse to register an applicant based on

considerations of supply or competition where those factors have no effect on the maintenance of controls against diversion.

Because the statute's text is unambiguous "and the ordinary meaning of that unambiguous language yields a reasonable result, the interpretive odyssey is at an end." *Morales v. Sociedad Espanola de Auxilio Mutuo y Beneficencia*, 524 F.3d 54, 57 (1st Cir. 2008). Congress "has directly spoken to the precise question at issue," *Chevron*, 467 U.S. at 842-43, and DEA's holding that Professor Craker's application was not in the public interest should therefore be reversed.

2. DEA's New Interpretation Of § 823(a)(1) Is Not A Permissible Reading Of The Statute.

Contrary to the plain language of § 823(a)(1), DEA required Professor Craker to prove that existing marijuana cultivators "are unable to produce an adequate . . . supply of that substance under adequately competitive conditions." *Final Order*, 74 Fed. Reg. at 2119 (Add. 119). Even if the statute allowed DEA to limit registrants in the absence of a risk of diversion—which it does not—DEA's new interpretation impermissibly transforms competition and supply from public interest criteria that should be promoted into obstacles to a new registration "*unless* DEA concludes that the addition of a particular

applicant is necessary to produce 'an adequate and uninterrupted supply of [a given substance] under adequately competitive conditions.'" *Id.* at 2127 (Add. 127) (emphasis added). DEA offered three justifications for this reading, none of which withstands scrutiny.

First, DEA argued that it must limit the number of registrants based on supply and competition "to avoid reading the limiting language of paragraph 823(a)(1) in a superfluous manner." *Id.* at 2121 (Add. 121). DEA noted that, elsewhere, the Controlled Substances Act contains a similar public interest factor that requires consideration of effective diversion controls without mentioning supply and competition. *See* 21 U.S.C. § 823(d)(1) (registration requirements for manufacturers of Schedules III-V substances). DEA contends that the additional language in § 823(a)(1) means that Congress intended supply and competition to be considered in every application under that section regardless of the risk of diversion.

In *Noramco*, the D.C. Circuit rejected the very argument that DEA now advances. 375 F.3d at 1154. As the D.C. Circuit stated, the text of § 823(a)(1) states that DEA "must still ensure that the number of importers and manufacturers is limited where such

limitation is necessary to maintain effective diversion controls; it is only where . . . DEA affirmatively finds that diversion will be effectively controlled without regard to limiting competition that it is not required to inquire into market competitiveness." *Id.*

Second, DEA argued that two public interest factors of § 823(a) address diversion, with the first factor directed at "preventing diversion on a registrant-wide scale," whereas the fifth factor "can be viewed as preventing diversion on an individual registrant basis." *Final Order*, 74 Fed. Reg. at 2128 (Add. 128). DEA did not explain, however, why such a distinction would permit it to evaluate the adequacy of supply or competition where there is no diversion concern. Even if the fifth factor addresses diversion with respect to an individual applicant, the first factor would still require that supply and competition concerns be analyzed in the context of "registrant-wide" controls against diversion. In other words, absent any concern that an additional supplier would increase the system-wide risk of diversion, DEA need not and may not deny an application based on the adequacy of supply and competition.

Third, DEA purported to look to the legislative history of § 823(a)(1), examining language from a 1960 predecessor to the Controlled Substances Act and certain hearing testimony. *Id.* at 2128-29 (Add. 128-29). But in 1974—when the passage of the Controlled Substances Act in 1970 was in the much more recent past—DEA stated that "[t]he legislative history of the Act clearly supports [DEA's now former] construction of the Act." *Bulk Manufacture*, 39 Fed. Reg. at 12138. DEA stated that "[t]he sole purpose of section [823(a)] was the prevention of diversion. Nowhere in the legislative history of the Act is there any indication that Congress based section [823(a)(1)] on a determination that fully effective competition of controlled substances or entry into these markets is in itself undesirable." *Id.* "Nor is the Administrator aware of any reason to limit competition to an 'adequate' level in the absence of a danger to the maintenance of effective controls against diversion." *Id.*

Despite that contemporaneous analysis of the legislative history, DEA now relies on language from the equivalent section of the Narcotics Manufacturing Act of 1960—which was *replaced* by the Controlled Substances Act—stating that DEA should consider limiting

registrants to "the smallest number of establishments which will provide an adequate and uninterrupted supply" of the substance. *Final Order*, 74 Fed. Reg. at 2128 (quoting Narcotics Manufacturing Act, 75 Stat. 55 (1960)) (Add. 128). DEA interprets the change from this provision to the language of § 823(a)(1) as "rais[ing] the ceiling on the number of manufacturers from that which can produce 'an adequate and uninterrupted supply' to a consideration of that which can product 'an adequate and uninterrupted supply . . . under adequately competitive conditions." *Id.* DEA thus concluded that Congress "placed the burden on the applicant" to "put forth evidence demonstrating either inadequate supply or inadequate competition." *Id.* at 2129 (Add. 129).

DEA's analysis of the legislative history is flawed. Although the Controlled Substances Act expanded the consideration of effective diversion controls to include competition in addition to supply, the Act *removed* the prior language requiring DEA to consider limiting registrants to "the smallest number of establishments." As the Supreme Court has stated, "When Congress acts to amend a statute, we presume it intends its amendment to have real and substantial effect."

Stone v. INS, 514 U.S. 386, 397 (1995). If Congress had intended that the number of registered manufacturers remain limited to "the smallest number of establishments" that could provide an adequate supply under adequately competitive conditions, it would not have *removed* that language from the statute. DEA's imposition of a "ceiling" at the "smallest number" of registrants is thus contrary to Congress's expressed intent.

Indeed, DEA has adopted a regulation contrary to its newfound interpretation of § 823(a)(1)—allowing DEA to register a number of importers that *exceeds* the number necessary to provide an adequate supply. The regulation provides, "In order to provide adequate competition, the Administrator shall not be required to limit the number of manufacturers in any basic class to a number less than that consistent *with maintenance of effective controls against diversion* solely because a smaller number is capable of producing an adequate and uninterrupted supply." 21 C.F.R. § 1301.33(b) (emphasis added). Contrary to DEA's current view, section 1301.33 suggests that the "ceiling" is the number that is "consistent with maintenance of effective controls against diversion." *Id.*

In short, nothing in the statute permits—much less requires—DEA to find that an application is not in the public interest under § 823(a)(1) where there is no risk of diversion. *A fortiori*, DEA cannot impose a free-standing condition that an applicant show that the current supplier "[is] unable to produce an adequate . . . supply of that substance under adequately competitive conditions." *Final Order*, 74 Fed. Reg. at 2119 (Add. 129). Because DEA's previous interpretation of § 823(a)(1) is required by the statute, DEA's conclusion that Professor Craker would effectively control against diversion, *id.* at 2126 (Add. 126), obviated the need for any inquiry into the adequacy of supply and competition. DEA thus acted arbitrarily and capriciously when it held Professor Craker's application was not in the public interest despite finding that there would not be a risk of diversion.

3. DEA's Shifting Interpretations Of § 823(a)(1) Evidence Arbitrary And Capricious Decisionmaking.

DEA's new interpretation is also arbitrary and capricious because DEA seeks to apply it to Professor Craker even while it applies a different standard in other cases.

As detailed above, DEA first recognized the import of the statute's plain language in 1974. *Bulk Manufacture*, 39 Fed. Reg. at 12138 (emphasis added). In 2002—while Professor Craker's original application was pending—DEA applied that interpretation in *Johnson Matthey*, 67 Fed. Reg. at 39043-44. DEA then successfully defended its original interpretation in *Noramco*, which was decided on July 23, 2004. 375 F.3d at 1153 (holding that § 823(a)(1) *did not* require DEA to consider supply and competition except "as a means to achieve 'maintenance' of . . . controls [against diversion]").

Less than five months later, on December 10, 2004, DEA issued Professor Craker the order to show cause in which it first announced a new interpretation of § 823(a)(1), stating: "DEA *must limit* the number of producers of research-grade marijuana to that which can provide an adequate and interrupted supply under adequately competitive conditions." (App. 14) (emphasis added).

Although an agency is not precluded from changing its interpretation of the statutes it administers, "the requirement that an agency provide reasoned explanation for its action would ordinarily demand that it display awareness that it *is* changing position." *FCC v.*

Fox Television Stations, Inc., 556 U.S. 502, 129 S. Ct. 1800, 1811 (2009). Accordingly, "[a]n agency may not, for example, depart from a prior policy *sub silentio* or simply disregard rules that are still on the books." *Id.* And "of course the agency must show that there are good reasons for the new policy." *Id.* An agency's change in position thus can be upheld so long as "the new policy is permissible under the statute, [ ] there are good reasons for it, and [ ] the agency *believes* it to be better." *Id.*

Here, DEA did not provide any reason—much less "good reasons"—for its abandonment of the interpretation of § 823(a)(1) it advanced in *Noramco* in favor of the interpretation announced in the order to show cause. DEA's brief in *Noramco* was filed on May 1, 2003—nearly two years after Professor Craker submitted his original application. Nevertheless, only a few months after winning approval of its interpretation from the D.C. Circuit, DEA applied the opposite standard to Professor Craker. And then DEA *changed positions again and yet again* after that.

On February 17, 2006—two years after the order to show cause—DEA applied its original interpretation of § 823(a)(1) in granting

the application of Chattem Chemicals, Inc. to import various Schedule II substances. *See* Chattem Chemicals, Inc., 71 Fed. Reg. 9834 (Feb 27, 2006) ("*Chattem*"). DEA found that Chattem "has met its burden of proof" to show that its registration "will not significantly interfere with the maintenance of effective controls against diversion." *Id.* at 9838. DEA then turned to the question of adequate competition and supply, reviewing what it termed the "DEA policy . . . of *not considering the adequacy of competition in* [ ] *the registration of bulk manufacturers of Schedule I and II controlled substances . . . if the Deputy Administrator finds that there are sufficient controls against diversion*." *Id.* (emphasis added). DEA determined that it would "follow the policy applied in Johnson Matthey and approved by the appellate court in *Noramco*." *Id.* DEA concluded: "Accordingly, in light of the Deputy Administrator's finding above concerning the lack of evidence of potential diversion, the Deputy Administrator will not consider the adequacy of competition or supply in this matter." *Id.*

Then, without mentioning *Chattem*, DEA shifted positions yet again when it denied Professor Craker's application. DEA did not acknowledge or explain its changing view of the statute.

DEA is applying a special standard to Professor Craker's application for the registration of marijuana that it does not apply to other applications. For applicants who seek to import other Schedule I and II drugs, DEA requires only a showing that the proposed registration would not increase the risk of diversion. *See Noramco*, 375 F.3d at 1153; *Chattem*, 71 Fed. Reg. at 9838; *Johnson Matthey,* 67 Fed. Reg. at 39043. But if an applicant wishes to manufacture marijuana, DEA requires that he affirmatively show inadequate supply or competition even in the absence of any diversion risk. There is no statutory or other basis for this approach.

B. In The Alternative, DEA Arbitrarily And Capriciously Applied The "Adequate Supply" And "Adequate Competition" Factors.

Even if DEA were permitted to consider "adequate supply" and "adequate competition" under § 823(a)(1) where there is no risk of diversion, its finding that those factors weighed against Professor Craker's registration was arbitrary and capricious.

Under DEA's interpretation, Professor Craker was required to show that "either supply or competition is inadequate." *Final Order*, 74 Fed. Reg. at 2119 (Add. 119). Professor Craker demonstrated that

both were inadequate. With regard to competition, DEA abused its discretion by applying a definition of competition at odds with the plain meaning and import of the statute. With regard to supply, DEA employed a circular definition of "supply" that improperly excluded from its consideration all evidence that NIDA's review process obstructs access to marijuana for research projects approved by FDA.

1. DEA's Definition Of Competition Is Contrary To The Plain Meaning Of The Statute.

There is no dispute that the University of Mississippi holds a monopoly on the supply of marijuana for medical and scientific research purposes. DEA's holding that this monopoly constitutes "adequately competitive conditions" is not a permissible construction of the Controlled Substances Act.

Monopoly is the opposite of competition. "Competition" is "[r]ivalry between *two or more* businesses striving for the same customer or market." American Heritage Dictionary of the English Language 271 (4th ed. 2009) (emphasis added). Monopoly is "[a] company or group having *exclusive* control over a commercial activity." *Id.* at 850 (emphasis added). Agreements that create or attempt to create a monopoly are "per se" violations of the antitrust laws because

their "nature and necessary effect are so plainly anticompetitive that no elaborate study of the industry is needed to establish their illegality." *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 692 (1978).

Congress's use of the phrase "adequately competitive conditions" expresses the legislative judgment that, even with regard to the supply of Schedule I and II drugs, competition is preferable to monopoly. By limiting the marijuana available for legitimate scientific purposes to a monopoly supplier, however, DEA concluded that "adequately competitive conditions" does not require any competition at all.

DEA based this remarkable reading of the statue on two factors, neither of which is persuasive. *First*, DEA determined that it could analyze "adequately competitive conditions" under § 823(a)(1) solely with reference to "the historical and present prices charged to those who lawfully acquire the controlled substance from the existing registered bulk manufacturers." *Final Order*, 74 Fed. Reg. at 2121 (Add. 121). Because NIDA provides marijuana to researchers "at cost or for free," DEA found no basis to conclude that cost is unreasonable, or that costs would be lower if Professor Craker's application were

granted. *Id.* DEA thus concluded that Professor Craker "has not demonstrated that competition is inadequate . . . by showing those prices to be unreasonable." *Id.*

DEA's reasoning that "at cost" pricing by a monopoly is reasonable disregards that "[t]he heart of our national economic policy long has been faith in the value of competition." *Standard Oil Co. v. FTC*, 340 U.S. 231, 248 (1951). The Sherman Act, for example, like § 823(a)(1), "reflects a legislative judgment that ultimately competition will produce not only lower prices, but also better goods and services." *Nat'l Soc'y of Prof'l Eng'rs*, 435 U.S. at 695. "The assumption that competition is the best method of allocating resources in a free market recognizes that all elements of a bargain—quality, service, safety, and durability—and not just the immediate cost, are favorably affected by the free opportunity to select among alternative offers." *Id.* DEA rejected Professor Craker's argument that "competitive conditions would, as they usually do, benefit the researcher-consumer" for lacking an "evidentiary basis." *Final Order*, 74 Fed. Reg. at 2121 (Add. 121). But laws of economics do not require empirical proof in every case in order to remain true.

Second, DEA concluded that "adequately competitive conditions" exist in the market for research marijuana because NIDA periodically conducts a competitive bidding process for the contract to provide research marijuana. That reading of "adequately competitive conditions" is not supported by the plain meaning of the statute and is inconsistent with DEA's own regulations regarding its consideration of competition. Section 823(a)(1) states that DEA may consider[15] "limiting" the registrations to manufacture a given controlled substance "to a number of establishments which can produce an adequate and uninterrupted supply . . . under adequately competitive conditions."

This language expressly requires DEA to consider what "number of establishments" is sufficient for the two factors listed in the statute. That is, DEA is directed to consider two questions: (1) How many establishments are enough to produce an adequate and uninterrupted supply?; and (2) How many establishments are enough to produce adequate competition? DEA's answer—that NIDA periodically

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[15] In the context of "maintenance of effective controls against diversion." *See supra* part I.A.

entertains bids to be the sole supplier for all research purposes—is not responsive to the questions Congress directed DEA to consider.

DEA has promulgated a regulation setting out the factors it will consider "[i]n determining whether competition among the domestic manufacturers of a controlled substance is adequate." 21 C.F.R. § 1301.34(d). DEA's factors make clear that it interprets "adequately competitive conditions" to mean competition in the market for the controlled substance—not competition for a contract. For example, one factor is "[t]he extent of service and quality competition among the domestic manufacturers *for shares of the domestic market*," including "shifts in market shares" and "shifts in individual customers among domestic manufacturers." *Id.* § 1301.34(d)(2) (emphasis added). Other factors include "price rigidity" and "competitive restraints imposed upon domestic manufacturers." *Id.* § 1301.34(d)(1), (4). Each of these factors assumes that competition is being analyzed in the market for the drug involved. Interpreting "adequately competitive conditions" to be satisfied by DEA's bidding process would render DEA's own regulations nonsensical.

Moreover, competition for a monopoly contract is not the same as competition to provide goods or services. Once the contract is granted, the monopolist has no incentive to reduce costs or prices, or to increase quality or service. Because neither a monopoly on the supply of research marijuana, nor a "competitive" bidding process to become the monopoly supplier can provide "adequately competitive conditions," Professor Craker showed that competition for the supply of marijuana is inadequate within the meaning of § 823(a)(1).

2. DEA's Conclusion That Supply Is Adequate Was Arbitrary And Capricious.

DEA also arbitrarily and capriciously applied the "adequate supply" factor by improperly narrowing the scope of the inquiry when it effectively concluded that the current supply of marijuana is adequate so long as it suffices to supply all NIDA-approved research.

In its examination of the "adequate supply" factor, DEA concluded that, because there is a large amount of marijuana currently in "the NIDA vault," that amount is sufficient to satisfy "all current and foreseeable research needs of the United States." *Final Order*, 74 Fed. Reg. at 2119 (Add. 119). DEA rejected Professor Craker's argument that the supply of marijuana is inadequate for another reason—through

its monopoly with the University of Mississippi, NIDA makes marijuana available only to those medical and scientific research projects that it approves. DEA held that NIDA-approved research is the only legitimate research that must be supplied under the Controlled Substances Act. *See id.* at 2120 (Add. 120).

DEA's interpretation of "supply" assumes the premise on which it is based. In DEA's view, the supply is adequate so long as the projects approved by NIDA are supplied. But, by statute, Congress has delegated to FDA—not to NIDA—the responsibility of evaluating the efficacy and safety of drug research. 21 U.S.C. § 393(b). FDA thus reviews research protocols and conducts "an assessment of the scientific quality of the clinical investigations." 21 C.F.R. § 312.22(a); *see also* 21 U.S.C. § 355. Accordingly, the adequacy of supply must be measured against the current provider's ability to supply marijuana to legitimate research projects approved by FDA, not NIDA.

It is undisputed that the current supplier—because of NIDA's review process—has not been able to meet the demand for marijuana research projects approved by FDA. NIDA did not approve research projects submitted by Dr. Abrams and Dr. Russo. DEA did not

deny that these projects were approved by FDA or that they were rejected by NIDA. Instead, DEA discounted certain projects because they occurred before HHS issued revised guidelines for approving marijuana research in 1999, and it discounted the rest based on its assertion that any research not approved by NIDA is not "bona fide" research under 21 U.S.C. § 823(f).

Contrary to the DEA's interpretation, NIDA approval does not qualify research as "bona fide" under 21 U.S.C. § 823(f). Although that section requires the Secretary of HHS to review proposed Schedule I and II controlled substances researchers' "qualifications and competency" as well as "the merits of the research protocol," NIDA does not conduct this review. Instead, HHS has delegated those functions to the FDA Commissioner. *See* FDA Staff Manual Guides Vol. II 1410.10(1)(A)(8). [16] FDA review therefore satisfies that provision of the statute.

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[16] This delegation of authority was originally codified at 21 C.F.R. § 5.10(a)(8). In 2004, FDA removed the delegation from the Code of Federal Regulations, stating that "the regulations on delegations of authority are no longer necessary" because FDA makes the information available on its website. Removal of Delegations of Authority and Conforming Changes to Regulations, 69 Fed. Reg. 17285, 17285 (continued…)

Moreover, § 823(f) sets out the requirements for DEA registration of a researcher, not the requirements for registration of a controlled substances manufacturer. There was no evidence before Judge Bittner that Dr. Abrams, Dr. Russo, and Chemic Laboratories were denied registration under § 823(f). Rather, they were denied marijuana based on NIDA's separate review process.

DEA's reliance on NIDA's change in procedures in 1999 is likewise misplaced. As DEA acknowledged in its order on reconsideration, NIDA's denial of marijuana to both Dr. Russo and to Chemic Laboratories occurred *after* the new guidelines were in place. *See Reconsideration Order*, 76 Fed. Reg. at 51407 (Add. 139). More recently, NIDA rejected a proposed study of the ability of marijuana to ease the effects of post-traumatic stress disorder in veterans. The rejection of the PTSD study occurred this year, well after the 1999 change.

* * *

(April 2, 2004). It is currently available at http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm080711.htm.

In sum, even under DEA's erroneous reading of § 823(a)(1), it abused its discretion in finding that the current supply of marijuana for medical and research purposes is adequate, and that it is provided under adequately competitive conditions. The public interest factor of § 823(a)(1) thus weighs in Professor Craker's favor whether considered in light of the maintenance of adequate controls *or* in light of the adequacy of competition and supply.

II. The DEA Incorrectly Interpreted The United States' International Obligations.

DEA's conclusion that Professor Craker's application is inconsistent with the Single Convention is fundamentally erroneous in two respects: *First,* the plain language of the treaty exempts "medicinal" marijuana from the controls it prescribes. *Second*, even if Professor Craker were not manufacturing "medicinal" marijuana, Professor Craker's compliance with system of DEA registration and FDA review established by the Controlled Substances Act satisfies the treaty.

Article 28 of the treaty requires any signatory nation permitting cultivation of marijuana to "apply thereto the system of controls as provided in article 23 respecting the control of the opium

poppy." *Id.* Art. 28 ¶ 1 (Add. 12). Article 23 of the Single Convention requires a country that permits the cultivation of opium poppy and the production of opium to apply five specific controls related to licensing, possession, and trade:

> "a) The Agency shall designate the areas in which, and the plots of land on which, cultivation of the opium poppy for the purpose of producing opium shall be permitted.
>
> b) Only cultivators licensed by the Agency shall be authorized to engage in such cultivation.
>
> c) Each license shall specify the extent of the land on which the cultivation is permitted.
>
> d) All cultivators of the opium poppy shall be required to deliver their total crops of opium to the Agency. The Agency shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest.
>
> e) The Agency shall, in respect of opium, have the exclusive right of importing, exporting, wholesale trading and maintaining stocks other than those held by manufacturers of opium alkaloids, medicinal opium or opium preparations. Parties need not extend this exclusive right to medicinal opium and opium preparations." Single Convention, Art. 23 ¶ 2 (Add. 11).

In considering whether Professor Craker's application is consistent with the United States treaty obligations, DEA focused on

the requirement that a government agency have the "exclusive right" of "wholesale trading," finding that if granted, Professor Craker's cultivation would violate this provision. 74 Fed. Reg. at 2114 (Add. 114). DEA concluded that the exemption for "medicinal" opium would not apply because "there is currently no such thing in the United States as 'medicinal cannabis.'" *Id.* at 2116 (Add. 116). Both conclusions are indefensible.

A. Professor Craker's Distribution Is Exempt From The Single Convention Under The Treaty's "Medicinal" Marijuana Exemption.

Article 23 of the Single Convention contains a broad exemption from the government's exclusive rights for opium used for medical purposes. The exemption applies not only to "medicinal opium" but also to "opium alkaloids" and "opium preparations." Single Convention, Art. 23 ¶ 2(e) (Add. 11). The exemption reflects the treaty's recognition "that the medical use of narcotic drugs continues to be indispensible for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes." *Id.* Preamble (Add. 7).

Through Article 28, the Convention applies an exemption to marijuana equivalent to the exemption for medicinal opium. Article 28 says that countries "shall apply" the same system of controls to marijuana as to opium. Specifically, "[i]f a party permits the cultivation of the cannabis plant for the production of cannabis or cannabis resin, it shall apply thereto the system of controls as provided in article 23 respecting the control of the opium poppy." *Id.* Art. 28 ¶ 1 (Add. 12). Employing a similar structure, Paragraph 1 of Article 23 applies the opium controls to "[a] party that permits the cultivation of the *opium poppy* for the production of *opium*." *Id.* Art. 23 ¶ 1 (Add. 11) (emphasis added). The structure of the two articles thus equates "the cannabis plant" with "the opium poppy" and "cannabis or cannabis resin" with "opium."[17]

When Article 23 is applied to marijuana, the exemption for "medicinal opium" thus translates into an exception for "medicinal

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[17] The Convention defines "cannabis plant" as "any plant of the genus Cannabis," and "cannabis" as "the flowering or fruiting tops of the cannabis plant." Single Convention, Art. 1 ¶ 1(b), (c) (Add. 7). "Cannabis resin" is defined as "the separated resin, whether crude or purified, obtained from the cannabis plant." *Id.* ¶ 1(d) (Add. 7).

cannabis" (and "medicinal cannabis resin"). "Medicinal opium" is defined by the treaty as opium "which has undergone the processes necessary to adapt it for medicinal use." Art. 1 ¶ 1(o) (Add. 7). By extension, "medicinal cannabis" means marijuana which has undergone the processes necessary to adapt it for medicinal use. Opium poppy and marijuana are, of course, different plants, and they are used differently for medicinal purposes. In the case of marijuana as a potential botanical medicine, the plant is appropriate for medicinal use once it is dried and denuded of leaves, seeds, and stems.

Professor Craker applied to DEA to cultivate marijuana exclusively for DEA-registered medical research. Marijuana used for bona fide medical research is necessarily being used "medicinally." This view is embodied in the Single Convention itself. The treaty's general requirement to prohibit drugs in the same schedule as marijuana contains an express exception "for amounts which may be necessary *for medical and scientific research* only, *including clinical trials* therewith to be conducted under or subject to the direct supervision and control of the Party." *Id.* Art. 2 ¶ 5(b) (Add. 8) (emphasis added). Because Professor Craker seeks to cultivate exclusively "medicinal marijuana,"

his registration would not contravene the Single Convention because the treaty exempts medicinal marijuana from the government's exclusive right of wholesale trading.

B. DEA's Interpretation Contravenes The Text And Purpose Of The Single Convention.

In the face of the treaty's plain language and its purpose, DEA employed a crabbed reading of "medicinal opium" that flatly contradicts the definition contained in the text of the Convention.

As noted above, the treaty defines "medicinal opium" as opium "which has undergone the processes necessary to adapt it for medicinal use." Single Convention, Art. 1 ¶ 1(o) (Add. 7). Rather than apply this straightforward definition to marijuana—as directed by Article 28 of the treaty—DEA relied on earlier treaties and outdated pharmacopia to conclude that the term referred exclusively to "a product which had not only been extracted from the opium poppy but which had also undergone several further processes (including the addition of another substance, lactose) to prepare it for use in other drugs and to obtain a specific and standardized content of morphine." *See Final Order*, 74 Fed. Reg. at 2116 (Add. 116). DEA noted that the term was replaced by "powdered opium" in pharmacopoeia published in

the late 1960s and is no longer used in current pharmacopoeia. DEA thus proclaimed that "the term 'medicinal opium' is now obsolete." *Id.* DEA stated, "The term's obsolescence itself provides ample reason to disregard it" in determining the United States' treaty obligations. *Id.*

DEA next asserted that there can be no "medicinal marijuana" because there were "recognized standards" for the "manufacture and composition" of medicinal opium, whereas there are no such standards for marijuana, nor is there currently an accepted medical use or FDA approval of marijuana. *Id.* DEA thus read the "medicinal marijuana" exemption out of the Convention altogether with the declaration that "there is currently no such thing in the United States as 'medicinal cannabis." *Id.*

DEA's tortured reasoning cannot avoid the plain meaning of the treaty. This is because "[t]he clear import of treaty language controls unless application of the words of the treaty according to their obvious meaning effects a result inconsistent with the intent or expectations of its signatories." *Stuart*, 489 U.S. at 365–66 (internal quotation and citations omitted). Here, the treaty itself broadly defines "medicinal opium" in a manner that readily applies to medicinal

marijuana, rendering the highly technical definitions of the same term used in other treaties or in pharmacopoeia irrelevant.

DEA argues that the Commentary to the Single Convention states that the treaty "'follows earlier narcotics treaties in defining 'medicinal opium' as a special form of opium in which that drug is used for medical treatment.'" *Final Order*, 74 Fed. Reg. at 2116 (quoting Commentary on the Single Convention at 21-22) (Add. 116). And indeed, the Commentary does describe the types of processes used to adapt opium for medicinal use. (App. 95). But the Commentary does not purport to supplant the definition of "medicinal opium" contained in the treaty, nor could it. Rather, the discussion simply serves to explain what processes are "necessary to adapt [opium] for medicinal use." Single Convention Art. 1. ¶ 1(o) (Add. 7). That different processes are used to adapt marijuana for medicinal use does not mean that there is "no such thing" as medicinal marijuana.

Moreover, the definitions of the earlier treaties cited by DEA expressly employed narrow definitions of "medicinal opium" in order to specifically identify the pharmacological product being regulated. The Single Convention's use of a broad, general definition of "medicinal

opium" shows an intentional *departure* from historic usage. *Cf.*, *e.g.*, *Oregon Dep't of Fish & Wildlife v. Klamath Indian Tribe*, 473 U.S. 753, 768 (1985) ("The language of the [later treaty] must be read with these terms of the [earlier treaty] in mind.").

DEA's argument that the term "medicinal opium" is now obsolete and thus may be "disregard[ed]" likewise contravenes the text of the Convention. Regardless of how the term is used in other contexts, it has a particular definition in the Single Convention, a definition that is useful and necessary in determining how the treaty's controls related to opium apply to marijuana. The lack of "recognized standards" for the medicinal use of marijuana is likewise irrelevant to how the definition of "medicinal opium" should be applied to marijuana.

DEA fundamentally misconstrued the Convention by treating the term "medicinal opium" as if it were defined by everything except the words used in the Convention.

C. DEA Registration And FDA Approval Satisfy The Single Convention's Requirement Of Governmental Controls Over Marijuana Distribution.

Even if Professor Craker were not manufacturing "medicinal" marijuana, his proposed registration would be consistent

with the Single Convention because it complies with governmental controls restricting the wholesale trade in marijuana. DEA's conclusion to the contrary was premised on a misunderstanding of the statutory and regulatory authority of NIDA.

Articles 23 and 28 of the Single Convention collectively prescribe five governmental controls over the cultivation of marijuana. The first three controls relate to the licensing of cultivators. Single Convention, Art. 23 ¶¶ 2(a)-(c) (Add. 11). Through the Controlled Substances Act, Congress assigned to this function to the Attorney General, who has delegated that authority to DEA. 28 C.F.R. § 0.100(b).

The fourth control requires a national agency to purchase and take physical possession of the crops. Single Convention, Art. 23 ¶ 2(d) (Add. 11). As both Judge Bittner and DEA found, no government agency actually takes physical possession of any marijuana cultivated by the University of Mississippi. (Add. 95); *Final Order*, 74 Fed. Reg.

at 2114-15 (Add. 114-15).[18] This requirement may be satisfied by detailed government regulation of persons possessing the substance. Indeed, the postratification conduct of the parties to the Single Convention has demonstrated that parties "are free to construe the term 'physical possession' as they see fit." (Add. 95). For example, the United Kingdom's protocol regarding the manufacture of marijuana states, "whenever a producer harvests cannabis, . . . a form of constructive purchase and possession will be deemed to have taken place between the Agency and producer with actual ownership and possession reverting immediately to the producer for the purposes for which the license was granted." (App. 120).

The final control is the government's exercise of an exclusive right over "importing, exporting, wholesale trading and maintaining stocks." Single Convention, Art. 23 ¶ 2(e) (Add. 11). As the Commentary to the Single Convention explains, the purpose of this

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[18] DEA did note that, although no one takes physical possession of the marijuana grown by the University of Mississippi, its contract with NIDA could be viewed as satisfying this requirement. *Reconsideration Order*, 76 Fed. Reg. at 51410 n.22 (Add. 142).

"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." (App. 105).

Congress addressed this final control by structuring the Controlled Substances Act to require a "closed system" of distribution in which *all* persons in the legitimate distribution chain of a controlled substance must obtain DEA registration. *See* 21 U.S.C. §§ 822-823. 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.

Again, the United Kingdom's system is similar. It formed a National Cannabis Agency to implement Article 28 through licensing. Under that agency's protocol, "any import, export or wholesale dealing from a licensed Agency site will be deemed to have taken place with the

explicit authority of Agency." (App. 120). Contrary to established legal principles, *see, e.g.*, *Medellin v. Texas*, 552 U.S. 491, 517 (2008); *Sanchez-Llamas v. Oregon*, 548 U.S. 331, 344 & n.3 (2006), DEA eschewed any reliance on the U.K.'s protocol. *See generally Zicherman v. Korean Air Lines Co.*, 516 U.S. 217, 226 (1996) ("Because a treaty ratified by the United States is not only the law of this land . . . but also an agreement among sovereign powers, we have traditionally considered as aids to its interpretation the negotiating and drafting history (*travaux preparatoires*) and the postratification understanding of the contracting parties.").

DEA denied Professor Craker's application because it believed that NIDA reviewed individual research protocols as part of DEA's registration process under the Controlled Substances Act, and thus was precisely the control "over the wholesale distribution of marijuana that the Single Convention demands." *Final Order*, 74 Fed. Reg. at 2115 (Add. 115). According to DEA, Professor Craker sought registration "so that MAPS—rather than HHS/NIDA—can control the distribution of marijuana," which DEA viewed as "antithetical" to the Convention. *Id.* at 2115, 2117 (Add. 115, 117).

As described above,§ 823(f) of the Controlled Substances Act requires that HHS "determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol." 21 U.S.C. § 823(f); *see also* 21 C.F.R. § 1301.32. But HHS expressly delegated this function to FDA, *not* to NIDA. *See* FDA Staff Manual Guides Vol. II 1410.10(a)(8).

DEA incorrectly stated that "[t]he process HHS has established to assess the scientific merit of proposed research studies involving marijuana is that described in the 1999 [guidelines]." *Final Order*, 74 Fed. Reg. at 2120 (Add. 120). But the 1999 guidelines cited by DEA address how NIDA determines which medical research projects to supply with marijuana. They do not address the registration of researchers under the Controlled Substances Act. Indeed, NIDA's Director has stated that "it is not NIDA's role to . . . contribute to DEA licensing procedures." (App. 193). Likewise, the Assistant to the Director testified that "we only provide the peer review [process] for materials that are provided by the government. So if somebody has materials that are not provided by the government, NIH or NIDA, PHS wouldn't get involved." (Test. of Steven Gust, Dec. 14, 2005, Tr. at

1648:20-1649:2). He further acknowledged that a privately funded researcher could "obtain the appropriate DEA Schedule I registration, have their protocol reviewed and approved by the FDA, and *still* be denied access to NIDA marijuana." (Add. 64) (emphasis added).

Because of its confusion, DEA repeatedly mischaracterized Professor Craker as "seeking through his application to dismantle the existing Government control over the distribution of cannabis." *Final Order*, 74 Fed. Reg. at 2117 (Add. 117). Judge Bittner correctly rejected this same argument: "The government contends that granting [Professor Craker's] application would amount to circumventing the Department of Health and Human Services policy with respect to providing marijuana to researchers . . . . But, as quoted above, the [1999] guidance by its own terms applies to marijuana that the Department of Health and Human Services makes available, not marijuana that might be available from some other legitimate source." (Add. 99).

Professor Craker has consistently maintained that he will distribute the marijuana he grows exclusively to researchers holding DEA registrations and with the concomitant FDA approval. DEA

dispatched this assurance as "effectively arguing that the provision of the Single Convention requiring a Government monopoly over the wholesale distribution of marijuana may be jettisoned whenever an applicant for registration promises to comply with the DEA regulations governing registration and security." *Reconsideration Order*, 76 Fed. Reg. at 51410 (Add. 142). When Professor Craker attempted to explain that FDA in fact conducts the very review that DEA believed NIDA was performing, DEA erroneously analyzed the FDA process for reviewing investigational new drug applications under 21 U.S.C. § 355, instead. *See id.* at 51408 (Add. 140). Only by evaluating the wrong process altogether did DEA conclude that FDA review is not a substitute for NIDA review.[19] *See id.* at 51409 (Add. 141).

In sum, DEA and Professor Craker *agree* about the controls required by the Single Convention. They also *agree* about which

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[19] DEA also failed to recognize that the very fact that Dr. Russo held a DEA registration at the time NIDA denied him marijuana means that the scientific review required under 21 U.S.C. § 823(f) *had already been completed. See id.* at 51408 (Add. 140) ("Thus, while the FDA appears to have concluded that allowing Dr. Russo's and Dr. Abrams's Phase 1 studies to proceed would not have presented an unacceptable risk of harm to the human research subjects, there is . . . no basis to conclude that FDA determined that the studies were scientifically meritorious within the meaning of 21 U.S.C. 823(f).").

statutory provision in the Controlled Substances Act implements those controls. They disagree only with respect to which agency effectuates those controls by reviewing research protocols on behalf of HHS, and in this regard DEA's conclusion is unmistakably erroneous. Because this Court must judge the propriety of DEA's action "'solely by the grounds invoked by the agency,'" DEA's erroneous conclusion must be reversed. *Wedgewood Village Pharmacy v. DEA*, 509 F.3d 541, 550 n.13 (D.C. Cir. 2007) (quoting *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947)).

Conclusion

For the foregoing reasons, Professor Craker's petition for review should be granted, and DEA's order should be reversed and remanded with instructions to grant Professor Craker's registration under 21 U.S.C. § 823(a).

Respectfully submitted,

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December 15, 2011

CERTIFICATE OF RULE 32(a) COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because the brief contains 13,513 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because the brief has been prepared in a proportionally-spaced typeface using Microsoft Word 2010 in 14-point Century Schoolbook.

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CERTIFICATE OF SERVICE

I hereby certify that on December 15, 2011, I electronically filed the foregoing document with the United States Court of Appeals for the First Circuit by using the CM/ECF system. I certify that the following parties or their counsel of record are registered as ECF Filers and that they will be served by the CM/ECF system:

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''(1) The nonmedical use of prescription drugs is a growing problem in the United States, particularly among teenagers.

''(2) According to the Department of Justice's 2009 National Prescription Drug Threat Assessment—

''(A) the number of deaths and treatment admissions for controlled prescription drugs (CPDs) has increased significantly in recent years;

''(B) unintentional overdose deaths involving prescription opioids, for example, increased 114 percent from 2001 to 2005, and the number of treatment admissions for prescription opioids increased 74 percent from 2002 to 2006; and

''(C) violent crime and property crime associated with abuse and diversion of CPDs has increased in all regions of the United States over the past 5 years.

''(3) According to the Office of National Drug Control Policy's 2008 Report 'Prescription for Danger', prescription drug abuse is especially on the rise for teens—

''(A) one-third of all new abusers of prescription drugs in 2006 were 12- to 17-year-olds;

''(B) teens abuse prescription drugs more than any illicit drug except marijuana—more than cocaine, heroin, and methamphetamine combined; and

''(C) responsible adults are in a unique position to reduce teen access to prescription drugs because the drugs often are found in the home.

''(4)(A) Many State and local law enforcement agencies have established drug disposal programs (often called 'take-back' programs) to facilitate the collection and destruction of unused, unwanted, or expired medications. These programs help get outdated or unused medications off household shelves and out of the reach of children and teenagers.

''(B) However, take-back programs often cannot dispose of the most dangerous pharmaceutical drugs—controlled substance medications—because Federal law does not permit take-back programs to accept controlled substances unless they get specific permission from the Drug Enforcement Administration and arrange for full-time law enforcement officers to receive the controlled substances directly from the member of the public who seeks to dispose of them.

''(C) Individuals seeking to reduce the amount of unwanted controlled substances in their household consequently have few disposal options beyond discarding or flushing the substances, which may not be appropriate means of disposing of the substances. Drug take-back programs are also a convenient and effective means for individuals in various communities to reduce the introduction of some potentially harmful substances into the environment, particularly into water.

''(D) Long-term care facilities face a distinct set of obstacles to the safe disposal of controlled substances due to the increased volume of controlled substances they handle.

''(5) This Act [see Short Title of 2010 Amendment note set out under section 801 of this title] gives the Attorney General authority to promulgate new regulations, within the framework of the Controlled Substances Act [21 U.S.C. 801 et seq.], that will allow patients to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion.

''(6) The goal of this Act is to encourage the Attorney General to set controlled substance diversion prevention parameters that will allow public and private entities to develop a variety of methods of collection and disposal of controlled substances, including some pharmaceuticals, in a secure, convenient, and responsible manner. This will also serve to reduce instances of diversion and introduction of some potentially harmful substances into the environment.''

PROVISIONAL REGISTRATION

Section 703 of Pub. L. 91–513, as amended by Pub. L. 99–514, § 2, Oct. 22, 1986, 100 Stat. 2095, provided that:

''(a)(1) Any person who—

''(A) is engaged in manufacturing, distributing, or dispensing any controlled substance on the day before the effective date of section 302 [this section], and

''(B) is registered on such day under section 510 of the Federal Food, Drug, and Cosmetic Act [section 360 of this title] or under section 4722 of the Internal Revenue Code of 1986 [formerly I.R.C. 1954, section 4722 of Title 26],

shall, with respect to each establishment for which such registration is in effect under any such section, be deemed to have a provisional registration under section 303 [section 823 of this title] for the manufacture, distribution, or dispensing (as the case may be) of controlled substances.

''(2) During the period his provisional registration is in effect under this section, the registration number assigned such person under such section 510 [section 360 of this title] or under such section 4722 [section 4722 of Title 26] (as the case may be) shall be his registration number for purposes of section 303 of this title [section 823 of this title].

''(b) The provisions of section 304 [section 824 of this title], relating to suspension and revocation of registration, shall apply to a provisional registration under this section.

''(c) Unless sooner suspended or revoked under subsection (b), a provisional registration of a person under subsection (a)(1) of this section shall be in effect until—

''(1) the date on which such person has registered with the Attorney General under section 303 [section 823 of this title] or has had his registration denied under such section, or

''(2) such date as may be prescribed by the Attorney General for registration of manufacturers, distributors, or dispensers, as the case may be,

whichever occurs first.''

§ 823. Registration requirements

(a) Manufacturers of controlled substances in schedule I or II

The 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 in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances 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;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(b) Distributors of controlled substances in schedule I or II

The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(c) Limits of authorized activities

Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 826 of this title.

(d) Manufacturers of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(e) Distributors of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(f) Research by practitioners; pharmacies; research applications; construction of Article 7 of the Convention on Psychotropic Substances

The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V and shall modify the registrations of pharmacies so registered to authorize them to dispense controlled substances by means of the Internet, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration or such modification of registration if the Attorney General determines that the issuance of such registration or modification would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of

each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 824(a) of this title. Article 7 of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this subchapter.

(g) Practitioners dispensing narcotic drugs for narcotic treatment; annual registration; separate registration; qualifications; waiver

(1) Except as provided in paragraph (2), practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)

(A) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

(B) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with section 827 of this title) on such drugs; and

(C) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

(2)(A) Subject to subparagraphs (D) and (J), the requirements of paragraph (1) are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).

(B) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to a practitioner are that, before the initial dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, the practitioner submit to the Secretary a notification of the intent of the practitioner to begin dispensing the drugs or combinations for such purpose, and that the notification contain the following certifications by the practitioner:

(i) The practitioner is a qualifying physician (as defined in subparagraph (G)).

(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to refer the patients for appropriate counseling and other appropriate ancillary services.

(iii) The total number of such patients of the practitioner at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, unless, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients. A second notification under this clause shall contain the certifications required by clauses (i) and (ii) of this subparagraph. The Secretary may by regulation change such total number.

(C) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to narcotic drugs in schedule III, IV, or V or combinations of such drugs are as follows:

(i) The drugs or combinations of drugs have, under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or section 262 of title 42, been approved for use in maintenance or detoxification treatment.

(ii) The drugs or combinations of drugs have not been the subject of an adverse determination. For purposes of this clause, an adverse determination is a determination published in the Federal Register and made by the Secretary, after consultation with the Attorney General, that the use of the drugs or combinations of drugs for maintenance or detoxification treatment requires additional standards respecting the qualifications of practitioners to provide such treatment, or requires standards respecting the quantities of the drugs that may be provided for unsupervised use.

(D)(i) A waiver under subparagraph (A) with respect to a practitioner is not in effect unless (in addition to conditions under subparagraphs (B) and (C)) the following conditions are met:

(I) The notification under subparagraph (B) is in writing and states the name of the practitioner.

(II) The notification identifies the registration issued for the practitioner pursuant to subsection (f) of this section.

(III) If the practitioner is a member of a group practice, the notification states the names of the other practitioners in the practice and identifies the registrations issued for the other practitioners pursuant to subsection (f) of this section.

(ii) Upon receiving a notification under subparagraph (B), the Attorney General shall assign the practitioner involved an identification number under this paragraph for inclusion with the registration issued for the practitioner pursuant to subsection (f) of this section. The identification number so assigned shall be appropriate to preserve the confidentiality of patients for whom the practitioner has dispensed narcotic drugs under a waiver under subparagraph (A).

(iii) Not later than 45 days after the date on which the Secretary receives a notification

under subparagraph (B), the Secretary shall make a determination of whether the practitioner involved meets all requirements for a waiver under subparagraph (B). If the Secretary fails to make such determination by the end of the such 45-day period, the Attorney General shall assign the physician an identification number described in clause (ii) at the end of such period.

(E)(i) If a practitioner is not registered under paragraph (1) and, in violation of the conditions specified in subparagraphs (B) through (D), dispenses narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, the Attorney General may, for purposes of section 824(a)(4) of this title, consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) of this section to be inconsistent with the public interest.

(ii)(I) Upon the expiration of 45 days from the date on which the Secretary receives a notification under subparagraph (B), a practitioner who in good faith submits a notification under subparagraph (B) and reasonably believes that the conditions specified in subparagraphs (B) through (D) have been met shall, in dispensing narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, be considered to have a waiver under subparagraph (A) until notified otherwise by the Secretary, except that such a practitioner may commence to prescribe or dispense such narcotic drugs for such purposes prior to the expiration of such 45-day period if it facilitates the treatment of an individual patient and both the Secretary and the Attorney General are notified by the practitioner of the intent to commence prescribing or dispensing such narcotic drugs.

(II) For purposes of subclause (I), the publication in the Federal Register of an adverse determination by the Secretary pursuant to subparagraph (C)(ii) shall (with respect to the narcotic drug or combination involved) be considered to be a notification provided by the Secretary to practitioners, effective upon the expiration of the 30-day period beginning on the date on which the adverse determination is so published.

(F)(i) With respect to the dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, a practitioner may, in his or her discretion, dispense such drugs or combinations for such treatment under a registration under paragraph (1) or a waiver under subparagraph (A) (subject to meeting the applicable conditions).

(ii) This paragraph may not be construed as having any legal effect on the conditions for obtaining a registration under paragraph (1), including with respect to the number of patients who may be served under such a registration.

(G) For purposes of this paragraph:

(i) The term ''group practice'' has the meaning given such term in section 1395nn(h)(4) of title 42.

(ii) The term ''qualifying physician'' means a physician who is licensed under State law and who meets one or more of the following conditions:

(I) The physician holds a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties.

(II) The physician holds an addiction certification from the American Society of Addiction Medicine.

(III) The physician holds a subspecialty board certification in addiction medicine from the American Osteopathic Association.

(IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than eight hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause.

(V) The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.

(VI) The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.

(VII) The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the 30-day period preceding the end of the 3-year period involved.

(H)(i) In consultation with the Administrator of the Drug Enforcement Administration, the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the National Institute on Drug Abuse, and the Commissioner of Food and Drugs, the Secretary shall issue regulations (through notice and comment rulemaking) or issue practice guidelines to address the following:

(I) Approval of additional credentialing bodies and the responsibilities of additional credentialing bodies.

(II) Additional exemptions from the requirements of this paragraph and any regulations under this paragraph.

Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.

(ii) Not later than 120 days after October 17, 2000, the Secretary shall issue a treatment improvement protocol containing best practice guidelines for the treatment and maintenance of opiate-dependent patients. The Secretary shall develop the protocol in consultation with the Director of the National Institute on Drug Abuse, the Administrator of the Drug Enforcement Administration, the Commissioner of Food and Drugs, the Administrator of the Substance Abuse and Mental Health Services Administration and other substance abuse disorder professionals. The protocol shall be guided by science.

(I) During the 3-year period beginning on the date of approval by the Food and Drug Administration of a drug in schedule III, IV, or V, a State may not preclude a practitioner from dispensing or prescribing such drug, or combination of such drugs, to patients for maintenance or detoxification treatment in accordance with this paragraph unless, before the expiration of that 3-year period, the State enacts a law prohibiting a practitioner from dispensing such drugs or combinations of drug.[1]

(J)(i) This paragraph takes effect the date referred to in subparagraph (I), and remains in effect thereafter.

(ii) For purposes relating to clause (iii), the Secretary and the Attorney General may, during the 3-year period beginning on December 29, 2006, make determinations in accordance with the following:

(I) The Secretary may make a determination of whether treatments provided under waivers under subparagraph (A) have been effective forms of maintenance treatment and detoxification treatment in clinical settings; may make a determination of whether such waivers have significantly increased (relative to the beginning of such period) the availability of maintenance treatment and detoxification treatment; and may make a determination of whether such waivers have adverse consequences for the public health.

(II) The Attorney General may make a determination of the extent to which there have been violations of the numerical limitations established under subparagraph (B) for the number of individuals to whom a practitioner may provide treatment; may make a determination of whether waivers under subparagraph (A) have increased (relative to the beginning of such period) the extent to which narcotic drugs in schedule III, IV, or V or combinations of such drugs are being dispensed or possessed in violation of this chapter; and may make a determination of whether such waivers have adverse consequences for the public health.

(iii) If, before the expiration of the period specified in clause (ii), the Secretary or the Attorney General publishes in the Federal Register a decision, made on the basis of determinations under such clause, that subparagraph (B)(iii) should be applied by limiting the total number of patients a practitioner may treat to 30, then the provisions in such subparagraph (B)(iii) permitting more than 30 patients shall not apply, effective 60 days after the date on which the decision is so published. The Secretary shall in making any such decision consult with the Attorney General, and shall in publishing the decision in the Federal Register include any comments received from the Attorney General for inclusion in the publication. The Attorney General shall in making any such decision consult with the Secretary, and shall in publishing the decision in the Federal Register include any comments received from the Secretary for inclusion in the publication.

(h) Applicants for distribution of list I chemicals

The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under clause (iv) or (v) of section 802(39)(A) of this title. In determining the public interest for the purposes of this subsection, the Attorney General shall consider—

(1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) compliance by the applicant with applicable Federal, State, and local law;

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) such other factors as are relevant to and consistent with the public health and safety.

(Pub. L. 91–513, title II, § 303, Oct. 27, 1970, 84 Stat. 1253; Pub. L. 93–281, § 3, May 14, 1974, 88 Stat. 124; Pub. L. 95–633, title I, § 109, Nov. 10, 1978, 92 Stat. 3773; Pub. L. 98–473, title II, § 511, Oct. 12, 1984, 98 Stat. 2073; Pub. L. 103–200, § 3(c), Dec. 17, 1993, 107 Stat. 2336; Pub. L. 106–310, div. B, title XXXV, § 3502(a), Oct. 17, 2000, 114 Stat. 1222; Pub. L. 107–273, div. B, title II, § 2501, Nov. 2, 2002, 116 Stat. 1803; Pub. L. 109–56, § 1(a), (b), Aug. 2, 2005, 119 Stat. 591; Pub. L. 109–177, title VII, § 712(a)(3), Mar. 9, 2006, 120 Stat. 263; Pub. L. 109–469, title XI, § 1102, Dec. 29, 2006, 120 Stat. 3540; Pub. L. 110–425, § 3(b), Oct. 15, 2008, 122 Stat. 4824.)

REFERENCES IN TEXT

Schedules I, II, III, IV, and V, referred to in subsecs. (a) to (f) and (g)(2), are set out in section 812(c) of this title.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (g)(2)(C)(i), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

This chapter, referred to in subsec. (g)(2)(J)(ii)(II), was in the original "this Act", meaning Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1236, as amended. For complete

[1] So in original. Probably should be "combinations of drugs.".

classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables.

AMENDMENTS

2008—Subsec. (f). Pub. L. 110–425, in introductory provisions, inserted ''and shall modify the registrations of pharmacies so registered to authorize them to dispense controlled substances by means of the Internet'' after ''schedule II, III, IV, or V'' and substituted ''or such modification of registration if the Attorney General determines that the issuance of such registration or modification'' for ''if he determines that the issuance of such registration''.

2006—Subsec. (g)(2)(B)(iii). Pub. L. 109–469, §1102(1), substituted ''unless, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients. A second notification under this clause shall contain the certifications required by clauses (i) and (ii) of this subparagraph. The'' for ''except that the''.

Subsec. (g)(2)(J)(i). Pub. L. 109–469, §1102(2)(A), substituted ''thereafter.'' for ''thereafter except as provided in clause (iii) (relating to a decision by the Secretary or the Attorney General that this paragraph should not remain in effect).''

Subsec. (g)(2)(J)(ii). Pub. L. 109–469, §1102(2)(B), substituted ''December 29, 2006'' for ''October 17, 2000'' in introductory provisions.

Subsec. (g)(2)(J)(iii). Pub. L. 109–469, §1102(2)(C), substituted ''subparagraph (B)(iii) should be applied by limiting the total number of patients a practitioner may treat to 30, then the provisions in such subparagraph (B)(iii) permitting more than 30 patients shall not apply, effective'' for ''this paragraph should not remain in effect, this paragraph ceases to be in effect''.

Subsec. (h). Pub. L. 109–177 substituted ''clause (iv) or (v) of section 802(39)(A) of this title'' for ''section 802(39)(A)(iv) of this title'' in introductory provisions.

2005—Subsec. (g)(2)(B)(iii). Pub. L. 109–56, §1(b), substituted ''The total'' for ''In any case in which the practitioner is not in a group practice, the total''.

Subsec. (g)(2)(B)(iv). Pub. L. 109–56, §1(a), struck out cl. (iv) which read as follows: ''In any case in which the practitioner is in a group practice, the total number of such patients of the group practice at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, except that the Secretary may by regulation change such total number, and the Secretary for such purposes may by regulation establish different categories on the basis of the number of practitioners in a group practice and establish for the various categories different numerical limitations on the number of such patients that the group practice may have.''

2002—Subsec. (g)(2)(I). Pub. L. 107–273, §2501(1), which directed the substitution of ''on the date of approval by the Food and Drug Administration of a drug in schedule III, IV, or V, a State may not preclude a practitioner from dispensing or prescribing such drug, or combination of such drugs,'' for ''on October 17, 2000, a State may not preclude a practitioner from dispensing or prescribing drugs in schedule III, IV, or V, or combinations of such drugs,'', was executed by making the substitution for the phrase which in the original began with ''on the date of the enactment of the Drug Addiction Treatment Act of 2000,'' rather than the editorial translation ''on October 17, 2000,'' to reflect the probable intent of Congress.

Subsec. (g)(2)(J)(i). Pub. L. 107–273, §2501(2), which directed the substitution of ''the date referred to in subparagraph (I),'' for ''October 17, 2000,'' was executed by making the substitution for text which in the original read ''the date of the enactment of the Drug Addiction Treatment Act of 2000,'' rather than the editorial translation ''October 17, 2000,'' to reflect the probable intent of Congress.

2000—Subsec. (g). Pub. L. 106–310 designated existing provisions as par. (1), substituted ''Except as provided in paragraph (2), practitioners who dispense'' for ''Practitioners who dispense'', redesignated former pars. (1) to (3) as subpars. (A) to (C), respectively, of par. (1) and redesignated former subpars. (A) and (B) of former par. (2) as cls. (i) and (ii), respectively, of subpar. (B) of par. (1), and added par. (2).

1993—Subsec. (h). Pub. L. 103–200 added subsec. (h).

1984—Subsec. (f). Pub. L. 98–473 amended subsec. (f) generally, substituting provisions relating to registration authority of Attorney General respecting dispensation or conduct of research with controlled research, and separate authority of Secretary respecting registration, for provisions relating to general registration requirements respecting dispensation or conduct of research with controlled or nonnarcotic controlled substances.

1978—Subsec. (f). Pub. L. 95–633 inserted provision relating to the construction of the Convention on Psychotropic Substances.

1974—Subsec. (g). Pub. L. 93–281 added subsec. (g).

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110–425 effective 180 days after Oct. 15, 2008, except as otherwise provided, see section 3(j) of Pub. L. 110–425, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 2005 AMENDMENT

Pub. L. 109–56, §1(c), Aug. 2, 2005, 119 Stat. 591, provided that: ''This section [amending this section] shall take effect on the date of enactment of this Act [Aug. 2, 2005].''

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103–200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103–200, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95–633, set out as an Effective Date note under section 801a of this title.

PROVISIONAL REGISTRATION

For provisional registration of persons engaged in manufacturing, distributing, or dispensing of controlled substances on the day before the effective date of section 822 of this title who are registered on such date under section 360 of this title or section 4722 of Title 26, Internal Revenue Code, see section 703 of Pub. L. 91–513, set out as a note under section 822 of this title.

§ 824. Denial, revocation, or suspension of registration

(a) Grounds

A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant—

(1) has materially falsified any application filed pursuant to or required by this subchapter or subchapter II of this chapter;

(2) has been convicted of a felony under this subchapter or subchapter II of this chapter or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical;

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by

SINGLE CONVENTION ON NARCOTIC DRUGS, 1961, AS AMENDED BY THE 1972 PROTOCOL AMENDING THE SINGLE CONVENTION ON NARCOTIC DRUGS, 1961

PREAMBLE

The Parties,

Concerned with the health and welfare of mankind,

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,

Recognizing that addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to mankind,

Conscious of their duty to prevent and combat this evil,

Considering that effective measures against abuse of narcotic drugs require co-ordinated and universal action,

Understanding that such universal action calls for international co-operation guided by the same principles and aimed at common objectives,

Acknowledging the competence of the United Nations in the field of narcotics control and desirous that the international organs concerned should be within the framework of that Organization,

Desiring to conclude a generally acceptable international convention replacing existing treaties on narcotic drugs, limiting such drugs to medical and scientific use, and providing for continuous international co-operation and control for the achievement of such aims and objectives,

Hereby agree as follows:[1]

Article 1

DEFINITIONS

1. Except where otherwise expressly indicated or where the context otherwise requires, the following definitions shall apply throughout the Convention:

a) "Board" means the International Narcotics Control Board,
b) "Cannabis" means the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated.
c) "Cannabis plant" means any plant of the genus Cannabis,
d) "Cannabis resin" means the separated resin, whether crude or purified, obtained from the cannabis plant.
e) "Coca bush" means the plant of any species of the genus Erythroxylon.
f) "Coca leaf" means the leaf of the coca bush except a leaf from which all ecgonine, cocaine and any other ecgonine alkaloids have been removed.
g) "Commission" means the Commission on Narcotic Drugs of the Council.
h) "Council" means the Economic and Social Council of the United Nations.
i) "Cultivation" means the cultivation of the opium poppy, coca bush or cannabis plant.
j) "Drug" means any of the substances in Schedules I and II, whether natural or synthetic.
k) "General Assembly" means the General Assembly of the United Nations.

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[1] *Note by the Secretariat*: The Preamble to the Protocol amending the Single Convention on Narcotic Drugs, 1961, reads as follows:

"*The Parties to the Present Protocol,*

"*Considering* the provisions of the Single Convention on Narcotic Drugs, 1961, done at New York on 30 March 1961 (hereinafter called the Single Convention),

"*Desiring* to amend the Single Convention

"*Have agreed* as follows:"

l) "Illicit traffic" means cultivation or trafficking in drugs contrary to the provisions of this Convention.

m) "Import" and "export" mean in their respective connotations the physical transfer of drugs from one State to another State, or from one territory to another territory of the same State.

n) "Manufacture" means all processes, other than production, by which drugs may be obtained and includes refining as well as the transformation of drugs into other drugs.

o) "Medicinal opium" means opium which has undergone the processes necessary to adapt it for medicinal use.

p) "Opium" means the coagulated juice of the opium poppy.

q) "Opium poppy" means the plant of the species *Papaver somniferum L*.

r) "Poppy straw" means all parts (except the seeds) of the opium poppy, after mowing.

s) "Preparation" means a mixture, solid or liquid, containing a drug.

t) "Production" means the separation of opium, coca leaves, cannabis and cannabis resin from the plants from which they are obtained.

u) "Schedule I", "Schedule II", "Schedule III" and "Schedule IV" mean the correspondingly numbered list of drugs or preparations annexed to this Convention, as amended from time to time in accordance with article 3.

v) "Secretary-General" means the Secretary-General of the United Nations.

w) "Special stocks" means the amounts of drugs held in a country or territory by the Government of such country or territory for special government purposes and to meet exceptional circumstances; and the expression "special purposes" shall be construed accordingly.

x) "Stocks" means the amounts of drugs held in a country or territory and intended for:

i) Consumption in the country or territory for medical and scientific purposes,

ii) Utilization in the country or territory for the manufacture of drugs and other substances, or

iii) Export;

but does not include the amounts of drugs held in the country or territory,

iv) By retail pharmacists or other authorized retail distributors and by institutions or qualified persons in the duly authorized exercise of therapeutic or scientific functions, or

v) As "special stocks".

y) Territory" means any part of a State which is treated as a separate entity for the application of the system of import certificates and export authorizations provided for in article 31. This definition shall not apply to the term "territory" as used in articles 42 and 46.

2. For the purposes of this Convention a drug shall be regarded as "consumed" when it has been supplied to any person or enterprise for retail distribution, medical use or scientific research; and "consumption" shall be construed accordingly.

Article 2

SUBSTANCES UNDER CONTROL

1. Except as to measures of control which are limited to specified drugs, the drugs in Schedule I are subject to all measures of control applicable to drugs under this Convention and in particular to those prescribed in article 4 *c)*, 19, 20, 21, 29, 30, 31, 32, 33, 34 and 37.

2. The drugs in Schedule II are subject to the same measures of control as drugs in Schedule I with the exception of the measures prescribed in article 30, paragraphs 2 and 5, in respect of the retail trade.

3. Preparations other than those in Schedule III are subject to the same measures of control as the drugs which they contain, but estimates (article 19) and statistics (article 20) distinct from those dealing with these drugs shall not be required in the case of such preparations, and article 29, paragraph 2 *c)* and article 30, paragraph 1 *b)* ii) need not apply.

4. Preparations in Schedule III are subject to the same measures of control as preparations containing drugs in Schedule II except that article 31, paragraphs 1 *b)* and 3 to 15 and, as regards their acquisition and retail distribution, article 34, paragraph *b)*, need not apply, and that for the purpose of estimates (article 19) and statistics (article 20) the information required shall be restricted to the quantities of drugs used in the manufacture of such preparations.

5. The drugs in Schedule IV shall also be included in Schedule I and subject to all measures of control applicable to drugs in the latter Schedule, and in addition thereto:

a) A Party shall adopt any special measures of control which in its opinion are necessary having regard to the particularly dangerous properties of a drug so included; and

b) A Party shall, if in its opinion the prevailing conditions in its country render it the most appropriate means of protecting the public health and welfare, prohibit the production, manufacture, export and import of, trade in, possession or use of any such drug except for amounts which may be necessary for medical and scientific research only, including clinical trials therewith to be conducted under or subject to the direct supervision and control of the Party.

6. In addition to the measures of control applicable to all drugs in Schedule I, opium is subject to the provisions of article 19, paragraph 1, subparagraph *f)*, and of articles 21 *bis*, 23 and 24, the coca leaf to those of articles 26 and 27 and cannabis to those of article 28.

7. The opium poppy, the coca bush, the cannabis plant, poppy straw and cannabis leaves are subject to the control measures prescribed in article 19, paragraph 1, subparagraph *e)*, article 20, paragraph 1, subparagraph *g)*, article 21 *bis* and in articles 22 to 24; 22, 26 and 27; 22 and 28; 25; and 28, respectively:

8. The Parties shall use their best endeavours to apply to substances which do not fall under this Convention, but which may be used in the illicit manufacture of drugs, such measures of supervision as may be practicable.

9. Parties are not required to apply the provisions of this Convention to drugs which are commonly used in industry for other than medical or scientific purposes, provided that:

a) They ensure by appropriate methods of denaturing or by other means that the drugs so used are not liable to be abused or have ill effects (article 3, paragraph 3) and that the harmful substances cannot in practice be recovered; and

b) They include in the statistical information (article 20) furnished by them the amount of each drug so used.

Article 3

CHANGES IN THE SCOPE OF CONTROL

1. Where a Party or the World Health Organization has information which in its opinion may require an amendment to any of the Schedules, it shall notify the Secretary-General and furnish him with the information in support of the notification.

2. The Secretary-General shall transmit such notification, and any information which he considers relevant, to the Parties, to the Commission, and, where the notification is made by a Party, to the World Health Organization.

3. Where a notification relates to a substance not already in Schedule I or in Schedule II,

i) The Parties shall examine in the light of the available information the possibility of the provisional application to the substance of all measures of control applicable to drugs in Schedule I;

ii) Pending its decision as provided in subparagraph iii) of this paragraph, the Commission may decide that the Parties apply provisionally to that substance all measures of control applicable to drugs in Schedule I. The Parties shall apply such measures provisionally to the substance in question;

iii) If the World Health Organization finds that the substance is liable to similar abuse and productive of similar ill effects as the drugs in Schedule I or Schedule II or is convertible into a drug, it shall communicate that finding to the Commission which may, in accordance with the recommendation of the World Health Organization, decide that the substance shall be added to Schedule I or Schedule II.

4. If the World Health Organization finds that a preparation because of the substances which it contains is not liable to abuse and cannot produce ill effects (paragraph 3) and that the drug therein is not readily recoverable, the Commission may, in accordance with the recommendation of the World Health Organization, add that preparation to Schedule III.

5. If the World Health Organization finds that a drug in Schedule I is particularly liable to abuse and to produce ill effects (paragraph 3) and that such liability is not offset by substantial therapeutic advantages not possessed by substances other than drugs in Schedule IV, the Commission may, in accordance with the recommendation of the World Health Organization, place that drug in Schedule IV.

6. Where a notification relates to a drug already in Schedule I or Schedule II or to a preparation in Schedule III, the Commission, apart from the measure provided for in paragraph 5, may, in accordance with the recommendation of the World Health Organization, amend any of the Schedules by:

a) Transferring a drug from Schedule I to Schedule II or from Schedule II to Schedule I; or

b) Deleting a drug or a preparation as the case may be, from a Schedule.

7. Any decision of the Commission taken pursuant to this article shall be communicated by the Secretary-General to all States Members of the United Nations, to non-member States Parties to this Convention, to the World Health Organization and to the Board. Such decision shall become effective with respect to each Party on the date of its receipt of such communication, and the Parties shall thereupon take such action as may be required under this Convention.

8. a) The decisions of the Commission amending any of the Schedules shall be subject to review by the Council upon the request of any Party filed within ninety days from receipt of notification of the decision. The request for review shall be sent to the Secretary-General together with all relevant information upon which the request for review is based;

b) The Secretary-General shall transmit copies of the request for review and relevant information to the Commission, the World Health Organization and to all the Parties inviting them to submit comments within ninety days. All comments received shall be submitted to the Council for consideration;

c) The Council may confirm, alter or reverse the decision of the Commission, and the decision of the Council shall be final. Notification of the Council's decision shall be transmitted to all States Members of the United Nations, to non-member States Parties to this Convention, to the Commission, to the World Health Organization, and to the Board;

d) During pendency of the review the original decision of the Commission shall remain in effect.

9. Decisions of the Commission taken in accordance with this article shall not be subject to the review procedure provided for in article 7.

Article 4

GENERAL OBLIGATIONS

The parties shall take such legislative and administrative measures as may be necessary:

a) To give effect to and carry out the provisions of this Convention within their own territories;

b) To co-operate with other States in the execution of the provisions of this Convention; and

c) Subject to the provisions of this Convention, to limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of drugs.

Article 5

THE INTERNATIONAL CONTROL ORGANS

The Parties, recognizing the competence of the United Nations with respect to the international control of drugs, agree to entrust to the Commission on Narcotic Drugs of the Economic and Social Council, and to the International Narcotics Control Board, the functions respectively assigned to them under this Convention.

4. If the situation is not satisfactorily resolved, the Board may utilize the provisions of article 14 where appropriate.

5. In taking its decision with regard to a deduction under paragraph 2 above, the Board shall take into account not only all relevant circumstances including those giving rise to the illicit traffic problem referred to in paragraph 2 above, but also any relevant new control measures which may have been adopted by the Party.

Article 22

SPECIAL PROVISION APPLICABLE TO CULTIVATION

1. Whenever the prevailing conditions in the country or a territory of a Party render the prohibition of the cultivation of the opium poppy, the coca bush or the cannabis plant the most suitable measure, in its opinion, for protecting the public health and welfare and preventing the diversion of drugs into the illicit traffic, the Party concerned shall prohibit cultivation.

2. A Party prohibiting cultivation of the opium poppy or the cannabis plant shall take appropriate measures to seize any plants illicitly cultivated and to destroy them, except for small quantities required by the Party for scientific or research purposes.

Article 23

NATIONAL OPIUM AGENCIES

1. A Party that permits the cultivation of the opium poppy for the production of opium shall establish, if it has not already done so, and maintain, one or more government agencies (hereafter in this article referred to as the Agency) to carry out the functions required under this article.

2. Each such Party shall apply the following provisions to the cultivation of the opium poppy for the production of opium and to opium:

a) The Agency shall designate the areas in which, and the plots of land on which, cultivation of the opium poppy for the purpose of producing opium shall be permitted.
b) Only cultivators licensed by the Agency shall be authorized to engage in such cultivation.
c) Each licence shall specify the extent of the land on which the cultivation is permitted.
d) All cultivators of the opium poppy shall be required to deliver their total crops of opium to the Agency. The Agency shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest.
e) The Agency shall, in respect of opium, have the exclusive right of importing, exporting, wholesale trading and maintaining stocks other than those held by manufacturers of opium alkaloids, medicinal opium or opium preparations. Parties need not extend this exclusive right to medicinal opium and opium preparations.

3. The governmental functions referred to in paragraph 2 shall be discharged by a single government agency if the constitution of the Party concerned permits it.

Article 24

LIMITATION ON PRODUCTION OF OPIUM FOR INTERNATIONAL TRADE

1. a) If any Party intends to initiate the production of opium or to increase existing production, it shall take account of the prevailing world need for opium in accordance with the estimates thereof published by the Board so that the production of opium by such Party does not result in overproduction of opium in the world.
b) A Party shall not permit the production of opium or increase the existing production thereof if in its opinion such production or increased production in its territory may result in illicit traffic in opium.

Article 26

THE COCA BUSH AND COCA LEAVES

1. If a Party permits the cultivation of the coca bush, it shall apply thereto and to coca leaves the system of controls as provided in article 23 respecting the control of the opium poppy, but as regards paragraph 2 *d)* of that article, the requirements imposed on the Agency therein referred to shall be only to take physical possession of the crops as soon as possible after the end of the harvest.

2. The Parties shall so far as possible enforce the uprooting of all coca bushes which grow wild. They shall destroy the coca bushes if illegally cultivated.

Article 27

ADDITIONAL PROVISIONS RELATING TO COCA LEAVES

1. The Parties may permit the use of coca leaves for the preparation of a flavouring agent, which shall not contain any alkaloids, and, to the extent necessary for such use, may permit the production, import, export, trade in and possession of such leaves.

2. The Parties shall furnish separately estimates (article 19) and statistical information (article 20) in respect of coca leaves for preparation of the flavouring agent, except to the extent that the same coca leaves are used for the extraction of alkaloids and the flavouring agent, and so explained in the estimates and statistical information.

Article 28

CONTROL OF CANNABIS

1. If a Party permits the cultivation of the cannabis plant for the production of cannabis or cannabis resin, it shall apply thereto the system of controls as provided in article 23 respecting the control of the opium poppy.

2. This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes.

3. The Parties shall adopt such measures as may be necessary to prevent the misuse of, and illicit traffic in, the leaves of the cannabis plant.

Article 29

MANUFACTURE

1. The Parties shall require that the manufacture of drugs be under licence except where such manufacture is carried out by a State enterprise or State enterprises.

2. The Parties shall:

a) Control all persons and enterprises carrying on or engaged in the manufacture of drugs;
b) Control under licence the establishments and premises in which such manufacture may take place; and
c) Require that licensed manufacturers of drugs obtain periodical permits specifying the kinds and amounts of drugs which they shall be entitled to manufacture. A periodical permit, however, need not be required for preparations.

3. The Parties shall prevent the accumulation, in the possession of drug manufacturers, of quantities of drugs and poppy straw in excess of those required for the normal conduct of business, having regard to the prevailing market conditions.

UNITED STATES DEPARTMENT OF JUSTICE
Drug Enforcement Administration

In the Matter of **Lyle E. Craker, Ph.D.**	Docket No. 05-16

OPINION AND RECOMMENDED RULING, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

MARY ELLEN BITTNER, ADMINISTRATIVE LAW JUDGE

APPEARANCES:

Brian Bayly, Esq.
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Dated: February 12, 2007

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UNITED STATES DEPARTMENT OF JUSTICE
Drug Enforcement Administration

In the Matter of	
Lyle E. Craker, Ph.D.	Docket No. 05-16

OPINION AND RECOMMENDED RULING, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

INTRODUCTION

This proceeding is an adjudication pursuant to the Administrative Procedure Act, 5 U.S.C. § 551 et seq., to determine whether an application for registration with the Drug Enforcement Administration (DEA) as a bulk manufacturer of the Schedule I substance marijuana should be denied. Without this registration, Respondent Lyle E. Craker, Ph.D., of Amherst, Massachusetts, will be unable lawfully to cultivate marijuana in order to supply it to analytical, preclinical, and clinical researchers.

On December 10, 2004, the Deputy Assistant Administrator, Office of Diversion Control, DEA, issued an Order to Show Cause to Respondent, proposing to deny his application to be registered as a bulk manufacturer of marijuana on grounds that such registration would not be consistent with the public interest as that term is used in 21 U.S.C. § 823(a) and with the United States' obligations under the Single Convention on Narcotic Drugs, 1961.[1] More specifically, the Order to Show Cause alleged, in substance, that:

1. On June 28, 2001, Respondent submitted an application to the DEA as a dosage form manufacturer of marijuana. The DEA did not process this application but returned it to Respondent and requested that he resubmit the application as a bulk manufacturer of marijuana and that he submit answers to questions about his plans for such manufacture. Respondent prepared answers

[1] Single Convention on Narcotic Drugs, March 30, 1961, 18 U.S.T. 1407, 520 U.N.T.S. 204 (as amended March 25, 1972, 26 U.S.T. 1439, 976 U.N.T.S. 3) [hereinafter Single Convention].

to these questions and resubmitted his application on August 28, 2002. Respondent noted in his answers, *inter alia*, that he, through the University of Massachusetts, Department of Plant and Soil Science, proposed to cultivate marijuana in order to supply it to analytical, preclinical, and clinical researchers.

2. On September 9, 2003, Mahmoud A. ElSohly, Ph.D., Research Professor and Director of the National Institutes of Health Marijuana Project, submitted comments on and objections to Respondent's application pursuant to 21 C.F.R. § 1301.33.

3. The National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), which is in turn a component within the Public Health Service (PHS) of the United States Department of Health and Human Services (HHS), oversees the cultivation, production, and distribution of research-grade marijuana on behalf of the United States Government. NIDA fulfills this obligation through a contract it administers currently with the University of Mississippi, National Center for Natural Products Research (National Center), which is the only entity currently registered with the DEA to manufacture (cultivate) marijuana for the purpose of supplying the United States with research-grade marijuana. Based on the NIDA contract, the National Center then supplies the marijuana it cultivates to the Research Triangle Institute (RTI). RTI, which is registered with the DEA to manufacture marijuana, has a subcontract with the University of Mississippi to process the National Center's marijuana into cigarettes. RTI then distributes the marijuana cigarettes to DEA-registered researchers who utilize the marijuana for experimental clinical use. All of the foregoing activities take place under the supervision of NIDA.

4. NIH, through NIDA, permits marijuana to be distributed to DEA-registered researchers only pursuant to the arrangement it has with the National Center and RTI. NIH's policy requires that to be eligible to receive marijuana through this arrangement, researchers must submit their research protocols for review and approval by a PHS interdisciplinary review process. The PHS

reviews the scientific quality of the proposed researcher's study, the quality of the researcher's peer-review process, and the objectives of the proposed research.

5. In accordance with the federal Food, Drug, and Cosmetic Act (FDCA), any researcher who seeks to develop a new drug for medical use must submit an Investigational New Drug (IND) application to the Food and Drug Administration (FDA) of HHS. To obtain approval for marketing under the FDCA, the researcher is required to conduct both clinical and preclinical studies to demonstrate the safety and effectiveness of the new drug. Prior to the new drug's introduction in humans, the researcher must demonstrate that it will be safe for use in initial, small-scale studies by presenting the appropriate preclinical data to the FDA. A Phase I study is the initial introduction of the investigational new drug into humans. It is conducted in a small number of healthy volunteers to characterize the drug's metabolic and pharmacologic action in humans, and the adverse effects associated with increasing doses of the drug. Phase II studies evaluate the drug's effectiveness in patients who have the disease or condition the product is intended to treat. Phase III studies evaluate the drug's safety, effectiveness, and dosage. These clinical trials are controlled and uncontrolled studies conducted in hundreds or thousands of patients. All INDs, whether they are controlled substances or not, must comply with these FDA procedures.

6. In addition, any researcher who seeks to conduct research in which humans will be supplied with marijuana must comply with the PHS review process as described above. If the researcher satisfies the criteria established by HHS, the researcher will be eligible to receive marijuana at cost through NIDA. NIDA makes the marijuana available to the researchers through its contract with the National Center.

7. If the University of Massachusetts' application to obtain a DEA registration to cultivate marijuana were granted, the Multidisciplinary Association for Psychedelic Studies (MAPS) would subsidize the University of Massachusetts' cultivation of marijuana. MAPS maintains that a second

manufacturing registration is needed because the researchers who obtain marijuana from the National Center through NIDA do not receive the quantity or quality of marijuana that they require. DEA personnel have contacted these researchers to determine whether MAPS' claims are substantiated. Based upon the contacts, the DEA determined that the researchers are obtaining from the National Center marijuana of sufficient quantity and quality to meet all of their legitimate and authorized research needs in a timely manner.

8. MAPS also maintains that NIDA is limited to supplying marijuana for research purposes and cannot supply marijuana on a prescription basis. MAPS further contends that this limitation effectively prohibits a sponsor (such as a pharmaceutical company) from expending the necessary large amounts of funds to conduct drug development studies resulting in a marijuana prescription product. MAPS contends that this problem will be resolved by granting Respondent's application to manufacture marijuana. MAPS, through these arguments, has not shown that granting Respondent's application would be consistent with the public interest based upon the following:

   a. Current marijuana research has not progressed to Phase II of the clinical trials because current research must utilize smoked marijuana, which ultimately cannot be the permitted delivery system for any potential marijuana medication due to the deleterious effects and the difficulty in monitoring the efficacy of smoked marijuana.

   b. In accordance with the Single Convention, the federal Government must limit marijuana available for clinical research to one source. Based upon this mandate of the Single Convention, HHS, through NIDA, submits a contract to open bidding every five years to determine which one enterprise will be allowed to cultivate marijuana. Since this HHS policy is consistent with the Single Convention, DEA has no authority to overturn it. Moreover, the DEA agrees with HHS' policy inasmuch as it accords with DEA's interpretation of the Single Convention.

9. In compliance with and consistent with 21 U.S.C. § 823(a) and the Single Convention, and consistent with marijuana's status as a Schedule I controlled

substance, DEA must limit the number of producers of research-grade marijuana to that which can provide an adequate and uninterrupted supply under adequately competitive conditions. For the past thirty-six years, the University of Mississippi has provided such supply under the foregoing criteria, and there is no indication that this registrant will fail to do so throughout the duration of its current registration. While the University of Massachusetts is free to compete with the University of Mississippi to obtain the next NIDA contract to produce research-grade marijuana for the United States, there is no basis under § 823(a) to add another producer.

10. MAPS maintains that Schedule I DEA research registrants are not required to undergo additional scrutiny of their proposals by the PHS except for Schedule I research registrants who perform clinical research with marijuana. MAPS, through this argument, has not shown that granting Respondent's application would be consistent with the public interest because:

    a. The latter policy is one that is mandated by HHS and, therefore, DEA has no statutory authority to overturn it.

    b. Marijuana is the most heavily abused of all Schedule I controlled substances, and limiting the supply of marijuana under these circumstances is reasonable.

    c. The system has not unduly limited clinical research with marijuana. Since 2000, there have been or are eleven approved clinical trials utilizing smoked marijuana, three approved clinical sub-studies on side effects of marijuana, and four approved preclinical trials in laboratory and animal modes. Current registered marijuana researchers administer marijuana to almost 500 human subjects. Research with other Schedule I controlled substances is not as extensive as it is with marijuana at this time.

Respondent, through counsel, timely filed a request for a hearing on the issues raised by the Order to Show Cause. Following prehearing procedures, a hearing was held in Arlington, Virginia, on August 22 through 26 and December 12 through 14 and 16, 2005. At the hearing, both parties called witnesses to testify and introduced documentary evidence. After the hearing, both parties filed proposed findings of fact, conclusions of

law, and argument. All of the evidence and posthearing submissions have been considered, and to the extent the parties' proposed findings of fact have been adopted, they are substantively incorporated into those set forth below.

ISSUE

Whether a preponderance of the evidence establishes that granting Respondent's application for registration as a manufacturer of the Schedule I controlled substance marijuana would be in the public interest, as that term is used in 21 U.S.C. § 823(a).

RELEVANT TREATY, STATUTORY, AND REGULATORY PROVISIONS

I. The Controlled Substances Act

The Controlled Substances Act provides, at 21 U.S.C. § 823(a), that the Deputy Administrator is to register an applicant to manufacture a Schedule I controlled substance if she determines that such registration is consistent with the public interest and with the United States' obligations under international treaties, and that in determining the public interest, the Deputy Administrator is to consider the following factors:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in Schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances 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;
(2) compliance with applicable state and local law;
(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;
(4) prior conviction record of applicant under federal and state laws relating to the manufacture, distribution, or dispensing of such substances;
(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and
(6) such other factors as may be relevant to and consistent with the public health and safety.

It should be noted here that Respondent has the affirmative burden of showing that his registration would be in the public interest.[2] It should also be noted that the Deputy Administrator may give each of the factors listed in 21 U.S.C. § 823(a) the weight she deems appropriate in determining whether a registration should be revoked or

[2] 21 C.F.R. § 1301.44(a).

an application for registration denied.[3]

The Controlled Substances Act further provides, at 21 U.S.C. § 823(f), that:

> Registration applications by practitioners wishing to conduct research with controlled substances in Schedule I shall be referred to the Secretary [of Health and Human Services], who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately control diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in Schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in [21 U.S.C. § 824]. Article 7 of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this subchapter.

II. The Single Convention on Narcotic Drugs

The Single Convention on Narcotic Drugs, 1961 (Single Convention) is an international treaty adopted in 1961 and amended in 1972 and to which the United States is signatory.[4] Article 4 of the Single Convention requires signatory parties to take such legislative and administrative measures as may be necessary:

a) To give effect to and carry out the provisions of this Convention within their own territories;
b) To cooperate with other States in the execution of the provisions of this Convention; and
c) Subject to the provisions of this Convention, to limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use, and possession of drugs.[5]

Article 23 of the Single Convention specifies a system of controls on the cultivation of opium poppies;[6] Article 28 applies those same controls to the cultivation of marijuana.[7] In combination, Articles 23 and 28 require a signatory country that permits the cultivation of marijuana to establish a government agency[8] to oversee such

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[3] *See Henry J. Schwarz, Jr., M.D.*, 54 Fed. Reg. 16,422 (1989).
[4] Single Convention, *supra* note 1.
[5] Single Convention, art. 4, para. 1.
[6] Single Convention, art. 23.
[7] Single Convention, art. 28.
[8] The Single Convention requires that there be only one such agency if the signatory's constitution permits it. Single Convention, art. 23, para. 3.

cultivation. This agency is responsible for designating the areas and plots of land on which cultivation may occur, licensing cultivators, and specifying in the licenses the extent of the land on which cultivation is permitted.[9] Paragraph 2 of Article 23 also requires that cultivators of the opium poppy deliver their total crops of opium to the government agency, that the agency purchase and take physical possession of the crops, and that the agency have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks other than those held by manufacturers of opium alkaloids, medicinal opium, or opium preparations.[10] Paragraph 2(e) adds that signatories need not extend this exclusive right to medicinal opium and opium preparations.[11]

Article 1, paragraph (1)(o) of the Single Convention defines "medicinal opium" as "opium which has undergone the processes necessary to adapt it for medicinal use."[12] Article 1, paragraph (1)(x) defines "stocks" as the amount of drugs held in a country or territory and intended for:

i) Consumption in the country or territory for medical and scientific purposes,
ii) Utilization in the country or territory for the manufacture of drugs and other substances, or
iii) Export;

but does not include the amount of drugs held in the country or territory:

iv) By retail pharmacists or other authorized retail distributors and by institutions or qualified persons in the duly authorized exercise of therapeutic or scientific functions, or
v) As "special stocks."[13]

The Commentary to the Single Convention notes that "special stocks" and likewise retail "stocks" (i.e. opium held in stock by retail pharmacists or other authorized retail distributors and by institutions or qualified persons in the duly authorized exercise of therapeutic or scientific functions) are both excluded from the scope of the obligatory Government monopoly. Such special stocks and retail stocks are not "stocks" within the meaning of the Single Convention.[14]

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[9] Single Convention, art. 23, para. 2(a)-(c).
[10] Single Convention, art. 23, para. 2(d)-(e).
[11] Single Convention, art. 23, para. 2(e).
[12] Single Convention, art. 1, para. 1(o).
[13] Single Convention, art. 1, para. 1(x).
[14] Commentary on the Single Convention on Narcotic Drugs, 1961 (prepared by the

III. Regulations Implementing the Controlled Substances Act

The DEA's regulations specify, at 21 C.F.R. § 1301.33(b), that "[i]n order to provide adequate competition, the [Deputy] Administrator shall not be required to limit the number of manufacturers in any basic class to a number less than that consistent with maintenance of effective controls against diversion solely because a smaller number is capable of producing an adequate and uninterrupted supply."

IV. Other Relevant DEA Statements

By notice published in the *Federal Register* on September 18, 1975, the DEA adopted a policy that it would no longer grant import registrations for Schedule I and II controlled substances if the applicant was seeking the registration in order to import only in the event of an emergency involving the domestic supply of raw material.[15] The policy therefore stated that all applicants for registration would be required to demonstrate that the requirements of 21 U.S.C. §§ 958(a) and 823(a) and of what is now 21 C.F.R. §§ 1301.34(b), (c), (d), (e), and (f) are satisfied. This same policy has been applied or considered in final orders on applications for registration to manufacture as well as applications for registration to import.[16]

FINDINGS OF FACT

I. Background

A. About Respondent

Marijuana is a Schedule I controlled substance, which means that it has a high potential for abuse, it has no currently accepted medical use in treatment in the United States, and there is a lack of accepted safety for its use under medical supervision.[17] As more fully discussed below, research with Schedule I substances is permitted, provided the Secretary of Health and Human Services deems the researcher qualified and has approved the research protocol, and provided that the researcher is registered with the

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Secretary-General), art. 23, para. 2(e), commentary 4.

[15] Registration of Importers; Statement of Policy and Interpretation, 40 Fed. Reg. 43,745 (1975).

[16] *Performance Construction, Inc.*, 67 Fed. Reg. 9,993 (2002); *Houba, Inc.*, 69 Fed. Reg. 8,696 (2004). I note, however, that these applications were not the subject of adjudicative proceedings.

[17] 21 U.S.C. § 812(b)(1).

DEA to conduct the research.[18]

There are more than 480 substances in marijuana, and about sixty-six of them are cannabinoids, chemical compounds that contain twenty-one carbons and in nature exist only in the marijuana plant. The major cannabinoid is tetrahydrocannabinol (THC), which exerts most of marijuana's pharmacological activities. There are several THCs, but the one usually referenced by the term tetrahydrocannabinol is delta-9-THC, and references to THC herein are to delta-9-THC unless otherwise indicated. Other cannabinoids mentioned in this proceeding are cannabichromene, a cannabinoid that does not have psychological activities but does have anti-inflammatory and antimicrobial activity, and cannabidiol, a variety-specific cannabinoid that is usually present in comparatively small amounts in the varieties of marijuana that have a high THC content.

Marijuana is a dioceous plant, i.e., it has both female and male plants; when plants are grown from seed, approximately half the resulting plants will be male and the other half will be female. Sensimilla is the buds from female plants that are not fertilized by male plants and thus do not produce seeds; the brach, the leafy structure that protects the ovaries, has the highest THC content in the plant, and the brach from sensimilla plants can have THC potencies of fifteen to twenty-four percent or more.

1. About the Risk of Diversion of Marijuana

As noted above, marijuana has a high risk of abuse, as indicated by its placement in Schedule I under the Controlled Substances Act. In a January 2005 report, NIDA stated that:

> Currently, marijuana is the most commonly used illicit drug in the [United States], with recent estimates from SAMHSA [the Substance Abuse and Mental Health Services Administration] of 14.6 million users in the past month and particularly heavy use occurring in adolescent populations (over 20 percent of all high school seniors). Approximately 2.4 million people use marijuana for the first time every year and [two thirds] of them are between 12 and 17 years of age. In addition, of the 3.5 million people who met criteria for past-year cannabis abuse or dependence in 2001, more than [two thirds] were between the ages of 12 and 25 years. An estimated 852,000 individuals reported marijuana as the specific substance for which they received their last or current treatment among persons who received treatments in the past year and approximately [one half] of those individuals were 25 years old or younger.

[18] 21 U.S.C. § 823(f).

> Sufficient research has been carried out to confirm that the use of cannabis can produce serious physical and psychological consequences. The consequences of cannabis use may be due to the acute effects of the drug or due to the chronic exposure that may ultimately produce abuse or dependence. The use of a large amount in a short period of time may induce hallucinations, delirium, and other perceptual manifestations compatible with a psychotic episode. Chronic users of cannabis may experience difficulty in stopping or controlling drug use, develop tolerance to the subjective and cardiovascular effects, and eventually present withdrawal symptoms after sudden discontinuation of use.[19]

Nora Volkow, M.D., Director of NIDA, gave a statement on medical marijuana to the Criminal Justice, Drug Policy, and Human Resources Subcommittee of the Government Reform Committee of the House of Representatives on April 1, 2004. Dr. Volkow stated that marijuana is the most commonly used illicit drug in the United States, and that according to the 2002 National Survey on Drug Use and Health, more than ninety-five million Americans twelve years of age and older had tried marijuana at least once.

Dr. Volkow stated that when an individual is intoxicated by marijuana, short-term memory, attention, judgment, and other cognitive functions are disrupted, and that marijuana has also been shown to impair coordination and balance and could increase heart rate. Dr. Volkow further stated that longer-lasting cognitive defects have been reported in heavy marijuana users, although these defects had been reversible after sustained abstinence, and that a marijuana withdrawal syndrome characterized by increased anxiety, drug craving, sleep difficulties, and decreased appetite can last from several days to a week following abstinence. According to Dr. Volkow, this withdrawal is similar to that experienced after abstaining from nicotine. Dr. Volkow further stated that early marijuana use is associated with an increased likelihood of lifelong drug problems, and that one study found that adolescents who had been prenatally exposed to marijuana performed worse on tasks requiring visual memory, analysis, and integration.

Eric Voth, M.D., F.A.C.P.,[20] is board-certified in internal medicine and

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[19] National Institute on Drug Abuse (NIDA), *Report on the Rare Diseases Research Activities at the National Institutes of Health FY 2003* (last reviewed Jan. 28, 2005) <http://rarediseases.info.nih.gov/html/reports/fy2003/nida.html>; Government exhibit 43, p. 9.

[20] F.A.C.P. is the abbreviation for Fellow of the American College of Physicians; the College bestows these fellowships upon physicians in recognition of academic and

specializes in that field of medicine and in addiction medicine. According to an article Dr. Voth co-authored that was published in 2004,[21] "[a]lthough most cannabis use is intermittent and time-limited, an estimated 10-20% of American and Australian adolescents who smoke cannabis become dependent on one or more drugs."[22] The article further cites a finding in a report by a working party of the Royal College of Psychiatrists and Royal College of Physicians which states that surveys in North America indicate that five to ten percent of persons who have used cannabis more than once become dependent.

Dr. Voth testified that the incidence of marijuana use drops "quite a lot"[23] after the age of twenty-five years, but that the incidence of physical dependence among fourteen- or fifteen-year-olds is at least five percent. Dr. Voth further testified that the earlier a person starts using a drug, the more likely he/she is to become addicted to it, and that individuals who do not use any intoxicant until they are at least twenty-one years old are much less likely to become addicted.

Dr. Voth testified that the short-term effects of ingesting THC include a sense of intoxication, along with concomitant behaviors and mood changes such as lack of coordination, concentration, and short-term memory involvement, increased heart rate, and sedation; and that dysphoria, panic attacks, and psychotic episodes can also occur. Dr. Voth testified that long-term effects of THC include habituation or dependence, worsening of memory disorders and ability to concentrate, and increasing risk of psychotic and other psychiatric disorders. Dr. Voth further testified, however, that it is impossible to ingest a lethal dose of THC because it does not affect the brain stem. Dr. Voth also testified that smoking marijuana with higher concentrations of THC increases the risk that adverse effects will occur. Dr. Voth testified that smoking marijuana causes harshness for the throat and lungs, unrelated to the concentration of THC in the material.

Dr. Voth testified that there are carcinogens in marijuana, but that there is a

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professional accomplishments.

[21] Richard H. Schwartz, M.D. & Eric A. Voth, M.D., *The use and toxicity of cannabis in teenagers*, *in* 21 RECENT ADVANCES IN PAEDIATRICS 131-144 (Royal Society of Medicine Press Ltd. 2004); Government exhibit 41.

[22] *Id.* at 139 (citing Wayne Hall & Nadia Solowij, *Adverse effects of cannabis*, 352 THE LANCET 1611-1616 (1998)); Government exhibit 41.

conflict in the literature as to whether smoking marijuana can cause cancer. Dr. Voth noted that marijuana does not contain nicotine, which definitely causes lung cancer.

Dr. Voth testified that he is opposed to the legalization of marijuana, i.e., the legality of leaf marijuana for recreational smoking, and that he considers medical marijuana an excuse for legalization and therefore opposes it. Dr. Voth further testified, however, that he supports research on the medical use of cannabinoids and other components of marijuana, and that there is evidence on the potential medical use of various cannabinoids.

According to the National Drug Intelligence Center's National Drug Threat Assessment 2005, published in February 2005, marijuana production within the United States was expected to increase, and:

> An increased supply of marijuana likely will result in increased exposure to the drug and consequently more new users, since initiates to drug use are more likely to start with a drug that is as readily available and easily obtainable as marijuana. Indeed, reporting from some areas has suggested that marijuana is easier for youths to obtain than alcohol or cigarettes. Among established users, particularly among older teens and young adults, the general softening of attitudes regarding the risks associated with and the disapproval of marijuana use, combined with increased availability of the drug, should presage a rise in consumption.[24]

A 2004 article[25] explored the risk of becoming dependent on marijuana within twenty-four months after the first use of the drug and found, among other things, that there was a strong association between beginning marijuana use at eleven to thirteen years of age and dependence, that educational attainment was inversely associated with the risk of becoming dependent soon after onset of use, and that there was more risk of dependence among those who had used three or more drugs (including tobacco and alcohol) prior to their first use of marijuana and among those with a family income of less than $20,000.

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[23] Transcript p. 1,947.

[24] National Drug Intelligence Center, *National Drug Threat Assessment 2005* (Feb. 2005) <http://www.usdoj.gov/ndic/pubs11/12620/marijuana.htm>; Government exhibit 45, p. 31.

[25] Chuan-Yu Chen, Megan S. O'Brien, & James C. Anthony, *Who becomes cannabis dependent soon after onset of use? Epidemiological evidence from the United States 2000-2001*, 79 DRUG AND ALCOHOL DEPENDENCE 11-22 (2005); Government exhibit 49.

2. The 1995 Petition to Reschedule Marijuana

In 2001 the DEA denied the March 10, 1995 petition of a Jon Gettman to initiate rulemaking proceedings to reschedule marijuana.[26] In a letter to Mr. Gettman published in the notice, the then-Administrator stated that before initiating rulemaking proceedings to reschedule a controlled substance, the Administrator must gather requisite data and request from the Secretary of the Department of Health and Human Services a scientific and medical evaluation and a recommendation as to whether the substance should be rescheduled. The then-Administrator noted that pursuant to 21 U.S.C. § 811(c), in determining whether to reschedule a controlled substance the Administrator must consider:

> (1) its actual or relative potential for abuse;
> (2) scientific evidence of its pharmacological effect, if known;
> (3) the state of current scientific knowledge regarding it;
> (4) its history and current pattern of abuse;
> (5) the scope, duration, and significance of abuse;
> (6) what, if any, risk there is to the public health;
> (7) its psychic or physiological dependence liability; and
> (8) whether it is an immediate precursor of a substance already controlled.

The then-Administrator found that the Assistant Secretary for the Department of Health and Human Services had determined that marijuana has a high potential for abuse, an assessment also supported by data the DEA had gathered, and that this finding alone required denying the petition; that the petitioner had not asserted that marijuana has a currently accepted medical use in the United States or was safe to use under medical supervision; and that the Department of Health and Human Services evaluation had reaffirmed the finding that marijuana did not have such a current accepted medical use and was not safe for use under medical supervision. The then-Administrator further stated in the letter that:

> when it comes to a drug that is currently listed in Schedule I, if it is undisputed that such drug has no currently accepted medical use in treatment in the United States and a lack of accepted safety for use under medical supervision, and it is further undisputed that the drug has at least some potential for abuse sufficient to warrant control under the [Controlled Substances Act], the drug must remain in Schedule I.[27]

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[26] Notice of Denial of Petition, 66 Fed. Reg. 20,038 (2001).
[27] Notice of Denial of Petition, 66 Fed. Reg. at 20,039.

3. The Institute of Medicine Report on Use of Marijuana for Medical Purposes

Barbara Roberts, Ph.D., senior policy analyst in the White House Office of National Drug Control Policy (ONDCP) from 1994 until 2003, and Acting Associate Deputy Director for ONDCP's Office of Demand Reduction from mid-2002 to August 2003, testified that the use of marijuana for medical purposes became a very controversial issue while she was working at ONDCP and that she consequently recommended that the Institute of Medicine[28] be asked to study the question. In 1999 the Institute of Medicine issued its report, *Marijuana and Medicine: Assessing the Science Base*.[29] Dr. Roberts characterized the response to the report as "muted,"[30] and testified that she did not think that very much was done with it.

> The report specifically recommended that:
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> (1) Research should continue into the physiological effects of synthetic and plant-derived cannabinoids and the natural function of cannabinoids found in the body. Because different cannabinoids appear to have different effects, cannabinoid research should include, but not be restricted to, effects attributable to THC alone.[31]
> (2) Clinical trials of cannabinoid drugs for symptom management should be conducted with the goal of developing rapid-onset, reliable, and safe delivery systems.[32]
> (3) Psychological effects of cannabinoids such as anxiety reduction and sedation, which can influence medical benefits, should be evaluated in clinical trials.[33]

The report also stated, among other things, that:

> Marijuana delivered in a novel way that avoids smoking would overcome some, but not all, of the regulatory concerns. Vaporization devices that permit inhalation of plant cannabinoids without the carcinogenic combustion products found in smoke are under development by several groups; such devices would also require

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[28] Dr. Roberts testified that the Institute of Medicine is a component of the National Academy of Sciences and is a "medical think tank" funded by Congress where leading researchers and scientists study specific issues. Transcript p. 287.
[29] JANET E. JOY, STANLEY J. WATSON, JR., & JOHN A. BENSON, JR., DIVISION OF NEUROSCIENCE AND BEHAVIORAL HEALTH, INSTITUTE OF MEDICINE, MARIJUANA AND MEDICINE: ASSESSING THE SCIENCE BASE (National Academy Press 1999); Respondent exhibit 1.
[30] Transcript p. 294.
[31] JOY, *supra* note 29, at 3.
[32] *Id.* at 4.
[33] *Id.* at 5.

regulatory review by the FDA.[34]

Dr. Roberts testified that she did not recall any effort within ONDCP to recommend to NIDA that it pursue the idea of vaporized marijuana, and that although there was discussion within the ONDCP about the report, no formal action was taken.

The report further stated, "The effects of cannabinoids on the systems studied are generally modest, and in most cases there are more effective medications,"[35] and that the Controlled Substances Act poses substantial regulatory obstacles to marketing marijuana, but that if marijuana receives FDA approval as a drug it would probably be rescheduled.

In addition, the report stated that:

> Defined substances such as purified cannabinoid compounds are preferable to plant products which are variable and of uncertain composition. Use of defined cannabinoids permits a more precise evaluation of their effects, whether in combination or alone. Medications that can maximize the desired effects of cannabinoids and minimize the undesirable effects can very likely be identified.[36]

Dr. Roberts testified that in her view, the Institute of Medicine report "in a way really provided a blueprint for us, . . . to investigate this and to put it to rest,"[37] and that "[a] tremendous amount of money is spent in the prohibition of [marijuana's] use for medicinal purposes, but certainly I think having the research to resolve this issue would be most beneficial."[38] Dr. Roberts further testified that she thought that having an alternative to NIDA as a supplier of marijuana for research would encourage competition and that she saw no reason not to have such an alternative source.

B. The Agencies and Organizations Involved in Marijuana Cultivation and Research

1. About the National Institute on Drug Abuse

The National Institute on Drug Abuse (NIDA) is one of the National Institutes of Health (NIH), which in turn is an agency of the Public Health Service within the Office of the Secretary of the Department of Health and Human Services. Dr. Roberts, the former Acting Associate Director of ONDCP, testified that NIDA is one of fifty-five agencies that have responsibilities for substance abuse issues and that report to the

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[34] *Id.* at 216.
[35] *Id.* at 3.
[36] *Id.* at 4.
[37] Transcript p. 302.

ONDCP, and that NIDA conducts about eighty-five percent of the world's research in substance abuse policy.

Steven Gust, Ph.D., Special Assistant to the Director of NIDA, testified that NIDA is one of the twenty-seven or so institutes and centers that comprise NIH, and that NIDA's mission is "to support research on the causes, consequences, prevention, and treatment of drug abuse and drug addiction."[39] NIDA also administers the National Drug Supply Program, which provides controlled substances and their precursors to researchers. The National Drug Supply Program supplies some other Schedule I substances to researchers and there are additional suppliers of some Schedule I substances, but NIDA is the sole supplier of marijuana for research purposes. Dr. Gust testified that it is not NIDA's mission to study medicinal uses of marijuana or to advocate for such research.

2. About the University of Mississippi's Work with Marijuana

The University of Mississippi is a state university with a campus in Oxford, Mississippi. Since about 1968 the University of Mississippi has held a registration from the DEA or its predecessor agency to cultivate marijuana for government use and research activities, and at some point the National Center for Natural Products (National Center), part of the Research Institute of Pharmaceutical Sciences of the University of Mississippi's School of Pharmacy, obtained a registration to manufacture marijuana specifically for NIDA. The National Center holds another manufacturer registration that permits it to develop pharmaceutical preparations from the marijuana plant.

The National Center is currently the only DEA-registered cultivator of marijuana. The University of Mississippi has a competitively-renewed contract with NIDA pursuant to which the National Center supplies marijuana to researchers for studies ranging from chemical research to preclinical toxicology in animals to clinical work on humans. As of the date of the hearing, the contract term was five years; prior to 1999 the contracts were awarded every three years. Starting with the 1999 contract, the University of Mississippi subcontracted to Research Triangle Institute (RTI) of North Carolina the manufacture of marijuana cigarettes, analysis of the THC and moisture content of the cigarettes, and

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[38] Transcript pp. 302-303.
[39] Transcript p. 1,625.

distribution of the cigarettes to researchers.[40]

The most recent contract covers the period March 16, 2005, through March 15, 2010, and requires the National Center to produce, store, analyze, and distribute marijuana as required by NIDA; to extract and isolate THC and other cannabinoids from marijuana for research purposes; to maintain specified stocks of high-THC content, low-THC content, and placebo cigarettes [g13/7]; and to maintain a specified stock of bulk marijuana. The contract also requires the National Center to analyze each month approximately 100 samples of confiscated marijuana provided by the DEA as a means of determining potency trends of illicit marijuana and of screening for herbicide contamination.

Dr. Gust testified that he oversees the NIDA contract with the University of Mississippi; that a program staff at NIDA develops a statement of work, outlining the work to be performed under the contract; that the statement of work is then put into a request for proposals and submitted to NIDA's Contract Procurement Office; and that that office announces the availability of the contract, receives applications for the contract, and reviews the applications. Dr. Gust further testified that NIDA does not inspect the National Center's growing operation or evaluate its security, nor does NIDA establish how much marijuana the National Center may grow other than pursuant to its contract with NIDA.

Dr. Gust testified that the DEA notified him of Respondent's instant application and that, consequently, he arranged for Respondent to be sent a notice of the availability of the most recent contract to cultivate marijuana. Dr. Gust testified that entities other than the University of Mississippi had bid on the contract to cultivate marijuana, but that he did not know who those entities were.

Mahmoud ElSohly, Ph.D., a research professor at the Research Institute of Pharmaceutical Sciences, is the Principal Investigator listed in the contract between the National Center and NIDA and as such, heads the National Center's work with marijuana. Dr. ElSohly testified that the National Center cannot ship marijuana or direct RTI to do so without obtaining approval from NIDA, that NIDA determines how much

[40] Prior to 1999 RTI manufactured the cigarettes, but pursuant to a separate contract with NIDA rather than as a subcontractor to the University of Mississippi.

marijuana the National Center will cultivate in a given year, and that in April 2004 the FDA inspected the University of Mississippi facility and did not find any deficiencies in its manufacturing practices.

Dr. ElSohly testified that the National Center analyzes marijuana samples from states as well as from the DEA, and that notwithstanding the contract provision requiring the National Center to analyze about 100 samples of confiscated marijuana per month, over the ten years preceding the hearing, the National Center had probably analyzed between 2,000 and 4,000 samples of marijuana per year. Dr. ElSohly testified that in about 1991 and 1992 the potency of the seized marijuana samples that the University of Mississippi analyzed averaged about three to three-and-half percent THC content, and that potency had been increasing thereafter, reaching about 7.3 or 7.4 percent in 2004.

Dr. ElSohly testified that the National Center cultivates marijuana by vegetative propagation, i.e., from cuttings, a technique that produces plants with the same genetic makeup as the mother plant. Dr. ElSohly also testified that the National Center has conducted research on indoor cultivation of marijuana, which enables the grower to control the environmental conditions in which the plants are grown, but that although the National Center could grow small amounts of marijuana indoors if the material it had in inventory did not meet the needs of a specific research project, it has not grown marijuana indoors for NIDA. Dr. ElSohly further testified that he had about 1,200 square feet available for indoor growing and that that space would permit him to grow tens of kilograms per year inside, as opposed to the hundreds of kilograms per year that he could grow outdoors on the National Center's twelve-acre plot.

Dr. ElSohly testified that the last time prior to the hearing that the National Center grew a marijuana crop at its outdoor facility was in 2001-2002, and that as of the date of the hearing he had enough marijuana in inventory, about a thousand kilograms, to cover what investigators needed.

The National Center's contract with NIDA specifies that the National Center's inventory of marijuana is to be maintained on a first-in, first-out system, i.e., that the oldest material is to be used first, unless the project officer at NIDA agrees to use newer material. Dr. ElSohly testified that the National Center keeps the marijuana it has cultivated in a secure vault in freezers to prevent the material from degrading over time.

Dr. ElSohly further testified that the National Center, as required by its contract with NIDA, conducts stability studies on the marijuana it cultivates to verify its potency after storage. Dr. ElSohly testified on cross-examination, however, that if he has two barrels of marijuana of the same composition, he will seek to use the newer material first, because "the fresher the material is, the better the material is."[41]

Dr. ElSohly testified that the National Center's marijuana crop is of various potencies, and that prior to the manufacturing process material of different potencies is mixed to achieve a batch of cigarettes of a consistent potency. According to Dr. ElSohly, the National Center has produced marijuana cigarettes with a potency of eight percent and bulk marijuana with a potency of thirteen or fourteen percent, and is capable of producing on a small scale (i.e., a few kilograms) marijuana with a potency of twenty percent or higher. Dr. ElSohly noted that the higher marijuana's potency, the more difficult it is to roll into cigarettes, but testified that he had been able to roll a batch of marijuana of six percent potency by machine and that the National Center had also made one batch of cigarettes with eight percent THC content when a researcher needed a higher-potency material that was too sticky to go through RTI's rolling machine.

Dr. ElSohly testified that the cannabichromene content of the marijuana available to researchers through NIDA is approximately .3 percent, and that the cannabidiol content ranges from about .1 percent to two percent.

3. About Research Triangle Institute

Kenneth Davis, Jr., Senior Program Director of RTI's Center for Chemistry Services, stated in a declaration that RTI is an independent non-profit organization formed in 1958 whose mission is scientific research and technology development to improve the human condition. RTI holds DEA registrations as a Schedule I through V manufacturer, including for bulk manufacture; as a Schedule I through V distributor; as a Schedule I through V importer, including in bulk; as a Schedule I through V exporter; as a Schedule I researcher; and as a Schedule II researcher. Mr. Davis oversees all of these registrations. Mr. Davis further stated that since 1968 RTI has produced and distributed marijuana cigarettes to researchers approved by the FDA, the DEA, and NIDA, and also has distributed marijuana cigarettes to patients in the experimental use program.

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[41] Transcript p. 1,573.

Mr. Davis further stated that RTI acquired the machine it uses to make marijuana cigarettes in 1976, that RTI gained technical expertise from North Carolina's tobacco industry, and that a dilemma the organization faced was how to produce cigarettes of varying potencies that are indistinguishable from each other. Mr. Davis stated that RTI receives barrels of manicured marijuana at about an 11.2 percent humidity level, processes the marijuana to reach a fifteen percent humidity level, and stores it in a cold room so it retains moisture. The marijuana is fed through a hopper into the rolling machine which, when it runs optimally, produces 800 to 1,000 cigarettes per minute.

Mr. Davis stated that RTI had produced thirty-two batches of machine-rolled cigarettes since the beginning of the NIDA marijuana project and that NIDA's needs and requests govern this production. Mr. Davis further stated that RTI had produced small batches consisting of 100 to 500 hand-rolled cigarettes, including a batch that was specified to be at eight percent potency, which is more challenging for mechanical rolling because material with a higher THC content is stickier. Mr. Davis stated that occasionally a researcher asks for bulk material, but that this is relatively rare.

Mr. Davis stated that RTI's goal is to develop and provide cigarettes that are consistent and standardized to meet the needs NIDA identifies, that RTI has received comments from NIDA about the quality of the cigarettes RTI produces, but that it had not received any comments since a few months before July 2002. Mr. Davis stated that RTI was able to respond to comments about the harshness of the marijuana it distributed by providing instructions on how to humidify it, that in 2001 the University of Mississippi added a machine that removed "the vast majority of seeds and stems"[42] from marijuana plant material, and that although initially RTI found this material too fine to go through its rolling machine, those problems were resolved and RTI has not received any recent complaints about seeds or stems in its finished products. Mr. Davis further stated that the ability to develop more potent material has been progressing, and that marijuana with eight percent THC content is available and marijuana with a content of ten percent THC could be accessible. Nonetheless, according to Mr. Davis, the project faced a challenge concerning the stability of higher-content THC material.

Finally, according to Mr. Davis, RTI had not, as of the date of his declaration

(January 6, 2006), received requests for marijuana products other than plant material, but had received inquiries about such products and would be willing and able to work on other delivery forms once it had "tool[ed] up."[43]

4. About the Multidisciplinary Association for Psychedelic Studies

The Multidisciplinary Association for Psychedelic Studies (MAPS) is a not-for-profit research and education organization that is tax-exempt pursuant to Section 501(c)(3) of the Internal Revenue Code. Its mission is to develop FDA-approved prescription drugs from Schedule I controlled substances and to educate the public about the risks and benefits of these substances. Richard Doblin, Ph.D., founded MAPS in 1986 and was its president as of the date of the hearing.

MAPS' 1,500 members include doctors, psychologists, and psychotherapists, as well as others who support scientific research into Schedule I drugs but would not necessarily use such research in their own professions. Dr. Doblin testified that psychedelic[44] drugs might have applications to treat conditions such as addiction (because such drugs may help addicts recognize their denial) or to enhance psychotherapy.

Dr. Doblin testified that most of the drugs that MAPS studies are not patent-protected, so pharmaceutical companies are not interested in funding research about them, and that these drugs are too controversial to attract government funding. Consequently, MAPS relies on private donors, including some foundations. Dr. Doblin further testified that ultimately, MAPS hopes to market the drugs it develops.

Dr. Doblin testified that MAPS' 2004 annual budget was about $800,000, and that there are about four full-time employees, plus researchers who are not employees but conduct studies pursuant to contracts with the organization. Dr. Doblin testified that probably at least one million of the roughly four million dollars that MAPS had spent in the four years prior to the hearing had been spent on research projects; that among other things, MAPS has sponsored studies of the use of ketamine (a Schedule III controlled

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[42] Declaration of Kenneth H. Davis, Jr., Jan. 6, 2006; Government exhibit 97, p. 3.
[43] Declaration of Kenneth H. Davis, Jr.; Government exhibit 97, p. 4.
[44] Dr. Doblin defined the word "psychedelic" as "mind-manifesting," i.e., revealing of the unconscious or subconscious, and testified that the term is not restricted to drugs, but also encompasses such things as dreams and meditation. Transcript p. 474.

substance) in treating alcoholics and heroin addicts and the use of methylenedioxymethamphetamine (MDMA) (a Schedule I controlled substance) for treatment of post-traumatic stress disorder; and that he was awaiting approval for a planned study of MDMA's potential use to treat anxiety in patients with terminal cancer. Dr. Doblin testified that MAPS also sponsored a study on using psilocybin (a Schedule I controlled substance) to treat obsessive-compulsive disorder, and that because neither NIDA nor the National Institutes of Mental Health was willing to sell psilocybin to use in the study, MAPS purchased it from a private producer at a cost of $12,250 for one gram.

Dr. Doblin testified to his personal belief "that marijuana should be a legal substance for both medical and non-medical purposes,"[45] that adults should be allowed to decide for themselves whether to use marijuana, and that prohibition on its use is counterproductive in reducing drug abuse. Dr. Doblin also acknowledged that as of the date of the hearing, he used marijuana recreationally approximately once per week, and that he started using marijuana in about 1971.[46] Dr. Doblin further testified that he considers smoked marijuana to be medicine, although he agreed that it has the potential for abuse. Dr. Doblin testified that although he thought that working through the FDA was the appropriate process in order to make marijuana into a medicine, the inability to obtain marijuana for research purposes has blocked that process.

5. About the Center for Medical Cannabis Research

Former California State Senator John Vasconcellos testified that after the voters of California adopted Proposition 215 in 1996,[47] he introduced legislation to establish the

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[45] Transcript p. 634.

[46] Respondent objected to this testimony at the hearing. I overruled the objection with the caveat that I might later decide that the testimony was irrelevant. Respondent renews the objection in his brief; I adhere to my ruling.

[47] Proposition 215 reads as follows:

> SEC. 1. Section 11362.5 is added to the California Health and Safety Code, to read:
> 11362.5. (a) This section shall be known and may be cited as the Compassionate Use Act of 1996.
> (b)(1) The people of the State of California hereby find and declare that the purposes of the Compassionate Use Act of 1996 are as follows:
> (A) To ensure that seriously ill Californians have the right to obtain and use marijuana for medical purposes where that medical use is deemed appropriate and has been recommended by a physician who has

University of California Center for Medical Cannabis Research (CMCR), hosted primarily at the University of California at San Diego and secondarily at the University of California at San Francisco. Mr. Vasconcellos testified that the establishing legislation required a scientific advisory committee to approve all proposals to conduct research funded by the CMCR, that all approved researchers were required to obtain appropriate federal licenses, and that research was ongoing as of the date of the hearing. Mr. Vasconcellos further testified that fifteen research projects had been selected and funded, but that as of the date of his testimony, there was no further state funding available. Mr. Vasconcellos testified that the purpose of the legislation was not to obtain FDA approval of marijuana as a drug, but "to demystify the roaring contentions of

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> determined that the person's health would benefit from the use of marijuana in the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief.
> (B) To ensure that patients and their primary caregivers who obtain and use marijuana for medical purposes upon the recommendation of a physician are not subject to criminal prosecution or sanction.
> (C) To encourage the federal and state governments to implement a plan to provide for the safe and affordable distribution of marijuana to all patients in medical need of marijuana.
> (b)(2) Nothing in this section shall be construed to supersede legislation prohibiting persons from engaging in conduct that endangers others, nor to condone the diversion of marijuana for non-medical purposes.
> (c) Notwithstanding any other provision of law, no physician in this state shall be punished, or denied any right or privilege, for having recommended marijuana to a patient for medical purposes.
> (d) Section 11357, relating to the possession of marijuana, and Section 11358, relating to the cultivation of marijuana, shall not apply to a patient, or to a patient's primary caregiver, who possesses or cultivates marijuana for the personal medical purposes of the patient upon the written or oral recommendation or approval of a physician.
> (e) For the purposes of this section, "primary caregiver" means the individual designated by the person exempted under this section who has consistently assumed responsibility for the housing, health, or safety of that person.
> SEC. 2. If any provision of this measure or the application thereof to any person or circumstance is held invalid, that invalidity shall not affect other provisions or applications of the measure that can be given effect without the invalid provision or application, and to this end the provisions of this measure are severable.

contrary viewpoints and to find out by science carefully designed and commissioned and arbitrated by the protocols to find out whether, in fact, it's of any use."[48]

Mr. Vasconcellos opined that "people have a right to know more about what might help them in their suffering and pain or illness, whatever it might be and that the more research, the better, provided it's rigorous and according to protocol and objective and careful and approved by everybody who has to approve it."[49]

The enabling legislation for the CMCR, California Health and Safety Code § 11362.9, commissions the California Marijuana Research Program and directs it to "develop and conduct studies intended to ascertain the general medical safety and efficacy of marijuana and, if [marijuana is] found valuable, . . . develop medical guidelines for the appropriate administration and use of marijuana."[50] The statute further provides that:

> In order to ensure objectivity in evaluating proposals, the program shall use a peer review process that is modeled on the process used by the National Institutes of Health, and that guards against funding research that is biased in favor of or against particular outcomes. Peer reviewers shall be selected for their expertise in the scientific substance and methods of the proposed research, and their lack of bias or conflict of interest regarding the applicants or the topic of an approach taken in the proposed research. Peer reviewers shall judge research proposals on several criteria, foremost among which shall be both of the following:
> (1) The scientific merit of the research plan, including whether the research design and experimental procedures are potentially biased for or against a particular outcome.
> (2) Researchers' expertise in the scientific substance and methods of the proposed research, and their lack of bias or conflict of interest regarding the topic of, and the approach taken in, the proposed research.[51]

The legislation, among other things, establishes a Scientific Advisory Council and directs it to develop a scientific plan pursuant to which funds are to be allocated to various research studies and to review requests for funding;[52] specifies that the studies "include the greatest amount of new scientific research possible on the medical uses of,

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[48] Transcript p. 403.
[49] Transcript p. 406.
[50] CAL. HEALTH & SAFETY CODE § 11362.9(a)(2) (Deering 2005); Government exhibit 32.
[51] CAL. HEALTH & SAFETY CODE § 11362.9(c) (Deering 2005); Government exhibit 32.
[52] CAL. HEALTH & SAFETY CODE §§ 11362.9(e)(4), (p) (Deering 2005); Government exhibit 32.

and medical hazards associated with, marijuana;"[53] requires that the program "be limited to providing for objective scientific research to ascertain the efficacy and safety of marijuana as part of medical treatment, and should not be construed as encouraging or sanctioning the social or recreational use of marijuana";[54] and states that prior to approving any proposals, the program is to try to obtain research protocol guidelines from NIH and if NIH issues such guidelines, to comply with them.[55]

Dale Gieringer, Ph.D., is on the CMCR's National Advisory Council as a public interest member. He testified that the CMCR funds and coordinates studies on the medical use of marijuana, and that it is purely a research organization; it does not seek to develop drugs or bring them to market.

Dr. Doblin testified that he thought the CMCR had been able to obtain marijuana from NIDA for several studies because unlike MAPS, the CMCR was not trying to make marijuana into a prescription medicine. Dr. Doblin testified that as far as he knew, NIDA had supplied marijuana to all of the approximately fifteen projects that the CMCR had undertaken.

II. Work to Develop a Pharmaceutical Product from Marijuana

A. The Process of Developing a New Drug Product

Douglas Throckmorton, M.D., the Acting Deputy Director of FDA's Center for Drug Evaluation and Research (CDER), stated in an affidavit in evidence as a Government exhibit that the federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(g), defines "drug" in relevant part as:

> (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), or (B), or (C), ...[56]

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[53] CAL. HEALTH & SAFETY CODE § 11362.9(g) (Deering 2005); Government exhibit 32.
[54] CAL. HEALTH & SAFETY CODE § 11362.9(l)(3) (Deering 2005); Government exhibit 32.
[55] CAL. HEALTH & SAFETY CODE § 11362.9(m)(1) (Deering 2005); Government exhibit 32.
[56] Declaration of Douglas C. Throckmorton, M.D., August 17, 2005; Government exhibit 92, p. 1.

Dr. Throckmorton further stated that 21 U.S.C. § 321(p) of the Food, Drug, and Cosmetic Act, in relevant part, defines the term "new drug" as:

> (1) Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . or (2) Any drug . . . the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.[57]

Dr. Throckmorton stated that in order for a drug to be generally recognized as safe and effective within the meaning of 21 U.S.C. § 321(p), a drug's "reputation must be based on adequate and well-controlled studies that establish that the drug is safe and effective";[58] the "studies must have been published in the scientific literature so that they are available to qualified experts";[59] and "qualified experts must generally recognize, based on those published studies, that the drug is safe and effective for its intended use."[60] Dr. Throckmorton further stated that even if an active ingredient in one drug product has been previously approved as safe and effective in another, the first drug product is considered a new drug if its particular formulation has not been previously approved or has not been found to be generally recognized as safe and effective. Dr. Throckmorton stated that any drug product derived from marijuana is a new drug within the meaning of 21 U.S.C. § 321(p) and that he was not aware of any evidence that any drug product derived from marijuana is exempt from the new drug requirements of the Food, Drug, and Cosmetic Act.

Dr. Throckmorton further stated that a new drug product may not be legally introduced into interstate commerce unless it has an approved new drug application (NDA), an approved abbreviated new drug application (ANDA), or a valid investigational new drug application (IND),[61] and that a new drug application is required

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[57] Declaration of Douglas C. Throckmorton, M.D.; Government exhibit 92, pp. 1-2.
[58] Declaration of Douglas C. Throckmorton, M.D.; Government exhibit 92, p. 2 (citing 21 C.F.R. § 314.126).
[59] Declaration of Douglas C. Throckmorton, M.D.; Government exhibit 92, p. 2.
[60] *Id.*
[61] *Id.* (citing 21 U.S.C. § 355).

to contain:

> (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use;
> (B) a full list of the articles used as components of such drug;
> (C) a full statement of the composition of such drug;
> (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;
> (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; and
> (F) specimens of the labeling proposed to be used for such drug.[62]

Dr. Throckmorton stated that in order to develop the necessary reports showing that a particular drug product is safe and effective, the NDA sponsor must complete certain clinical investigations, i.e., experiments in which the drug is administered to, dispensed to, or used in one or more human subjects, and that clinical investigations of unapproved new drugs must be conducted under valid INDs.[63] The IND must include the name of the drug and all its active ingredients, its structural formula, the formulation of the dosage form, the route of administration, a summary of previous human experience with the drug, a description of the overall plan for investigating the drug product for the next year, and a protocol for the study. Dr. Throckmorton stated that INDs generally must:

> have a section describing the composition, manufacture, and control of the drug product. In each phase of the investigation sufficient information is required to be submitted to assure the proper identification, quality, purity, and strength of the investigational drug product. FDA recognizes that modifications to the method of preparation of a new drug substance and dosage form are likely as the investigation progresses. Final specifications for the drug substance and drug product are not expected until the end of the investigational process.[64]

Dr. Throckmorton described the three phases of the clinical investigation of a previously untested drug product as, in substance: Phase I, the initial introduction into humans, which is designed to determine the metabolic and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and if possible to obtain some evidence of effectiveness; Phase II, controlled clinical studies to explore the drug's effectiveness for a particular indication and determine its common short-term side

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[62] Declaration of Douglas C. Throckmorton, M.D.; Government exhibit 92, p. 3.
[63] *Id.* (citing 21 U.S.C. § 355(i) and 21 C.F.R. Part 312).
[64] Declaration of Douglas C. Throckmorton, M.D.; Government exhibit 92, pp. 3-4.

effects and risks; and Phase III, expanded controlled and uncontrolled clinical trials intended to obtain additional information about effectiveness and safety needed to evaluate the benefit-risk relationship and provide an adequate basis for labeling.

Irwin Martin, Ph.D., and David Auslander, Ph.D., testified on behalf of Respondent and the Government, respectively, as experts on new drug development. Dr. Auslander testified that at the end of Phase III of the investigation of a new drug, the sponsor submits the NDA to the FDA. Dr. Martin described the process of developing new drugs, starting with basic research: the discovery of a compound, an idea of how to use it, synthesis of the molecule, and testing in animals to show that it is pharmacologically active. Dr. Martin testified that once researchers conclude that the product is viable, a management team decides whether or not to test it in humans; if that decision is affirmative, the next step is assembly of a project team to work toward an IND, which is necessary in order to study the drug in humans.[65] Once the IND is in effect, according to Dr. Martin, the developers conduct Phase I studies in which the drug is tested in healthy volunteers to demonstrate its safety and its biopharmaceutical properties, i.e., how the body handles it. When the company concludes that it has sufficient data from these studies, it proceeds to Phase IIA, studies in which the drug is tried on a small group of patients who would be expected to benefit from it; in Phase IIB, the developers test the drug in larger groups of patients. Finally, in Phase III the drug is tested for safety in thousands of patients. [99] When the Phase III studies are complete the developers prepare and submit to the FDA an NDA summarizing the results of all of the studies.

Dr. Martin testified that the FDA takes up to ten months to review the NDA and approve the application or comment on it, and may seek additional information. Dr. Auslander added that after the sponsor of a drug development program provides the NDA, the FDA's Bureau of Compliance will conduct a pre-approval inspection to ensure that the facility designated in the NDA can produce the product as specified in the application. Dr. Martin further testified that often pharmaceutical companies conduct Phase IV studies, i.e., studies to gather additional information about a currently marketed

[65] Dr. Martin testified that an IND goes into effect in thirty days unless the FDA objects to it.

drug's safety and/or efficacy.

Dr. Martin testified that throughout the process of developing a drug, the developers maintain contact with the FDA, and that the entire process of drug development from identification of a likely compound to FDA approval averages about seven to eight years. Dr. Martin further testified that the ratio of INDs to approved NDAs is approximately ten to one, i.e., about ten percent of the drugs that undergo clinical testing are eventually marketed, but agreed with the comment in the Institute of Medicine's report that about one in five drugs that have been tested in humans obtains FDA approval for marketing. Dr. Martin further testified that a Tufts University research group estimated that it costs about $800 million (including opportunity costs) to successfully develop a new drug.[66]

Dr. Doblin testified that more than half of the $880 million estimate he provided of the cost of developing a new drug is opportunity cost, i.e., the cost of investing in research instead of something else, that this cost is calculated on assumptions that the rate of return on alternative investments would be twelve percent per year, compounded, and that it could take up to fifteen years to develop a drug. Dr. Doblin further testified that the calculation of opportunity costs also amortizes the costs of the projects that do not result in a marketable drug into the return of the projects that do.

Dr. Martin testified that in determining whether to develop a drug, pharmaceutical companies consider issues such as how many patients would have the condition or symptom that the drug would treat; how long such patients would use the drug; what competing products are already on the market; what research is being conducted by other companies on the same issue; and the patentability of the drug and/or its delivery system. Dr. Martin testified that assuring a reliable and consistent source of supply is critical to the development of a drug.

Dale Gieringer, Ph.D., is the California coordinator for the National Organization for the Reform of Marijuana Laws (NORML). Dr. Gieringer testified that the FDA requires anyone seeking approval of a drug to have a Drug Master File containing

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[66] Dr. Martin explained that this figure includes the research and development costs of those drugs that do not ever get to market, i.e., a company's total research and development costs divided by the number of NDAs approved in a year.

proprietary information such as the source of the drug under consideration, its production process, and evidence of its purity and quality.

Dr. Martin testified that scheduling of a drug as a controlled substance is a deterrent to its development because access to controlled substances is more restricted, physicians are disinclined to prescribe them, there may be a stigma associated with these drugs, the developer must incur additional expense for abuse liability studies, and the scheduling process at both the state and federal levels may result in expensive delays.

Dr. Martin testified that the FDA's criteria for approval of a drug are safety, efficacy (i.e., assurance that the drug does what it is supposed to do), and quality (the manufacturing controls that assure that the dosage form tested is the same as the one delivered to a patient).

B. Developing Botanical Products into Pharmaceuticals

Dr. Throckmorton defined botanical products as:

> finished, labeled products that contain vegetable matter as ingredients. Botanical products that meet the definition of a drug under 21 U.S.C. § 321(p) are subject to regulation as a drug. However, botanical drug products have certain unique characteristics that are taken into account in the application of FDA regulations. For instance, because of the complex nature of a typical botanical drug and the lack of knowledge of its active constituent(s), FDA may rely on a combination of tests and controls to ensure the identity, purity, quality, strength, potency, and consistency of botanical drugs.[67]

Dr. Martin noted that assuring quality is more complex for botanical products than for chemical ones, but that the FDA has issued a guidance document on how to submit an application for botanically derived material, thus indicating that the agency is willing to consider such applications.

The guidance document to which Dr. Martin referred is the Guidance for Industry, Botanical Drug Products (Botanical Drug Guidance), issued in June 2004 by the FDA's Center for Drug Evaluation and Research. The Botanical Drug Guidance explains when a botanical drug may be marketed as an over-the-counter product and when an NDA is required to market the drug. The Botanical Drug Guidance also contains nonbinding recommendations to sponsors on submitting INDs for botanical drug products. The Botanical Drug Guidance includes among the information that should be provided for

[67] Declaration of Douglas C. Throckmorton, M.D.; Government exhibit 92, p. 5.

botanical drug substances qualitative and quantitative descriptions of the substance, including the quantities of the active constituents, and the physical and chemical properties, biological activity, and clinical indications of the botanical raw material. The Botanical Drug Guidance also specifies that both a biological activity and chemical assay should be performed if the botanical drug substance is potent, toxic, addictive, or has abuse potential, and specifically lists marijuana as having abuse potential.

Dr. Auslander testified that there is a difference between synthetic material of established purity and defined attributes, and botanicals, which are much more complex. Dr. Auslander further testified that the FDA recognizes the difficulties of going through its approval processes for botanical materials by permitting different approaches, such as fingerprinting and markers, than are used in synthetic products. Dr. Auslander testified that a marker is a response to chromatography that does not match the response of the source, i.e., a surrogate for some material believed to be active; that the FDA expects this material to be consistently present in the botanical product being studied; that the markers are quite important; and that at the advanced clinical stage, Phase III, the FDA would want them to be characterized and quantified.

Dr. Auslander testified that the "fingerprints" of a material are determined by spectroscopic and chromatographic procedures and provide a better understanding of what the material looks like and how it should behave. Dr. Auslander testified that chemical assay is a quantitative as opposed to qualitative analysis: "Qualitative just says this material exists. A chemical assay or quantitative assay will give you the evidence this material exists to what extent, how much of it exists."[68] Dr. Auslander noted that the FDA accepts the proposition that the chemical assay of a botanical material may not be feasible at the early stage and that it is sufficient to say that specific materials exist in the product without determining the extent to which they are present. Dr. Auslander testified that a biological assay is an alternative approach to analyzing botanical products and consists of administering the material to an animal and assessing the results.

Dr. Auslander testified that the Botanical Drug Guidance calls for an IND for a botanical to include a qualitative description, i.e., a description of what the material is and what it purports to be, of the drug substance that is the subject of the clinical program, as

opposed to a quantitative description, and would also include its biological activity and clinical indications, if known.

Dr. Auslander testified that potency relates to chemistry and manufacture control, and is in a sense a measure of the purity of the substance; efficacy pertains to whether the drug has the desired effects; and safety is the consideration of avoiding undesirable effects. Dr. Auslander testified that because botanical products are more complex than synthetic ones, it is more complicated to achieve the consistent quality necessary for efficacy and safety, and that the more active constituents a botanical product has, the more complicated it is. Dr. Auslander testified that some of the complications arising from using botanicals can be alleviated by extracting from them the active ingredient needed for development of a pharmaceutical product. However, Dr. Auslander noted that although extraction is always theoretically feasible, it may require a tremendous effort.

Dr. Auslander testified that his understanding of the Botanical Drug Guidance is that if the product is potent, highly active, toxic, addictive, or has abuse potential, the FDA "really wants"[69] either a biological or chemical assay. Dr. Auslander further testified that if the sponsor of a proposed new botanical product switched to a different source during the IND process, the sponsor would need to update the IND and submit the update to the FDA. Dr. Auslander testified that Phase I and II clinical studies would not necessarily have to be repeated if the sponsor switched sources, but the sponsor would have to show that the material from the two sources was equivalent. Dr. Auslander testified that it "would be a major exercise to go from source A to B during the advanced clinical trials, in particular where efficacy and safety profiles are being established. It would not be a trivial experience. It would be a major undertaking."[70]

Dr. Doblin testified that cloning enables reproduction of a plant's chemical composition, and that the FDA has held that it is acceptable to assess a plant's safety and efficacy by testing the plant as a whole, not each of its constituent compounds. Dr. Doblin noted that although there are probably more than 400 chemical compounds in marijuana, the FDA has developed guidelines for developing other botanical products

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[68] Transcript p. 2,012.
[69] Transcript p. 2,016.
[70] Transcript p. 2,029.

with similar numbers of compounds in them. Dr. Voth testified that marijuana's chemistry is known, and that although he did not think it was impossible to reproduce marijuana's chemistry, it would be difficult.

C. Evidence About Developing Pharmaceutical Products from Marijuana and/or Its Components

1. Background

In testimony before the Subcommittee on Criminal Justice, Drug Policy, and Human Resources, Committee on Government Reform, of the House of Representatives on April 1, 2004, Robert J. Meyer, M.D., Director of the Office of Drug Evaluation II of FDA's Center for Drug Evaluation and Research, described the FDA's process for demonstrating the safety and efficacy of new drugs and also discussed research with marijuana. Dr. Meyer stated that the Department of Health and Human Services and FDA:

> support the medical research community who intend to study marijuana in scientifically valid investigations and well-controlled clinical trials, in-line [sic] with the FDA's drug approval process. HHS and FDA recognize the need for objective evaluations of the potential merits of cannabinoids for medical uses. If the scientific community discovers a positive benefit, HHS also recognizes the need to stimulate development of alternative, safer dosage forms. In February 1997, an NIH-sponsored workshop analyzed available scientific information and concluded that "in order to evaluate various hypotheses concerning the potential utility of marijuana in various therapeutic areas, more and better studies would be needed."[71]

Dr. Meyer further stated that "FDA will continue to be receptive to sound, scientifically-based research into the medicinal uses of botanical marijuana and other cannabinoids. FDA will continue to facilitate the work of manufacturers interested in bringing to the market safe and effective products."[72]

In her April 1, 2004 testimony before the House subcommittee, Dr. Volkow noted the 1999 Institute of Medicine report discussed above, as well as the results of a two-day meeting convened by NIH in February 1997 that examined the research on the medical

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[71] Testimony by Robert J. Meyer, M.D., Director, Office of Drug Evaluation II, Center for Drug Evaluation and Research, FDA, before the Subcommittee on Criminal Justice, Drug Policy, and Human Resources of the House Committee on Government Reform (April 1, 2004); Respondent exhibit 54, p. 4.

[72] *Id.*; Respondent exhibit 54, p. 5.

uses of marijuana and its constituents, and stated that:

> Both reports found that there are too few scientific studies to determine marijuana's therapeutic utility, but that research is justified into marijuana's use for certain conditions or diseases including pain, neurological and movement disorders, nausea in patients who are undergoing chemotherapy for cancer, and loss of appetite and weight (cachexia) related to AIDS.[73]

Dr. Volkow further stated that subsequent to these reports, NIH had supported two studies on marijuana for medical use, one on the effects of smoked marijuana on HIV levels, appetite, and weight loss associated with HIV-related wasting syndrome; and the other on the effects of smoked and oral THC on HIV-infected individuals with unintended weight loss. Dr. Volkow noted that as of the date of her statement, the Department of Health and Human Services had approved seventeen clinical or preclinical studies undertaken by CMCR.

Dr. Volkow also stated that recent research had discovered a major class of cannabinoid receptors in the brain and another class found mostly on immune system cells, and that the brain receptor system was yielding insights into how marijuana disrupts memory traces. She added that recent research showed connections between the cannabinoid system and neuronal processes connected to relapse into cocaine abuse.

As noted above, the Institute of Medicine report on medicinal use of marijuana stated that purified cannabinoid compounds would be preferable as medicine to marijuana. Dr. Doblin testified that he disagreed with this statement because the botanical product may have ingredients with synergistic effects or ingredients that moderate the toxicity of other ingredients, but pharmaceutical companies may prefer to market only the isolated ingredients, which they can patent.

As also noted above, the Institute of Medicine report concluded that in most cases there are more effective medications than cannabinoids. Dr. Doblin testified, however, that marijuana seems to have a substantial effect in controlling nausea for some cancer chemotherapy patients when other medications do not work, and marijuana substantially stimulates appetite for some patients with AIDS wasting syndrome, and sometimes

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[73] Statement of Nora D. Volkow, M.D., Director, National Institute on Drug Abuse, National Institutes of Health, U.S. Department of Health and Human Services, before the Subcommittee on Criminal Justice, Drug Policy, and Human Resources of the House Committee on Government Reform (April 1, 2004); Government exhibit 31, p. 3.

controls pain that other medications do not.

2. NIDA, MAPS, and Developing a Pharmaceutical Product from Marijuana

NIDA holds and submits to the FDA the Drug Master File for the marijuana grown by the National Center. Dr. Gieringer testified that marijuana from the NIDA supply could not be used for an NDA because the developer would not have control over the drug – NIDA would, and thus NIDA or the contractor who grows marijuana for NIDA, rather than the developer, would have the Drug Master File for it. Dr. Gieringer acknowledged that NIDA could decide to develop a drug from the marijuana grown under contract with it, but testified that it would not make sense for a commercial company to rely on a supply of marijuana from NIDA because the company could not control the supply. Dr. Gieringer also emphasized that NIDA has stated that its mission does not include studying the medical uses of marijuana or advocating for support of research on such uses.

Dr. Doblin testified that MAPS was not doing any marijuana research because of the inability to obtain the drug, but that he thought that if MAPS had its own supply, it could raise the five to ten million dollars that it would cost to make marijuana into medicine, noting that more than fifteen million dollars had been spent on medical marijuana initiatives in various states. Dr. Doblin testified that he did not think that any for-profit pharmaceutical companies were working on making marijuana into medicine because it would be difficult to patent and because of the political obstacles to that effort.

Dr. Doblin testified that safety studies of potential new drugs analyze safety in thousands of patients, but that various governments have already assessed the risks of marijuana and these assessments are available in the scientific literature, so that the safety of marijuana could be tested on a much smaller group of 500 to 600 patients. In addition, Dr. Doblin testified, because MAPS is a non-profit organization, it has lower overhead and receives donated labor, and researchers work for non-profit organizations for less than they would charge for-profit pharmaceutical companies.

With respect to the factors to consider in determining whether marijuana has an accepted medical use, Dr. Doblin testified that he thought: (1) marijuana has a known and reproducible chemistry, as indicated by the FDA's acceptance of NIDA's Drug Master File; (2) there have not been adequate safety studies for the FDA to make marijuana into

medicine; (3) there have not been adequate efficacy studies; (4) there are qualified experts who have accepted marijuana as a medicine; and (5) there is substantial and widely available scientific evidence.

Dr. Doblin testified that the process for rescheduling a Schedule I drug requires adequate and well-controlled studies of both its safety and efficacy and then convincing the FDA that "you've demonstrated a balance of safety and efficacy that suggests that [the drug at issue] should be approved."[74] Dr. Doblin further testified that once the FDA has approved a Schedule I drug as a prescription medicine, it is up to the DEA to determine in which schedule the drug belongs.

D. Dr. ElSohly's Work with Marijuana Other Than for NIDA

Dronabinol is a synthetic form of THC and is a Schedule III controlled substance; Marinol is the brand name for a drug made from dronabinol and is used to enhance appetite and treat nausea.[75] Dr. ElSohly testified that there is currently one manufacturer of synthetic THC and that this company has an exclusive license with the manufacturer of Marinol and cannot produce the synthetic product for anyone else. Dr. ElSohly further testified that it would be very difficult for someone else to develop a new process to make synthetic THC and establish the facility to manufacture it, and that, consequently, a good alternative is to extract and purify THC from plant material.

The National Center also grows marijuana to prepare extracts that Tyco Healthcare, a division of Mallinckrodt, uses to develop pharmaceutical products. This marijuana is grown on the same plot on which the marijuana for NIDA is grown and could have a THC content as high as twenty-three percent.

In October 1999 the DEA and the National Center entered into a Memorandum of Agreement that permitted the National Center to develop THC in a pharmaceutically acceptable dosage form suppository and to provide a crude THC extract for further purification by a DEA-registered manufacturer. The memorandum noted, among other things, that the Single Convention prohibits private trade in marijuana, but that it does not prohibit private trade in "cannabis preparations," which would include the extract that the

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[74] Transcript p. 627.

[75] Dr. Voth testified that marijuana is most often abused in its plant form, and that he had not determined any significant abuse of dronabinol or Marinol in the United States.

National Center was developing. Consequently, the memorandum permitted the National Center to distribute THC extract to private entities as long as it complied with the Controlled Substances Act and DEA regulations.

By letter dated June 15, 2005, the DEA granted the National Center a manufacturing quota for 2005 of 4,500 kilograms for Mallinckrodt to use to produce a generic THC product. As of the date of the hearing, according to Dr. ElSohly, the National Center had about one thousand kilograms of bulk plant material in inventory for extract production, which he hoped would be used in suppositories that were in Phase I clinical trials.

Dr. ElSohly has patented processes to isolate THC from marijuana plant material, to convert THC to various ester analogs, to formulate suppositories containing readily available THC, to identify the country of origin of marijuana, and to prepare cannabichromene.

Dr. ElSohly is also the president and laboratory director of ElSohly Labs, Incorporated (ElSohly Labs), an analytic forensic laboratory in Oxford, Mississippi.

III. The Events Leading Up to Respondent's Application

A. About Research Utilizing Marijuana

The parties stipulated that "research continues about how cannabis may be of therapeutic benefit to patients."[76]

Dr. ElSohly testified that preclinical research encompasses the work performed before a drug is introduced into humans, e.g., chemical analysis, study of animal toxicology, or study of animal pharmacology; and that clinical research refers to studies of the drug in humans. Most of the research discussed in this proceeding was clinical research in humans and was undertaken using marijuana supplied by the National Center as authorized by NIDA.

As discussed above, the National Center cultivates marijuana pursuant to a contract with NIDA and supplies it to RTI, which rolls the marijuana into cigarettes and ships them to researchers as directed by NIDA. If research utilizing marijuana is funded by NIDA, the marijuana is provided free of charge; researchers who have approval to use

[76] Prehearing Ruling issued May 23, 2005; ALJ exhibit 5, p. 1.

marijuana but who are not federally funded are required to pay for the marijuana at a price set by NIDA.

The National Center produces marijuana with various contents of THC, including placebo material.[77] Dr. ElSohly testified that this material is prepared by extracting all the THC and other cannabinoids from active marijuana, but that the resulting material is rather dry and does not smell or taste like cannabis, and so experienced marijuana smokers can infer that they are getting placebo. Consequently, Dr. ElSohly was asked to develop a variety of the marijuana plant that would have almost no cannabinol, but would have the other components so that it would smell and appear more like active marijuana.

B. MAPS' Research Efforts

1. MAPS' Work with Donald Abrams, M.D.

Dr. Doblin testified that for his master's thesis he surveyed oncologists about the differences between Marinol and smoked marijuana, and that his study showed that some oncologists found smoked marijuana was more effective than Marinol in controlling nausea resulting from chemotherapy. Dr. Doblin further testified that after the FDA approved Marinol as a prescription medicine, research into smoked marijuana came to a halt, but he eventually contacted Donald Abrams, M.D., a leading researcher on acquired immune deficiency syndrome (AIDS), and worked with him to develop a protocol that eventually received the requisite authorizations to study marijuana's potential benefits for AIDS patients. Dr. Doblin testified that when Dr. Abrams applied to NIDA to purchase marijuana, NIDA did not act on his application for nine months and then declined to provide the marijuana.

By letter dated April 28, 1995, Dr. Abrams wrote to the then-Director of NIDA, responding to various concerns apparently raised by NIDA and expressing disappointment at NIDA's denial of his application. The letter stated, in part:

> As an AIDS investigator who has worked closely with [the] National Institutes of Health and the U.S. Food and Drug Administration for the past 14 years of this

[77] Dr. ElSohly testified that the placebo effect occurs when a subject thinks he is feeling the effects of a drug although he is not taking that drug but, rather, a product that does not contain the drug's active ingredient. Dr. ElSohly testified that in studies using marijuana placebo, the subjects rotate among using low-THC, high-THC, and placebo cigarettes, reporting on the effects of each use but not knowing which product they are using.

> epidemic, I must tell you that dealing with your Institute has been the worst experience of my career! The lack of any official communication for nine months is unheard of, even in the most cumbersome of government bureaucracies.[78]

Dr. Doblin testified that MAPS and Dr. Abrams attempted to obtain marijuana from a licensed company in the Netherlands, but that although the DEA said that an export permit from the Dutch government was a prerequisite to DEA approval, the Dutch government said it wanted the DEA to issue the import permit first, and in the end the marijuana was not imported. By letter dated May 10, 1995, Dr. Doblin asked Dr. ElSohly to supply marijuana for Dr. Abrams' study. By memorandum dated May 12, 1995, Dr. Doblin advised that he thought Dr. Abrams would also be willing to test a marijuana suppository on which Dr. ElSohly held a patent[79] if Dr. ElSohly could arrange for funding for the extra costs.

By memorandum dated May 24, 1995, Dr. Doblin advised Dr. Abrams that the Public Citizen Litigation Group had offered to help him challenge NIDA's decision not to provide marijuana for the proposed study and had suggested that Dr. Abrams file a Freedom of Information Act request pertaining to that decision. On May 25, 1995, Dr. Doblin sent a fax to Dr. ElSohly advising him that Dr. Abrams had agreed to expand the proposed study to include a group of patients who would receive a suppository, if Dr. ElSohly could fund that portion of the study and make appropriate marijuana available, and if Dr. Abrams could secure approval for that portion of the study from the various authorities who had already approved the initial proposal. Dr. ElSohly testified that he received the May 10, May 12, and May 25, 1995 letters but that he could not find any record of his responses, and that he was not sure whether he responded or not. Dr. ElSohly further testified that he did not feel that he could provide material for studies outside of his contract with NIDA because NIDA owned the marijuana he cultivated and because the contract required him to provide marijuana only to NIDA-approved researchers.

On June 1, 1995, Dr. Doblin wrote to Lester Grinspoon, M.D., advising him about

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[78] Letter from Donald I. Abrams, M.D., to Alan I. Leshner, Ph.D. (April 28, 1995); Respondent exhibit 15.

[79] Dr. Doblin testified that he did not think that at this point Dr. ElSohly had conducted any study of this suppository on humans and that the effort to develop the suppository was separate from Dr. ElSohly's contract with NIDA.

Dr. Doblin's efforts to obtain marijuana from a Swiss producer and about a representative of that producer's comments that he did not think the Swiss Minister of Health would "stand up to the DEA and authorize the export of marijuana"[80] to the United States. In that same memorandum, Dr. Doblin advised that he had not heard from Dr. ElSohly about obtaining marijuana from the National Center.

Eventually, Dr. ElSohly declined to provide marijuana for the study and Dr. Abrams did not undertake it. However, according to Dr. Doblin, following passage of California's Proposition 215 in 1996, NIDA contacted Dr. Abrams and said it would be interested in a study of the risks of marijuana use by HIV-positive patients. Dr. Abrams accepted this offer and NIDA provided the marijuana and one million dollars in funding. Dr. Doblin testified that the study showed that marijuana use did not hurt the immune system, increase viral load (the amount of virus in the blood), or negatively interact with the protease inhibitors[81] that the study subjects were taking, and that the subjects increased their caloric intake and gained weight.

Dr. Doblin also noted that the use of protease inhibitors had reduced the incidence of AIDS wasting in the United States, and that Dr. Abrams had concluded that rather than revisiting the rejection of his protocol on that subject, he would more effectively spend his research efforts on other clinical issues.

2. MAPS' Work with Ethan Russo, M.D.

Dr. Doblin testified that after NIDA refused to supply marijuana to Dr. Abrams, Dr. Doblin began working with Ethan Russo, M.D., a neurologist seeking funding from NIDA for a study on treating migraines with marijuana. Dr. Doblin testified that over about a four-year period, from roughly 1996 to 1999, NIDA rejected Dr. Russo's protocol several times and eventually Dr. Russo submitted his protocol to the FDA and to his own institutional review board, both of which approved it, but NIDA refused to supply marijuana. Dr. Doblin testified that as of the date of the hearing, Dr. Russo had been hired by a pharmaceutical company as a scientific advisor, and therefore could not do any further work on marijuana independently of that company.

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[80] Memorandum from Richard Doblin, Ph.D., to Lester Grinspoon, M.D. (June 1, 1995); Respondent exhibit 33.

[81] Protease inhibitors apparently inhibit replication of the virus.

3. The Orphan Drug Designation

By letter dated May 25, 1999, FDA's Office of Orphan Products Development notified Dr. Doblin that it had approved MAPS' application for designation of marijuana as an orphan drug[82] for the treatment of HIV-associated wasting syndrome. Dr. Doblin testified that MAPS has not been able to use this orphan drug designation because it has not been able to obtain marijuana from NIDA. According to Dr. Doblin, developing marijuana into a prescription medicine "is MAPS' explicit goal, so therefore, I think that sends up red flags, and anything that we do gets shut down."[83]

4. MAPS' Work with Chemic

Dr. Doblin testified that burning marijuana, as occurs when it is smoked, releases products that may be harmful, and that it seemed clear that developing a way to vaporize marijuana would be a step toward making the end product less irritating to the lungs. Consequently, according to Dr. Doblin, he felt it necessary to try to develop a vaporizing device that would deliver marijuana without combustion, and he and Dr. Gieringer initially looked at water pipes, using marijuana supplied by NIDA. Dr. Doblin testified that this study showed that water pipes filtered out cannabinoids as well as particulate matter, and that the various ingredients were in similar proportions in the water pipe smoke to what they were in the traditionally produced smoke.

Consequently, Dr. Doblin started working with Chemic Labs (Chemic), a DEA-registered laboratory that performs research under contract to pharmaceutical companies, so that Chemic could conduct research on using a vaporizer as a delivery device for marijuana. Chemic applied to NIDA for ten grams of marijuana and also applied to import ten grams from the Netherlands to use in studies to determine the consequences of

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[82] Dr. Doblin testified that an orphan drug designation carries tax incentives that do not apply to a non-profit organization like MAPS, but that it also sometimes causes the FDA to accept data from smaller groups of patients than it would require for other drugs. Dr. Throckmorton stated that dronabinol was given orphan drug designation for the stimulation of appetite and the prevention of weight loss in AIDS patients in 1991, but that this designation has no bearing on whether any other drug containing any component of marijuana will receive orphan drug designation in the future. Dr. Throckmorton also noted that determination of orphan drug status is made as of the time the request is made, and that a condition that meets the criteria of a rare disease at one point in time may not continue to meet those criteria in the future.

[83] Transcript pp. 689-690.

using the vaporizing device; according to Dr. Doblin, the NIDA marijuana had almost no cannabidiol but the Dutch marijuana did. Dr. Doblin testified that the purpose of this study was solely to test the device; no human use of marijuana was involved.

On May 19, 2004, Dr. Doblin wrote to Dr. Volkow, the Director of NIDA, protesting its failure to act on Chemic's application to purchase the ten grams of marijuana. According to Dr. Doblin's letter, Chemic Labs had filed its application on June 24, 2003, and applied to the DEA for an import permit for the Dutch marijuana on the same date. By letter dated June 9, 2004, Dr. Volkow responded to Dr. Doblin, advising that:

> As you know, NIDA is just one of the participants on the HHS review panel and continues, on behalf of the U.S. Government, to provide supplies of well-characterized cannabis for both NIH and non-NIH-funded research. The latter is conducted according to the procedures established in 1999 by HHS for obtaining access to marijuana for research purposes. It is not NIDA's role to set policy in this area or to contribute to the DEA licensing procedures. Moreover, it is also not NIDA's mission to study the medicinal uses of marijuana or to advocate for the establishment of facilities to support this research. Therefore, I am sorry but I do not believe that we can be of help to you in resolving these concerns.[84]

Shortly before the hearing in the instant case, NIDA rejected Chemic's application. In a letter to Chemic dated July 27, 2005, Joel Egertson, apparently Assistant Secretary for Health, Office of Public Health and Science of the Department of Health and Human Services, advised Chemic's president that the Department of Health and Human Services' program for providing marijuana for research focused on clinically meaningful research, and that a committee of scientists from the Public Health Service had concluded that the proposed project would not add significantly to the scientific knowledge base, that the rationale for each aim of the proposal was not clearly defined in the proffered protocol, and that the significance of the study with respect to furthering the field of knowledge and the study's clinical potential were not presented. Consequently, the committee recommended that NIDA not provide marijuana for the study.

Chemic responded by letter dated September 9, 2005, emphasizing, among other things, that the study it proposed to undertake was not a clinical investigation, and that it wished to evaluate differing vaporization efficiencies of cannabidiol and cannabinol.

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[84] Letter from Nora D. Volkow, M.D., to Richard Doblin, Ph.D. (June 9, 2004); Respondent exhibit 13.

Dr. Doblin testified that Chemic did not intend to redesign its protocol, but would challenge NIDA's conclusion that it was not scientifically meritorious. Dr. Doblin further testified that Chemic had applied for DEA registration to import marijuana and as a researcher and that the study was intended both to compare the Dutch marijuana to that produced for NIDA and to evaluate the vaporizer in terms of the consistency of its performance. Dr. Doblin testified that because this study would not involve testing on humans, no FDA approval is required, but that MAPS needed Public Health Service and NIDA approval to obtain the marijuana.

5. Dr. Doblin's Obtaining of Marijuana via the Drug Detection Laboratory

Dr. Doblin testified that the Drug Detection Laboratory in Sacramento, California, has permission from the DEA to accept samples of drugs from anonymous senders, and that he arranged for the Drug Detection Laboratory to send some marijuana to Chemic for the vaporizer studies described above. Dr. Doblin testified that he thought that the Drug Detection Laboratory was authorized to send marijuana to Chemic.

Dr. Doblin testified that he had "multiple relationships"[85] with the Drug Detection Laboratory and that, among other projects, he had made it publicly known that he would like some marijuana that patients in the compassionate use program had received from NIDA to be sent to the Drug Detection Laboratory so that its potency could be compared with that of marijuana from marijuana buyers' clubs. An unidentified compassionate use patient sent marijuana to the Drug Detection Laboratory, which analyzed it and then sent it, at Dr. Doblin's behest, to Chemic. Dr. Doblin testified that Jeff Zender, the head of the Drug Detection Laboratory, told him that representatives of the DEA talked to him about this incident; according to Dr. Doblin, "I didn't get the impression that it was necessarily forbidden, but I certainly got the impression that what we want to do was to go directly to NIDA, that that would be a preferable approach. And that's what we've done."[86]

C. About Current Arrangements to Supply Marijuana for Research

Dr. ElSohly testified that researchers wanting to utilize marijuana in their studies must seek it from NIDA, and that if NIDA approves the request, it directs Dr. ElSohly either to ship bulk material from his facility or to direct RTI to ship marijuana cigarettes.

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[85] Transcript p. 670.

Dr. Gust, the Special Assistant to NIDA's Director, testified that there are suppliers in addition to NIDA for some Schedule I controlled substances, but that for many of these substances NIDA is the sole supplier. Dr. Gust testified that he did not know whether there was any requirement that NIDA be the sole source for any Schedule I substances other than marijuana.

Dr. Gust testified that when a request for any controlled substance that NIDA provides for research is sent to the Drug Supply Program, there are three steps that must be completed: 1) the research proposal must undergo a peer review for scientific merit; 2) the researcher must obtain a DEA registration; and 3) the researcher must file an IND with the FDA. Upon completion of these requirements, the researcher submits a DEA order form to NIDA to obtain the marijuana.

According to an NIH Guidance released May 21, 1999, and still in effect as of the date of the hearing, NIDA evaluates non-NIH-funded studies as to scientific quality, the quality of the organization's peer-review process, and the objectives of the proposed research. The introduction to the NIH Guidance advises:

> The intent of this document is to provide guidance to the biomedical research community who intend to study marijuana in scientifically valid investigations and well-controlled clinical trials on the procedures of the Department of Health and Human Services (HHS) for providing research-grade marijuana to sponsors.[87]

Specifically, the NIH Guidance lists as factors it will consider in determining whether to provide marijuana:

> The extent to which the protocol incorporates the elements of good clinical and laboratory research; the extent to which the protocol describes an adequate and well-controlled clinical study to evaluate the safety and effectiveness of marijuana and its constituent cannabinoids in the treatment of a serious or life-threatening condition; the extent to which the protocol describes an adequate and well-controlled clinical study to evaluate the safety and effectiveness of marijuana and its constituent cannabinoids for a use in which there are no alternative therapies; the extent to which the protocol describes a biopharmaceutical study designed to support the development of a dosage form alternative to smoking; [and] the extent to which the protocol describes high-quality research designed to address basic, unanswered scientific questions about the effects of marijuana and its constituent

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[86] Transcript p. 677.

[87] National Institutes of Health, Announcement of the Department of Health and Human Services' Guidance on Procedures for the Provision of Marijuana for Medical Research (May 21, 1999); Government exhibit 24, p. 1.

cannabinoids or about the safety or toxicity of smoked marijuana.[88]

The NIH Guidance also specifies that the goal of the program "must be to determine whether cannabinoid components of marijuana administered through an alternative delivery system can meet the standards enumerated under the federal Food, Drug, and Cosmetic Act for commercial marketing of a medical product . . . ."[89] Dr. Gust testified that the Public Health Service review process would thus favor research on the derivatives of the marijuana plant and non-smoked delivery systems, but he also testified that research with the plant material and smoked marijuana is a necessary first step prior to research purifying marijuana's components and developing alternative delivery systems.

The NIH Guidance also states, quoting the Institute of Medicine report referenced above, that "'the purpose of clinical trials of smoked marijuana would not be to develop marijuana as a licensed drug, but such trials could be a first step towards the development of rapid-onset, non-smoked cannabinoid delivery systems.'"[90] Dr. Gust testified that he could not say that research seeking to develop marijuana as a licensed drug would be inconsistent with that goal, because that issue would be a question for the FDA rather than for NIDA, and he observed that the sentence quoted was from the Institute of Medicine, not the Public Health Service. Dr. Gust also testified, however, that "there is a strong endorsement of this concept within NIH and HHS that ultimately there's going to be pharmaceuticals developed based on the components of marijuana, that there will be purified pharmaceuticals. They won't be in a smoked product, and they'll probably develop to be administered through alternative delivery devices."[91]

The NIH Guidance further states:

> The focus of HHS's program is the support of quality research for the development of clinically meaningful data. HHS intends to make available a sufficient amount of research-grade marijuana to support those studies that are the most likely to yield usable, essential data. However, it should be noted that NIDA's supply of marijuana is subject to a number of constraints associated with the cultivation of a research-grade crop and that the supply at times may be

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[88] *Id.*; Government exhibit 24, pp. 2-3.
[89] *Id.*; Government exhibit 24, p. 2.
[90] *Id.*
[91] Transcript p. 1,706.

variable.[92]

The NIH Guidance interprets Articles 23 and 28 of the Single Convention as providing "that if a country allows cultivation of the cannabis plant for research purposes, the country must establish a national agency to control the cultivation and distribution of the crop."[93] The Guidance goes on to note, "Currently, the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), oversees the cultivation of research-grade marijuana on behalf of the United States Government."[94]

Dr. Gust testified that the NIH Guidance applies to applications to do research on medical uses of marijuana in human patients, and thus does not apply to basic research, some animal research, or research in healthy human volunteers. Dr. Gust further testified that NIDA does not have expertise in reviewing applications involving the use of controlled substances for treatment of disease, because such studies do not fall within NIDA's mission, so the Department of Health and Human Services moved the review of such applications to the Public Health Service. Dr. Gust acknowledged that Public Health Service review is required only for research proposals seeking to utilize marijuana, and not for other Schedule I drugs made available through NIDA's Drug Supply Program or for controlled substances not provided by the federal government. Dr. Gust testified that the members of the Public Health Service Review Committee are from the Public Health Service's component agencies, and are drawn primarily from FDA, NIH, and SAMHSA.[95]

Dr. Gust testified that a researcher seeking NIH funding for research with marijuana undergoes an NIH peer review process as part of the application for funding; a privately-funded researcher seeking to obtain marijuana for non-medical research undergoes an ad hoc review conducted by NIDA; and a researcher seeking marijuana for medical research undergoes the Public Health Service peer review. A researcher who does not request controlled substances from NIDA does not undergo any review from

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[92] National Institutes of Health, Announcement of the Department of Health and Human Services Guidance on Procedures for the Provision of Marijuana for Medical Research (May 21, 1999); Government exhibit 24, p. 2.
[93] *Id.*; Government exhibit 24, p. 1.
[94] *Id.*
[95] Dr. Gust testified that the committee, and not NIDA's director or deputy director, makes the final decision as to scientific merit.

that agency, but does undergo an FDA review. Dr Gust testified that the FDA process focuses primarily on safety rather than scientific merit, although he acknowledged that the NIH Guidance states that:

> FDA's primary objectives in reviewing an IND are, in all phases of the investigation, to assure the safety and rights of subjects, and, in Phase 2 and 3, to help assure that the quality of the scientific evaluation of drugs is adequate to permit an evaluation of the drug's effectiveness and safety. Therefore, although FDA's review of Phase 1 submissions will focus on assessing the safety of Phase 1 investigations, FDA's review of Phases 2 and 3 submissions will also include an assessment of the scientific quality of the clinical investigations and the likelihood that the investigations will yield data capable of meeting statutory standards for marketing approval.[96]

Dr. Gust testified that the Public Health Service review process generally takes three to six months.

Dr. Gust testified that in determining whether to provide marijuana for a study, the Public Health Service committee follows a similar procedure to that NIH uses in assessing the scientific merit of a proposal submitted to it for funding: NIH's peer review committees first determine which proposed projects they will not further consider and then review all the other proposals and assign them a grade from one to five, with one being the highest score. The projects are then considered for funding by the NIH institute to which they are assigned. Dr. Gust testified that as a practical matter, due to lack of funding, the cutoff for funding is generally a score somewhere between one and two. Dr. Gust testified that in determining whether to provide marijuana, the Public Health Service peer review committee generally does not distinguish between proposals with lower scores and those with higher scores: "any project that has scientific merit is approved."[97] Indeed, according to Dr. Gust, "anything that gets approved gets NIDA marijuana. So it gets approved for NIDA marijuana with high enthusiasm, medium enthusiasm, or low enthusiasm. It doesn't matter, they're all approved to receive NIDA marijuana."[98] Dr. Gust also testified that he thought that a researcher seeking to obtain FDA approval to make whole-plant smoked marijuana into a prescription medicine would not have a problem obtaining marijuana from NIDA as long as the researcher had

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[96] *Id.*; Government exhibit 24, p. 3.
[97] Transcript p. 1,700.
[98] Transcript p. 1,701.

an IND from the FDA.

Asked on cross-examination about the Institute of Medicine statement that the purpose of clinical trials would not be to develop a licensed drug from smoked marijuana, Dr. Gust iterated his earlier statement that he thought that ultimately, any approved medication made from marijuana would be a purified constituent delivered in a non-smokable form. Nonetheless, according to Dr. Gust, there was not, in his experience, a bias against approving marijuana as medicine at the Public Health Service review level. However, Dr. Gust responded affirmatively when asked on cross-examination, "A privately funded researcher might well obtain the appropriate DEA Schedule I registration, have their protocol reviewed and approved by the FDA, and still be denied access to NIDA marijuana by a Public Health Service committee under the conditions and priorities that are set forth in this document; isn't that correct?"[99]

Dr. Gust further testified that as a general practice, the Public Health Service review committee did not disapprove any project, but would point out deficiencies and weaknesses to the researcher and deny approval until those deficiencies and weaknesses were corrected and a revised protocol was submitted. Dr. Gust testified that NIDA had approved "probably dozens"[100] of applications to receive marijuana for research in the ten years prior to the hearing.

Dr. Gust testified that there are only a "handful"[101] of Schedule I controlled substances available from commercial sources. Respondent subsequently introduced into evidence exhibits showing that thirty Schedule I substances are available from commercial sources; the Government asked me to take administrative notice that there are 125 Schedule I substances, which I did. The Government asserts that these exhibits do not impeach Dr. Gust's credibility.

D. MAPS' Decision to Seek Alternative Sources of Marijuana

1. Complaints About NIDA-Provided Marijuana

Dr. Doblin testified that the marijuana from NIDA had a low THC content, that using higher-potency marijuana would result in patients inhaling less particulate matter

[99] Transcript p. 1,694.
[100] Transcript p. 1,740.
[101] Transcript p. 1,644.

for a given quantity of cannabinoids, and that he also wanted to experiment with strains of marijuana that contained other cannabinoids as well as THC. In addition, according to Dr. Doblin, some NIDA marijuana contained seeds, stems, and sticks; the presence of seeds meant that the female marijuana plants had not been separated from the male plants.[102] Dr. Doblin testified that female plants that have formed buds but that have not been allowed to go to seed are higher potency and that he thought that marijuana from such plants would be more likely to result in a satisfactory risk-benefit analysis from the FDA. Dr. Doblin further testified that the THC tends to be concentrated in the buds of the marijuana plant, and that leaves have lower concentrations of THC. Dr. Doblin testified that some of the NIDA marijuana was old, having been stored for years, and that it was also harsh.

In an article in the *Journal of Cannabis Therapeutics*, Ethan Russo, M.D., and his co-authors stated that patients complained that the NIDA-supplied marijuana was "harsh" or tasted "chemically treated."[103] The article further stated that the contents of the NIDA-supplied marijuana cigarettes were "a crude mixture of leaf with abundant stem and seed components . . . . The odor is green and herbal in character. The resultant smoke is thick, acrid, and pervasive."[104] The article concluded with a number of recommendations, including that "Improvement in a clinical cannabis program would include a ready and consistent supply of sterilized, potent, organically grown unfertilized female flowering top material, thoroughly cleaned of extraneous inert fibrous matter."[105]

Dr. ElSohly testified that he had seen this article, including a photograph in the article that showed debris in marijuana cigarettes. Dr. ElSohly testified that "there is no way that [the material shown in the photograph] is material that is actually in the

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[102] Dr. Voth, however, testified that he had "never seen anything systematic that said that seeds and stem constituents necessarily cause greater or less irritation."

[103] Ethan Russo, M.D., et al., *Chronic Cannabis Use in the Compassionate Investigational New Drug Program: An Examination of Benefits and Adverse Effects of Legal Clinical Cannabis*, 2(1) JOURNAL OF CANNABIS THERAPEUTICS 3, 48 (2002); Respondent exhibit 19. Dr. Doblin testified that there were four patients involved in the study.

[104] *Id.* at 49.

[105] *Id.* at 52.

cigarettes,"[106] because material of the size shown would have punctured the cigarette paper. Dr. ElSohly further testified that it was possible that some of the bulk material would look like that shown in the photograph.

Dr. Doblin testified that a Philip Alden, a patient who used marijuana in a NIDA study, complained to him about four years prior to the hearing in this matter that the marijuana provided by NIDA caused him to contract bronchitis and that his physician told him that the illness was due to the poor quality of the marijuana he had used, and that consequently Mr. Alden withdrew from the study. Dr. Doblin further testified that Mr. Alden told him that he had previously used a higher potency marijuana that he had obtained from buyers' clubs in California and that that marijuana use had improved his health. Dr. Doblin also testified that Mr. Alden declined to testify in this matter because he was concerned about the possibility that he would be prosecuted under federal law.

Dr. ElSohly testified that he had not received any complaints that the marijuana grown at the National Center had too many stems and/or seeds to be used for clinical research, but that Dr. Abrams had made comments to the effect that the marijuana had seeds in it. Dr. ElSohly further testified that from the inception of the marijuana growing program at the National Center, the growers had made an effort to remove seeds and other large particles from the plant material, but that the de-seeding machines they originally used made the material too fine to roll into cigarettes, and so RTI had said that it would be responsible for removing seeds from the material. Dr. ElSohly further testified that in 2001 the National Center worked with a company in Canada that designed a machine specifically to de-seed marijuana, and that the machine was put into operation that same year and removed seeds, stems, and any other heavy particles prior to shipping the marijuana material to RTI. Dr. ElSohly also observed that any large particles in the material would puncture the cigarette paper, and that the number of cigarettes that would have been subject to that problem even before 2001 would have been insignificant.

Dr. ElSohly testified that as of the date of the hearing, he had not received any formal complaints about the marijuana that the National Center provided. Dr. ElSohly testified that researchers from CMCR had requested marijuana at eight percent potency, and that he had offered to contact NIDA on their behalf and seek approval to make

[106] Transcript p. 1,306.

cigarettes at eight percent potency and that he had obtained the approval and made the cigarettes. Dr. ElSohly further testified that the cigarettes had turned out to have a potency above seven percent, that the variation between the actual potency and eight percent was not substantial enough to make a difference to the study, and that one of the researchers told him that he needed a batch of six percent potency because the seven-plus percent potency material was too strong for the subjects to tolerate.

Dr. Gust testified that he was not aware of any formal written complaints about the quality of NIDA-provided marijuana, nor had any researcher, doctor, or patient called him to advise him of any such complaints.

2. Other Concerns about NIDA Marijuana

Dr. Doblin testified that he had concluded that MAPS would need to obtain a source other than NIDA for marijuana, noting that NIDA is not in the business of supporting medical marijuana research and is not authorized by Congress to sell marijuana for prescription use. More specifically, Dr. Doblin testified that because MAPS seeks to obtain FDA approval for marijuana as a prescription medicine, it needs to establish a Drug Master File for a specific product and then conduct research on that product and have it available for marketing if it receives FDA approval. Dr. Doblin testified that MAPS would need a source of supply that would provide specific strains and quantities of marijuana whenever required, which NIDA does not do. Dr. Doblin further testified that although making a profit on a marijuana product is not MAPS' primary goal, it would need a reliable source of supply nonetheless and would also need to have control over the source of supply in order to meet FDA requirements. Dr. Doblin emphasized, in that connection, that the FDA requires the marketed drug to be the same one that was used in research. Dr. Doblin also noted that because NIDA marijuana is less potent than the marijuana that MAPS would like to use for research, the risk/benefit ratio of NIDA marijuana is less favorable, which would make it more difficult to secure FDA approval. In addition, Dr. Doblin testified, because Congress has not authorized NIDA to sell marijuana on a commercial basis, MAPS would have to negotiate with Dr. ElSohly, who would be a monopolist supplier and set whatever price he chose.[107]

[107] Dr. Doblin testified that he did not know whether Dr. ElSohly was precluded from supplying marijuana to anyone except pursuant to NIDA instructions.

IV. About Respondent and His Application for Registration

A. About Respondent

Respondent is a full professor in the Department of Plant, Soil, and Insect Sciences at the University of Massachusetts at Amherst. He received a Bachelor of Science degree in agronomy from the University of Wisconsin and in 1967 received a Ph.D. in the same subject from the University of Minnesota. Following active duty in the United States Army Chemical Corps, he was hired at the University of Massachusetts' University Experiment Station in Waltham, Massachusetts, where he worked from 1969 to 1976. Respondent then took a sabbatical leave in Cambridge, England, for six months and was hired at the Amherst campus on his return.

Respondent testified that he has done substantial work on the effect of air pollution on plant growth and development and that he also specializes in medicinal plants. Respondent testified that he receives funding for his research from, among other sources, the United States Environmental Protection Agency and the United States Department of Agriculture. Respondent testified that he is interested in growing marijuana for use in research trials because of his work with medicinal plants.

B. Respondent's Application for Registration as a Manufacturer of Marijuana

Dr. Doblin testified that once he concluded that MAPS would need its own source for marijuana, he concluded that inasmuch as Dr. ElSohly was affiliated with the University of Mississippi, a university affiliation would enhance the likelihood of obtaining DEA approval for registration as a manufacturer. Dr. Doblin further testified that he wanted someone with expertise in medicinal plants who was a tenured faculty member so that his or her career would not be jeopardized by involvement in a controversial issue and who would be able to resist pressure to withdraw the application. Finally, Dr. Doblin testified, he wanted someone who had not had any previous involvement in efforts to legalize marijuana. Dr. Doblin testified that he contacted various persons involved in botanical medicines and eventually someone recommended Respondent. Dr. Doblin testified that he telephoned Respondent and explained that MAPS focused on FDA-approved research rather than attempting to bypass the FDA via state initiatives, and that he would like to contract with Respondent to grow marijuana for

FDA- and DEA-approved projects. He told Respondent that MAPS would provide a grant to the university to cover the costs of growing marijuana if Respondent could obtain the requisite licensure. Dr. Doblin subsequently visited Respondent and discussed with him, among other things, the needs for various strains of marijuana, problems with obtaining marijuana from NIDA, and the risks of doing research with a drug that might not be available for prescription use. Dr. Doblin testified that he and Respondent also talked about MAPS' desire to operate like a standard pharmaceutical company and to obtain a supply of marijuana that it could take through the requisite testing process, as well as his decision to work on an alternative to smoking as a system to deliver marijuana.

Dr. Doblin testified that he and Respondent entered into a memorandum of understanding providing that MAPS would cover all costs associated with the project, that any equipment purchased would remain the property of the university if the contract ended, that MAPS would not claim any proprietary interest in any information that Respondent might obtain from the project, that MAPS would indicate where any marijuana Respondent grew would be used, and that the marijuana would only be used in government-approved studies.

Dr. Doblin testified that at this point he had stopped trying to develop marijuana research projects and was working on the vaporizer research and on obtaining an independent source of supply of marijuana. Dr. Doblin further testified that he knew that there was a pent-up demand for research on medical uses of marijuana, so that once he had a supply, it would not be difficult to develop appropriate projects.

Respondent testified that after his conversations with Dr. Doblin he spoke with various university officials, including his department head, his dean, personnel at the Office of Grants and Contracts, and the Vice Chancellor for Research, and that none of them had any objection. Respondent then submitted the appropriate internal university forms and, on June 25, 2001, an application for registration with the DEA.

Respondent testified that he had heard that marijuana was grown for research purposes, but that until Dr. Doblin contacted him he had no interest in cultivating marijuana himself. Respondent testified that several years earlier the state of Massachusetts had approached him about growing marijuana for medical uses and he had

done a little bit of research on the subject, and that after he talked to Dr. Doblin he researched the possibilities of marijuana "as perhaps a medicine that should be available to the public, not to violate security regulations or not to see it diverted into a recreational drug, but to – I thought it could be a medicine that could be used."[108]

Respondent testified that from his conversations with Dr. Doblin he understood that his role would be to produce marijuana and that MAPS would have direct contact with researchers and refer them to Respondent to obtain the marijuana they needed. Similarly, Respondent testified that his role with respect to research using vaporizers would be limited to supplying the marijuana used in testing the vaporizer.

Respondent testified that all research at the University of Massachusetts is done by source of funding, that he would not have filed the application to cultivate marijuana had Dr. Doblin not approached him, and that all the costs of growing marijuana, including the requisite expenditures for security, would have to be funded by a research grant to the university. Respondent also testified that at the time he filed his application, he had no idea how much marijuana the University of Mississippi produced and had only a minimal idea that there had been some complaints about the quality of the University of Mississippi's marijuana. Respondent testified that he became concerned about whether sufficient marijuana from the University of Mississippi was available to researchers.

Shortly after Respondent submitted the application, state investigators came to the university and discussed state security requirements, and also told Respondent that a state permit would depend upon obtaining federal registration.

C. Respondent's Process for Growing Marijuana

Respondent testified that he would grow marijuana much the same way he would grow other plants: he would grow plants from seed in a growing medium in a greenhouse, germinating the seeds in flats and then transferring the seedlings to pots. Respondent said that he would probably prefer to obtain seeds from an outside source rather than collecting seeds from the plants he grew, but that he would follow DEA instructions on the matter. Respondent testified that he had a room available that had one wall in the earth and only one door, as required.

Respondent testified that he would have to purchase a drying oven because those

[108] Transcript p. 212.

that he had were too large and could not be secured. Respondent testified that it would be possible to grow marijuana in a completely controlled environment, thereby making it possible to obtain more information about optimal conditions for growing the plant for various purposes, but whether he could construct that environment would depend on his funding.

D. How the Marijuana Respondent Proposes to Grow Would Be Utilized

Respondent testified that as a non-profit institution the University of Massachusetts would not make any profit on the marijuana he would grow, and that he had not sorted out the details as to how much researchers would have to pay for marijuana he supplied to them.

Respondent testified that he did not know who the potential customers for his marijuana would be and that MAPS might direct researchers to him, but that in any case those researchers would be properly licensed. Respondent testified that he knew that MAPS planned to sponsor research using a vaporizer device to deliver marijuana without burning it, but that he did not know who would develop the device, whether the company was currently permitted to receive marijuana for research, or what quantity or quality of marijuana the company would need.

Dr. Doblin testified that if Respondent's application is approved, Respondent will manufacture marijuana according to MAPS' requests for certain potencies, that Respondent would provide it to researchers at MAPS' direction, and that MAPS would allocate the marijuana first to projects it sponsored and then, if sufficient marijuana was available, to other researchers either for free or at cost. Dr. Doblin emphasized that MAPS would at no time have possession of any marijuana.

Dr. Doblin testified that if Respondent's application is approved, MAPS intends to develop a clinical plan in consultation with the FDA, which will include the selected patient population, the sequence of studies to be conducted, and the time frame for those studies. He said that MAPS would then solicit researchers to conduct the studies.

Respondent testified that if he becomes registered, he has no intention of replacing NIDA as a supplier of marijuana for research, but only to provide an alternative supplier. Respondent also testified that he would pursue the application even if he knew that the National Center supplied an adequate quality and quantity of marijuana to

researchers, because under the current arrangement the government decides what research is relevant and because an alternative source of supply would be appropriate for comparison purposes.

E. The DEA's Actions With Respect to Respondent's Application

1. Initial Activity

Respondent testified that eight or nine months after submitting his application, he still had not heard from the DEA, so he contacted the agency and eventually was referred to Diversion Investigator Sharon Lick, who advised that the DEA had not received Respondent's application and that he should file it again. Subsequently, however, Respondent received the June 25, 2001 application back from the DEA; it was date stamped June 28, 2001. Respondent again called Investigator Lick and told her that the application had been returned to him. According to Respondent, Investigator Lick then told him that he filled out the application incorrectly and should submit a new one, but when he went through the form with her, she had no corrections to make.

On August 22, 2002, Respondent resubmitted his application, along with written responses to various questions that Investigator Lick had sent him. Specifically, Respondent stated, among other things, that the purpose of applying for a registration to manufacture marijuana was to supply a defined (i.e., grown to specifications) marijuana product to investigators undertaking clinical trials with marijuana; that MAPS would provide the funding for the work; that the research would involve either smoked marijuana or marijuana delivered by a vaporizer device; that the marijuana would be grown in a secure and environmentally controlled room; and that Respondent estimated that about twenty-five pounds of marijuana (dry weight) would be grown in the first year with a THC level of seven to fifteen percent. Respondent testified that Dr. Doblin assisted him in preparing answers to these questions.

Although in responding to the questions Investigator Lick sent him Respondent referred to smoked marijuana, he testified that the only proposed use of which he was aware for the marijuana he sought to grow is vaporizer studies, and that he would need the authority to grow marijuana to be smoked in order to allow for comparisons between smoked and non-smoked material. Respondent testified that he probably referred to smoked marijuana because smoking is a common delivery system for the drug, but that as

of the date of the hearing and because he had read more about smoked marijuana, he found that a "less attractive delivery means."[109] Respondent further testified that if he produced marijuana for use by researchers who utilized it in smoked form, he would provide it in bulk, not rolled into cigarettes.

Respondent testified that about six to eight weeks after he submitted the August 2002 application, two DEA investigators visited the campus and met with Respondent, his department head, the dean, and the Vice Chancellor for Research. Respondent testified that he thought the DEA personnel were trying to discourage the university from undertaking the project, but that the university officials said that the university was a research institution and that "these are the type of problems that we worked on."[110]

Respondent testified that DEA personnel made a second visit to the university in either the fall of 2003 or the spring of 2004, and that during this visit they walked around the campus with him and discussed where and how the marijuana would be grown. Respondent testified that the DEA personnel thought the room he proposed to use to grow marijuana could be made secure and that he also showed them a room which would be connected to the growth room and where he would dry the material.

In a letter dated June 2, 2003, to Frank Sapienza, then Chief of the Drug and Chemical Evaluation Section of the DEA's Office of Diversion Control, Respondent stated that testing marijuana for medical use would cost several million dollars, an expense that private drug companies would be hesitant to incur unless they were assured that they would be able to evaluate various sources for marijuana. Respondent testified that he based this statement on anecdotal evidence of the cost of developing new drugs, but that he had not received any specific information on the subject from any pharmaceutical company. Respondent also stated in the letter that in private conversations, researchers had indicated to him that they were afraid they would lose their access to marijuana if they complained about the material currently available to them. Respondent testified that he based this statement on conversations with Dr. Doblin, on conversations at a conference he had attended, and from emails from various individuals, but that he did not know if these emails were from legitimate researchers and

[109] Transcript p. 241.
[110] Transcript p. 43.

did not have any information about whether any legitimate researchers had stated their complaints to NIDA.

Respondent attached to the letter a copy of an article dated January 24, 2003, from the *San Mateo Times* and a copy of a letter dated March 11, 2003, from Dr. Russo, the neurologist with whom MAPS had been working, to Mr. Sapienza. The newspaper article stated that doctors conducting a study to discover whether marijuana cigarettes could be safely provided to HIV/AIDS and cancer patients to treat symptoms and side effects of the treatment of their diseases "want better quality weed from the federal government."[111] The article quoted Dennis Israelski, M.D., as saying that "[t]he study continues, but is going slowly for a variety of factors,"[112] and also advised that "some believe the apparently low-grade marijuana used in the program – grown at the University of Mississippi by the federal government – has discouraged participants who can treat themselves with the drug through other channels. And stringent physical requirements on often terminally ill patients have also slowed membership in the study."[113] The article also stated that Phillip Alden (about whom Dr. Doblin testified, as noted above) dropped out of the study when he contracted bronchitis, and quoted Mr. Alden as stating that he would rejoin the research if the quality of the marijuana improved and that he believed the papers in which the cigarettes were rolled contained toxins.

The letter from Dr. Russo stated, among other thing, that he had held Schedule I registration since 1996 and possessed 100 grams of NIDA marijuana since 1997, but that "the material was of such poor quality, we did not deem it to be representative of true medical cannabis, and have not yet ascertained an appropriate set of biochemical experiments for which to utilize it."[114] Dr. Russo further stated that the only reason he had not completed his clinical study of cannabis in migraine was that NIDA had refused to supply the material, that the reason the University of Massachusetts facility was necessary is that "all FDA-worthy studies should have access to clinical cannabis without

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[111] Jean Whitney, *Doctors Want Better Marijuana for Study*, SAN MATEO TIMES, Jan. 24, 2003; Government exhibit 30a.
[112] *Id.*
[113] *Id.*
[114] Letter from Ethan Russo, M.D., to Frank Sapienza (March 11, 2003); Government exhibit 30b, p. 1.

superfluous, expensive, and redundant Public Health Service oversight,"[115] and that he was taking over another researcher's compassionate use IND because NIDA had not responded to that researcher's request for higher-potency material. Dr. Russo stated that he admired Dr. ElSohly and his colleagues and harbored no personal animus against them, and that he had not said NIDA was incapable of producing quality marijuana, but that "[d]espite protestations to the contrary, NIDA continues to supply seeded material that is poorly cured, and relatively impotent."[116] Dr. Russo further stated that in light of the cost of Phase III clinical trials, "no sponsor of cannabis research is likely to accept a situation in which they have no control over the product that they hope to be marketing in the future."[117] Dr. Russo closed his letter by stating that "it is grossly evident that NIDA is profoundly conflicted in serving as purveyor of cannabis for medical studies, and there is no better reason that the University of Massachusetts should advance with the project."[118]

Respondent testified that he received a notice by mail inviting him to bid on the contract to grow marijuana for NIDA, but concluded that there was little likelihood that he could put forward a successful bid in light of the University of Massachusetts' lack of experience in growing marijuana. Respondent also testified that he was not interested in analyzing seized material, which would be required by the contract, although he had the instruments to do that work.

2. Dr. ElSohly's Comments and Objections to Respondent's Application

Dr. ElSohly testified that the DEA sent him the *Federal Register* notice of Respondent's application,[119] and that he filed comments and objections to that application in a letter dated September 9, 2003. In the letter, Dr. ElSohly stated, among other things, that the University of Mississippi provided its subcontractor with marijuana that had

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[115] *Id.*
[116] *Id.*
[117] *Id.*
[118] *Id.*; Government exhibit 30b, p. 2.
[119] The DEA's regulations, at 21 C.F.R. § 1301.33, require the agency to mail copies of the *Federal Register* notices of applications for registration to bulk manufacture a Schedule I or II controlled substance to all persons who are currently registered or have applied for registration to manufacture that basic class of substance.

"absolutely no seeds or heavy stem particles,"[120] that the University of Mississippi had not received any formal complaints about the adequacy of the marijuana it provided for research, and that "we strongly feel that it is absolutely unnecessary to approve another manufacturer's registration to manufacture (cultivate) marijuana and tetrahydrocannabinols for distribution to approved researchers. Approval of the University of Massachusetts-Amherst [application] would result in a duplication of existing resources without any foreseeable benefits."[121] Dr. ElSohly testified that he meant by this statement that the "duplication of efforts in terms of production of marijuana for research and distribution of that marijuana for research is a duplication of effort where there is no deficiency to be covered at this time as far as I can see, and so there is no benefits other than you just have another producer."[122]

In a draft of his comments that he had sent to Dr. Gust on August 29, 2003, Dr. ElSohly stated, "Those researchers with projects that do not meet the scientific approval criteria by NIDA would not receive marijuana free of charge. Rather, if those researchers wish to carry out their research project(s), they are nonetheless still allowed to receive their needs of marijuana but they are required to pay for the material (the cost of production has been calculated and the researchers would pay just the production costs),"[123] and that "In addition to the above-described NIDA program and the availability of materials through that program, we at the University of Mississippi have a separate DEA registration . . . to manufacture (cultivate) marijuana and manufacture tetrahydrocannabinols. Materials could be made available to researchers that are properly registered with the DEA and that for some reason do not want or choose to go through the NIDA program or somehow do not qualify to receive materials under the NIDA program. We are prepared to meet any need, qualitatively and quantitatively, in this area."[124] These statements do not appear in Dr. ElSohly's comments as submitted to the DEA, and on cross-examination Dr. ElSohly testified that he should not have included

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[120] Letter from Mahmoud A. ElSohly, Ph.D., to the Deputy Assistant Administrator, Office of Diversion Control, DEA (September 9, 2003); Government exhibit 5, p. 3.
[121] *Id.*
[122] Transcript p. 1,423.
[123] Draft of *Federal Register* comments attached to an email from Dr. ElSohly to Dr. Gust on August 29, 2003; Respondent exhibit 5.

these statements and that he knew he could not provide plant material except through NIDA.

Dr. Gust testified that he commented on Dr. ElSohly's response to Respondent's application, but that his review was primarily for factual accuracy.

3. The DEA's Investigation Pertaining to Respondent's Application

Matthew Strait, Unit Chief for the Quota and U.N. Reporting Unit, Drug and Chemical Evaluation Section, of the DEA's Office of Diversion Control,[125] testified that when the Office of Diversion Control receives an application for registration to bulk manufacture a Schedule I or II controlled substance, the application is sent to the Registration Unit, which assigns a control number to the application and forwards it to the appropriate section of the agency (as of September 2004, Mr. Strait's office) for further action. Mr. Strait further testified that according to the normal practice in 2001, Respondent's application would have been assigned to a diversion investigator.

Mr. Strait testified that Respondent's application did not come to his attention until October 2002 and that he thought that the delay was due to the then-Administrator's criticism of the Office of Diversion Control for not informing the Administrator's office about registrations of certain researchers to work with marijuana and a consequent "virtual paralysis when anything came out with regard to marijuana."[126] Mr. Strait further testified that Respondent's application was filled out incorrectly because although Respondent listed the drug code number for marijuana, he failed to circle it, as required by the application's instructions.[127] Mr. Strait further testified, however, that he did not discuss this point with Investigator Lick, who apparently was then the diversion investigator in charge of the DEA's Registration Unit, and that he did not know whether

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[124] *Id.*

[125] The Office of Diversion Control is a component of DEA's Division of Operations and consists of sections which are further divided into units.

[126] Transcript p. 923.

[127] The drug code numbers are handwritten on Respondent's application. The application form states, in item 8, that applicants for registration to manufacture substances in "Schedule I, II, III, IIIN in addition to codes furnished, . . . MUST Circle Below those 'Basic Classes' of controlled substances in Schedule I and II which you propose to 'Manufacture in Bulk'[.]" [Emphasis in original.] Mr. Strait testified that "I know it seems like a [moot] point, but if they [applicants] don't circle it, it has a vastly different way that it's processed within the office." Transcript p. 929.

this defect contributed to the delay in processing the application. Mr. Strait testified that Respondent's application raised other issues as well, notably that Respondent sought to manufacture a Schedule I substance in order to develop a pharmaceutical product; the right of the University of Mississippi to comment on the application, which might result in a hearing; and the DEA's longstanding concerns about MAPS and Dr. Doblin.

On March 4, 2003, Mr. Sapienza wrote to Respondent, advising that it appeared that the basis for Respondent's application was an alleged need for more potent and higher quality marijuana and that the DEA had legal and international treaty concerns about the application. Mr. Sapienza wrote that the DEA also disagreed with Respondent's assessment of the availability of marijuana to the research community because the agency had contacted NIDA, the Department of Health and Human Services, and various researchers and had concluded that the quantity and quality of marijuana available from NIDA was acceptable. The letter further stated that the DEA had received a copy of Dr. Russo's letter, that Dr. Russo was not registered by the DEA to conduct research with marijuana, and that the agency was not persuaded by Dr. Russo's arguments. Mr. Sapienza closed by asking Respondent to provide any credible evidence of his assessment of the issue and especially any correspondence with NIDA on the matter.

a. The Interviews of Researchers

On September 23, 2003, Mr. Strait and Diversion Investigators Lydia Bagley and Lucia Bartolomeo met in San Diego, California, with staff members of the CMCR and researchers working under CMCR auspices. Mr. Strait testified that he opened the meeting by explaining that he was there because the DEA had received an application for registration to cultivate marijuana, that the application had raised issues about the quality and potency of the National Center marijuana, and that the DEA wanted to know the researchers' thoughts on these issues. Dr. Igor Grant, head of CMCR, provided an overview of CMCR and its three-stage research mission: (1) look at the effect of smoked marijuana in certain patient populations; (2) identify novel drug delivery systems, such as inhalants, sprays, and vaporizer devices; and (3) research the constituent cannabinoids or slightly altered forms of them, to see if they could be used in certain populations. Mr. Strait testified that at the time of his meeting with CMCR personnel, the research was in the first of the three stages.

Mr. Strait gave the researchers a questionnaire, which the participants discussed at the September 23 meeting; Heather Bentley, a CMCR staff member, then wrote in additional comments and returned the questionnaire to Mr. Strait about two-and-a-half months later. The questionnaire asked whether CMCR was responsible for coordinating with NIDA to obtain marijuana; what the process was for obtaining marijuana; what forms and strengths of marijuana CMCR used; who placed the request for the drug; how the order was placed; how CMCR determined how much marijuana its researchers needed; how the marijuana was shipped; what security measures were in place during shipment; how much time elapsed between placing the order and shipment; whether CMCR was billed for the material; the cost of each cigarette; how the cost of marijuana compared to other potentially efficacious substances used in research; how the cigarettes were stored; what security measures were in place; whether ample stocks were available; how the cigarettes were dispensed to patients; whether any patients had encountered problems obtaining the marijuana cigarettes they were prescribed; whether any problems in obtaining marijuana had compromised the study; whether the method by which CMCR received marijuana cigarettes from NIDA was adequate; what CMCR's future research interests were with respect to marijuana; whether CMCR had any information that marijuana would be unavailable through NIDA in the future or that the supply would be insufficient; whether CMCR had had any difficulty in obtaining marijuana from NIDA in all the requisite strengths; whether such difficulties had been documented, whether they threatened the integrity of the research protocol, and how the issue had been resolved; whether NIDA had ever refused to supply marijuana to CMCR researchers with approved protocols; whether, based on its anticipated future research needs, CMCR had any concerns about the availability of research-grade marijuana from NIDA; whether the person responding to the questionnaire had visually inspected the cigarettes received from NIDA and whether there was a visual difference between the placebo and the non-placebo product; whether there was a visual difference among the cigarettes containing different levels of THC; whether the potency of the current product was consistent; whether the person responding had observed any physical deformities in the cigarettes' appearance; what plant parts had been observed in the cigarettes; whether the presence of plant parts rendered any of the cigarettes unacceptable for research; whether any patients

had complained about the harshness of the material; whether any issues of quality of the material had adversely affected the research; the potency of the marijuana currently approved for research; whether the current product was adequately potent; whether information received from any of the ongoing studies indicated that the potency of the marijuana was inadequate; whether the responder had sought a higher-potency product; whether it would be clinically important to evaluate the efficacy of a higher-potency cigarette; whether any information suggested that a higher-potency product would have a beneficial outcome compared to the product NIDA currently provided and, if so, whether the benefits would outweigh the risks; what alternative potency could be safely administered; what safety concerns would be associated with a higher-potency product; and whether CMCR had contacted NIDA to ascertain whether producing a higher-potency product would be feasible.

At the meeting, Dr. Grant said that visual examination of both the placebo and non-placebo NIDA marijuana disclosed no differences between them; and that he had visited the University of Mississippi growing operation and was satisfied with the consistency of its product. He added that the product was mostly devoid of seeds and stems, but that there was some variation within a range of potency. Dr. Grant told Mr. Strait that the marijuana from the National Center was sometimes harsh and caused patients to cough, but that nothing in the quality of the product affected CMCR's research. Ms. Bentley subsequently added to CMCR's responses to the questionnaire a comment that the researchers would prefer that the strength of the marijuana in the cigarettes they received from the National Center be more consistent. Mr. Strait further testified that Dr. Grant told him that the National Center guaranteed the potency of its marijuana within a specified range and that pursuant to discussions with NIDA, CMCR had concluded that a potency of eight percent was appropriate.

Also on September 23, 2003, Mr. Strait telephonically interviewed Ronald Ellis, M.D., Ph.D. The questionnaire that Mr. Strait prepared for Dr. Ellis and other researchers differed from that he gave to the CMCR personnel; the questionnaire Mr. Strait gave to Dr. Ellis asked, in substance: whether patients had experienced problems obtaining marijuana cigarettes they were prescribed for research; whether the method by which the researcher received marijuana from NIDA was adequate; what future research interests

the responder had that would require using marijuana; whether the responder had any information indicating that the supply of marijuana from NIDA would be insufficient in the future; whether the researcher had visually examined the NIDA marijuana and, if so, whether there were any visible differences between the placebo and non-placebo product or among products with varying levels of THC; whether the potency of the current product was consistent; what plant parts the researcher had observed in the product; whether any of the plant parts in the product rendered it unacceptable for research; whether patients had complained about the "freshness" of the marijuana; whether issues concerning the quality of the marijuana had adversely affected the research; what the potency was of the marijuana used in the responder's research; whether the potency of the product was adequate for the research; whether the researcher had sought a higher-potency product; whether it would be clinically important to evaluate the efficacy of a higher-potency product for the researcher's patient population and, if so, what would be the benefits and risks, whether the former would outweigh the latter; what alternative potency could be safely administered to the patient population; and what would be the safety concerns.

Dr. Ellis said, in substance, that his patients had not had problems obtaining marijuana he prescribed to them; that the method by which he obtained marijuana from NIDA was adequate; that he had no information indicating that the supply of marijuana in the future would be insufficient; that he had not visually examined the cigarettes supplied to his patients; that there had been some variation in at least two marijuana shipments between the stated and the measured potency, and "they have been very responsive";[128] that some patients had reported the smoke was harsh and they found it difficult to finish the cigarette, but this had not adversely affected the research, although one patient had dropped out of the study because he developed a cough related to the harshness of the marijuana; and that although marijuana that was supposed to be a potency of eight percent had tested as seven percent, this potency was adequate and potency was not a limiting consideration in his research.

Dr. ElSohly testified that he thought that the notation about the variability between the stated and the analyzed THC content referred to the batch of cigarettes,

described above, that was supposed to be at eight percent potency and that was analyzed at seven-plus percent potency. Dr. ElSohly further testified that he never received any formal complaints about the harshness of the cigarettes that the National Center provided, but he did hear unofficially about harshness, particularly attributed to the placebo material, and that he thought this harshness would be due to the nature of placebo material: all the components had been extracted out.

Also on September 23, 2003, Mr. Strait interviewed Jody Cory-Bloom, M.D., Ph.D., in person. Dr. Cory-Bloom said that patients had not had any problems obtaining the marijuana prescribed to them; that the method for obtaining marijuana from NIDA was adequate; that she was interested in research into delivering marijuana by means other than smoking; that she had not observed any visual difference between the placebo and non-placebo products; that she used marijuana of four percent potency, did not need a higher potency for her current study but would be interested in using higher concentrations perhaps in future work, and did not know whether the potency of the product she received was consistent, apparently because she was a blinded investigator, i.e., she did not know what the research subjects received; that a patient had complained to her that the product he had used was harsh, but she did not know whether he had used marijuana or the placebo; and that she found it difficult to recruit patients to participate in studies using smoked marijuana because people were not smoking marijuana as much as they used to, there were many criteria for inclusion in the study, and a time commitment was required.

Dr. ElSohly testified that he had not received this complaint about harshness, and that it may have been the case that the patient in question was being administered placebo material.

Also on September 23, 2003, Mr. Strait telephonically interviewed Dennis Israelski, M.D. Dr. Israelski said that his patients had not had problems obtaining the marijuana he prescribed; the method for obtaining marijuana from NIDA was adequate; he had no reason to believe that the supply from NIDA would be insufficient in the future; the potency of the product he had received was consistent; he had not observed any physical deformities in the product; he did not recall any complaints from patients

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[128] Government exhibit 17, p. 6.

about the freshness of the marijuana; and that the potency of the product he received was adequate for his research. Dr. Israelski also discussed the *San Mateo Times* article that Respondent had sent to the DEA, and denied making comments to the newspaper about the quality of the marijuana he obtained from the National Center. Indeed, according to Mr. Strait, Dr. Israelski said he had stopped reading that newspaper and was very upset because the article misrepresented him. Mr. Strait testified that with respect to Mr. Alden's comments in the article, Dr. Israelski said that subjects' perceptions of quality sometimes differ from that of the researcher, and that he wished he had prescreened Mr. Alden's comments to the reporter.

On September 24, 2003, Mr. Strait interviewed Mark Wallace, M.D., by telephone. Dr. Wallace said that his patients had not had difficulty obtaining the marijuana he prescribed for them; the method by which he received marijuana from NIDA was adequate; he did not have information indicating that the supply of marijuana from NIDA would be insufficient in the future; he was a blinded researcher and therefore would not have been in a position to distinguish active material from placebo; he could not comment on whether the potency of the product was consistent; patients had not complained about the freshness of the marijuana; and that the potency of the product he received was adequate but that future studies could look at higher potencies, which would have less tar and other components found in smoke.

That same day, Mr. Strait interviewed John Pollich, Ph.D., of the Scripps Research Institute. Dr. Pollich said he had not had any difficulty obtaining marijuana from NIDA; the method by which he received marijuana from NIDA was adequate; he had no information to indicate that a sufficient supply of material would not be available from NIDA in the future; there was no visible difference between the placebo and the non-placebo material; the potency of the material was consistent and adequate; he was very impressed and pleased with the material and had not seen any seeds or stems in it; plant parts would have made the material unacceptable for his research; of more than 100 subjects, no more than three might have complained that the product was harsh; the quality of the material did not adversely affect his research; and the product was adequate for his research.

On September 29, 2003, Mr. Strait telephonically interviewed Dr. Abrams, the

researcher on AIDS about whom Dr. Doblin testified. Dr. Abrams said that his subjects were all in an inpatient setting and had no difficulty obtaining the marijuana he prescribed to them; the method by which he received marijuana from NIDA was adequate; he would in the future like to do research on marijuana using a vaporizer protocol and on comparing cannabis with standard anti-nausea drugs in cancer patients; he had no information indicating that the future supply of marijuana from NIDA would be insufficient; he had visually inspected the marijuana from NIDA and had seen no difference between the placebo and non-placebo material; the cigarettes were nicely rolled, but some material spilled out of the ends; he had observed seeds, leaf, and some stems in the product, which made the potency inconsistent and adversely affected his research because the material did not mimic that which was available in the San Francisco area and because he was trying to minimize the harmful components resulting from smoke while optimizing the medical value of the THC; the harshness of the product caused a cough that was different from the cough generally caused by smoking marijuana; about four of the fifty patients in his studies had left because of the harshness of the marijuana; he wanted to conduct research with a higher-potency marijuana that would be more similar to what was available on the street but the Scientific Review Board of the University of California at San Diego, which would have to approve his study, and CMCR, which funded his work, had raised questions about doing so; and he thought that using a higher-potency product would enable his patients to obtain a pharmacologic effect from consuming a smaller quantity of material.

Dr. ElSohly testified that Dr. Abrams had mentioned the issue of harshness in passing when Dr. Abrams and Dr. ElSohly were walking with a group at an International Cannabis Research Society meeting, but had not asked him to take any action and that there was nothing he could have done about it. Dr. ElSohly also testified that it is to be expected that some material would fall out of the cigarettes. Dr. ElSohly testified that the cigarettes are placed vertically in cans, 300 cigarettes per can, and that the tops and bottoms of the cigarettes are open because that is how the rolling machine makes them. Dr. ElSohly further testified that he did not think it made any sense to try to match the potency of marijuana found in any one geographical area, but rather to consider national potency data. Dr. ElSohly also emphasized that in clinical trials the subjects must smoke

the entire cigarette, not merely a portion of it, and that it would be irresponsible to provide subjects with material whose potency was above average.

With respect to the comment that two or three subjects dropped out of the study because of the harshness of the NIDA-provided marijuana, Dr. ElSohly testified that it was not known whether these subjects used the placebo or the active material and that even if four of the fifty patients dropped out, ninety-two percent of the subjects completed the study, which was a good outcome.

Also in September 2003, Mr. Strait visited two facilities in La Jolla, California, where researchers from the University of California at San Diego were conducting studies using marijuana.

On December 18, 2003, Mr. Strait interviewed Aaron Lichtman, Ph.D., of Virginia Commonwealth University. Dr. Lichtman said he had not had any problems obtaining marijuana from NIDA; the method by which he received marijuana from NIDA was adequate; he had no information indicating the supply from NIDA would be insufficient in the future; he obtained bulk marijuana and observed that the active material was sticky, while the placebo was not, the placebo burned more quickly, and there was a slight difference in smell between the two; the potency of the material he received was consistent; he had observed leaves, seeds, buds, and twigs in the material, which he removed and which did not adversely affect his research; he would prefer higher-potency material, but as of the last time he had received product, in approximately 1999, the highest potency available was three to four percent; and he had not checked recently to see if a higher-potency product was available.

Mr. Strait testified that he believed that he contacted all the researchers who were working on studies of marijuana as medicine, but that he did not contact the patients using NIDA-supplied marijuana in compassionate use programs because they were not researchers.

b. The Meetings with Other Agencies

In October 2003, Mr. Strait visited RTI and in December of that year he visited the University of Mississippi. In mid-January 2004, Mr. Strait and other DEA personnel met with representatives of NIDA, including Dr. Gust, to discuss NIDA's marijuana cultivation program and its contract with the National Center. Mr. Strait testified that in

December 2003 he also met with Mr. Egertson of the Department of Health and Human Services to talk about the Public Health Service process and that during the meeting with Mr. Egertson, he also spoke via conference call with FDA personnel.

Dr. Gust testified that he met with representatives of the DEA in January 2004 and discussed Respondent's application, but that he had little recollection of the meeting other than that it occurred. Dr. Gust testified that he thought the meeting was essentially for the DEA to provide NIDA with information about the application, and that although he did not recall ever having been asked to participate in a meeting about an application for DEA registration to manufacture a controlled substance before, he did meet with DEA representatives on a variety of topics. Dr. Gust testified that NIDA did not oppose Respondent's application and that although there was discussion within NIDA about whether to respond to the *Federal Register* notice of Respondent's application, NIDA's director or deputy director decided that NIDA would not submit a response.

c. Further Developments

Respondent testified that the DEA published a notice of his application in July 2003, but that he heard nothing more from the agency so he filed a lawsuit in December 2004. Apparently, MAPS also sued NIDA over its failure to make a decision on the Chemic application. Dr. Doblin testified that the United States Circuit Court of Appeals for the District of Columbia Circuit asked the DEA to explain why it had not acted on Respondent's application and dismissed the case against NIDA.

Mr. Strait testified that in the fall of 2004 he attended another meeting of DEA personnel to discuss Respondent's application. As a result of that meeting, the then-Deputy Assistant Administrator for the Office of Diversion Control directed Mr. Strait and Diversion Investigator Helen Kaupang to draft a decision paper for the Deputy Administrator to enable her to provide guidance as to how to proceed on Respondent's application. On December 10, 2004, the then-Deputy Assistant Administrator of DEA's Office of Diversion Control issued the Order to Show Cause that gave rise to this proceeding.

Respondent testified that he considered the allegations in the Order to Show

Cause pertaining to smoked marijuana "curious"[129] because he had made it clear in his application for registration that he intended to cultivate marijuana for research using a vaporizer, not smoked marijuana. Respondent further testified, with respect to the statements in the Order to Show Cause about New Drug Applications, that there was nothing in the application materials suggesting that an NDA was a prerequisite for a manufacturing registration.

V. Other Evidence

A. Evidence About Commercial Use of Marijuana Outside the United States

An English company, GW Pharma Ltd., produces Sativex, which contains extracts of THC and cannabidiol in an oral spray and is used to treat neuropathic pain in patients with multiple sclerosis. It is marketed in Canada but not in the United States. Dr. Doblin testified that GW Pharma, Ltd., obtained permission from the Home Office to grow marijuana that it uses to produce extracts and a sublingual spray, and that the company is seeking approval for its products in England, and plans to try to obtain approval in the United States.

In the United Kingdom the National Cannabis Agency, an office within the Home Office's Drugs Branch, is the government agency responsible for regulating marijuana pursuant to the Single Convention. According to a protocol in effect since April 1, 2005, premises licensed to produce, possess, or supply marijuana are designated as sites of the National Cannabis Agency, and 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 . . . ."[130] The protocol further provides that "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 the [National Cannabis] Agency"[131] and that marijuana on a producer's premises is to be treated as stock held constructively by the

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[129] Transcript p. 53.
[130] United Kingdom National Cannabis Agency: Protocol, paragraph 6(b); Respondent exhibit 26, p. 2.
[131] United Kingdom National Cannabis Agency: Protocol, paragraph 6(c); Respondent

National Cannabis Agency unless at the point of cultivation the producer designates it for distribution to third parties, in which case it is to be separately identified on the producer's premises.

B. Other Support for Respondent's Application

Dr. Doblin testified that Respondent had told him that he had been contacted by the state of Massachusetts some years earlier about growing marijuana for the state's medical marijuana program, but that the state had not had any funds for such a project. Dr. Doblin testified that consequently, it was deemed necessary to obtain support for Respondent's application from members of the Massachusetts delegation in Congress.[132]

By letter dated June 6, 2002, Representatives Barney Frank, John Olver, James McGovern, William Delahunt, and Michael Capuano wrote to the then-Administrator of the DEA to support registering private funded sources of marijuana for use in federally approved studies. In a response dated July 1, 2002, the then-Administrator noted, among other things, that:

> The Single Convention requires any party that permits the cultivation of marijuana for scientific purposes to ensure that such cultivation occurs only under the oversight of a national government agency, with the agency maintaining a monopoly over the distribution of all marijuana grown for research. Cultivation of marijuana by private growers not under the oversight of a national agency is prohibited by the treaty, as is distribution of marijuana by private entities. These requirements are necessary to minimize the likelihood that marijuana grown for research will be stolen or diverted into illicit channels, or that individuals will use their authority to cultivate for research as a subterfuge for illicit production and distribution. Such concerns are particularly heightened in the United States, where marijuana is the most widely used illegal drug.[133]

The Administrator further stated that:

> Both the Single Convention and the [Controlled Substances Act] contemplate that domestic production of marijuana for scientific purposes must be limited to the minimum number of establishments that can produce an adequate supply. For more than 30 years, the University of Mississippi has produced an adequate supply to meet the entire United States demand for research-grade marijuana. There is no indication that this supply is currently inadequate or will become

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exhibit 26, p. 2.

[132] Dr. Doblin testified that "we felt it was necessary," but did not provide an antecedent for the pronoun. Transcript p. 585.

[133] Letter from Asa Hutchinson, Administrator, DEA, to John Olver, Member, United States House of Representatives (July 1, 2002); Government exhibit 55, p. 1.

> inadequate in the future. As long as the University continues to meet the nation's needs for research-grade marijuana while maintaining the highest level of safeguards against diversion, the Single Convention and the [Controlled Substances Act] dictate that it remain the sole domestic producer.[134]

By letter dated October 20, 2003, United States Senators Edward Kennedy and John Kerry expressed support for Respondent's application. By letter dated July 26, 2005, various members of the House of Representatives from Massachusetts also expressed their support for Respondent's application.

C. Other Evidence Pertaining to the Statutory Factors

Respondent testified that he intends to comply with all applicable state and local laws if his DEA application is granted, and that he would not make any marijuana he grew available to anyone other than researchers who have the appropriate federal approval to use it.

With respect to technical advances in the art of manufacturing controlled substances, Respondent testified that he thought that by being able to supply marijuana to investigators he would advance the understanding of any potential clinical use for it, and that he also would learn more about how the environment in which marijuana is grown would affect the plant's constituents. Respondent testified that the purpose of manufacturing marijuana would be to test various delivery systems and determine whether they would be effective.

Respondent testified that he did not hold any patents with respect to medicinal plants.

With respect to his conviction record, Respondent testified that he once received a speeding ticket, and has never been convicted of anything else.

Respondent testified that he had never grown marijuana or any other controlled substance and thus had no experience in controlling against diversion, but that he had been working closely with the DEA personnel who visited his facility to establish appropriate conditions, that he had agreed to their requirements, and that the university understood the need for appropriate security. Respondent also testified that as far as he knew, only the one current registered manufacturer of marijuana has experience in its licit

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[134] *Id.*; Government exhibit 55, p. 2.

cultivation.

Finally, Respondent testified that as a scientist he seeks to advance the inquiry into whether marijuana can be used clinically.

Dr. ElSohly testified that a cultivator of marijuana that did not want to perform analysis of samples provided by the DEA required by the National Center's contract with NIDA could subcontract that portion of the contract.

THE PARTIES' CONTENTIONS

The Government asserts, in substance, with respect to the statutory factors, that (1) Respondent has not shown that the marijuana distributed by the National Center is of insufficient quality and potency, and even if there were problems with this product, Respondent has not offered any evidence as to what he would do about it; (2) the Administrator has discretion pursuant to 21 C.F.R. § 1301.33(b) to limit the number of registered manufacturers and also has discretion to give each of the factors listed in 21 U.S.C. § 823(a) the weight she deems appropriate; (3) Respondent has not established that there is a need for a second cultivator of marijuana; (4) there is no competition issue in this case because Respondent is seeking a contingent registration while he seeks a pharmaceutical company that would develop a medicinal marijuana plant product, which would violate the DEA's policy against shelf registration; (5) Respondent has not shown that his registration would result in a pharmaceutical company developing a marijuana plant drug product; (6) competition in the manufacture of marijuana, as the term "competition" is used in 21 U.S.C. § 823(a)(1), is afforded by the bidding process to obtain contracts with NIDA to supply marijuana for research because (a) there is extremely limited demand for marijuana for research and it therefore makes no sense to treat it like a Schedule II commercial drug, (b) the bidding system is reasonable because marijuana is the most commonly abused drug, and (c) the competitive bid system is more consistent with the Single Convention than registering multiple marijuana producers; (7) there is no allegation or proof that Respondent has not complied with applicable state and local statutes and regulations, but Dr. Doblin admittedly abuses marijuana routinely and he has also diverted marijuana from a compassionate use patient to an analytical laboratory; (8) Respondent has not proposed any technical advances in cultivating marijuana or indicated any plans to develop new substances, nor has he explained how he

would control potencies or alter marijuana's constituents, in contrast to the various developments to which Dr. ElSohly testified; (9) Dr. Doblin has no conviction record; (10) the Government does not assert that Respondent will not maintain effective controls against diversion, but his application is nonetheless deficient because of his lack of experience with controlled substances; (11) Dr. Doblin's conduct is relevant inasmuch as he asked Respondent to file the instant application and assisted Respondent throughout this process and would designate the researchers who would receive marijuana from Respondent if he obtains a registration; (12) Dr. Doblin believes that marijuana should be legalized, abuses marijuana routinely, and diverted marijuana intended for consumption by an experimental use patient to Chemic, which indicates that he would not be adverse to acting outside the scope of the DEA's regulations; (13) Respondent, by seeking to supply marijuana to researchers who have not undergone the Public Health Service review process, is inviting the DEA to violate Health and Human Services policy, which the DEA may not do; and (14) there is no reason to register Respondent in order to have marijuana available in the event of an emergency at the National Center.[135]

Respondent contends, in substance, that as a threshold matter, pursuant to 21 U.S.C. § 823, if an application does not pose an increased risk of diversion and the applicant meets the other requirements, the DEA must grant the application regardless of whether there is an existing adequate supply. Respondent further contends that registering Respondent as a bulk manufacturer of marijuana would be consistent with the public interest because: (1) creating an alternative to the current NIDA-controlled monopoly would promote the advancement of science and research by adding competition without increasing the risk of diversion, citing *Noramco of Delaware v. DEA*, 375 F.3d 1148, 1153 (D.C. Cir. 2004), for the proposition that DEA may limit competition only in order

[135] The Government offered into evidence at the hearing various final orders issued by the DEA's Deputy Administrator. I rejected these proffered exhibits because they were not based upon an adjudicatory proceeding, but rather on the investigative file after the respondents waived their rights to a hearing. The Government contends that this ruling was in error and requests that I admit the exhibits at issue, on grounds that they are admissible hearsay and provide general information about marijuana. I adhere to my ruling, as these final orders are based on reports of investigations rather than evidence adduced in adjudicated proceedings. With respect to the contention that these final orders provide general information about marijuana, there is sufficient information in the record

to control diversion; (2) the current system does not provide an adequate and uninterrupted supply of marijuana for legitimate purposes, emphasizing that NIDA does not make marijuana available for all legitimate medical and scientific research, but only to those studies it considers the most likely to produce usable and essential data, that NIDA has determined that the goal of any research for which it will supply marijuana must be to determine whether cannabinoids administered through a delivery system other than smoking can meet the FDA's standards for medical products, and that NIDA does not meet the legitimate needs of a sponsor seeking to develop marijuana into an FDA-approved pharmaceutical product; (3) Respondent has agreed to provide a defined marijuana product that will suit both MAPS' and researchers' needs, and Respondent expects to be able to provide a more uniform product than the National Center currently does; (4) FDA, not the DEA or NIDA, has the responsibility for determining whether marijuana has a medical use, and DEA cannot use its registration authority to prevent a sponsor from seeking FDA approval of marijuana, especially inasmuch as the parties stipulated that "research continues about how cannabis may be of therapeutic benefit to patients;"[136] (5) NIDA's monopoly on the supply of marijuana to researchers fails to fulfill the requirement of 21 U.S.C. § 823(a)(1) that marijuana be supplied under adequately competitive conditions, and opening the contract to supply marijuana to NIDA to competitive bidding does not cure the defect, noting particularly that (a) the contract requires other services, such as analysis of samples, as well as the manufacture of marijuana, (b) the contract assures only that NIDA pays a competitive price, but not that the price researchers pay is competitive, (c) although NIDA supplies marijuana at cost, there are additional benefits to competition, including improved product quality and reliability, among others,[137] and (d) for those researchers whom NIDA refuses to supply, competition as to cost is irrelevant inasmuch as they have no other supplier; (6) even if the current system of supplying marijuana produced an adequate and uninterrupted supply under adequately competitive conditions, there is no evidence that registering Respondent would increase the risk of diversion, inasmuch as (a) Respondent's security

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on the subject.

[136] Prehearing Ruling issued May 23, 2005; ALJ exhibit 5, p. 1.

[137] Respondent quotes *Noramco*, 375 F.3d at 1158.

measures satisfied DEA requirements, (b) the Deputy Administrator found in *Chattem Chemicals, Inc.*, 71 Fed. Reg. 9834 (Feb. 27, 2006) that inasmuch as DEA establishes manufacturing and procurement quotas to avoid overproduction and the demand for retail controlled substances was the major factor in increased bulk manufacturing, registering an additional importer would not likely be a significant cause of diversion at the retail level, and (c) in June 2005 the DEA agreed to seek United Nations approval to increase the National Center's manufacturing quota from 913 to 4,500 kilograms, which it would not have done if it thought that increase would lead to increased diversion; (7) information about marijuana as a drug of abuse in general does not establish that registering Respondent would increase the risk of diversion; (8) there is no evidence that MAPS' role as a sponsor of developing marijuana as a pharmaceutical product would increase the difficulty of preventing diversion, emphasizing that MAPS has sponsored DEA-licensed researchers in various Phase I and II drug trials of controlled substances with no allegation of diversion, that neither Dr. Doblin nor any other MAPS personnel or any other unauthorized person would have access to the marijuana Respondent would grow, and that Dr. Doblin's personal use of marijuana is irrelevant and evidence on that issue should not have been admitted; (9) Respondent has demonstrated that he has and will continue to comply with applicable state and local law; (10) registering Respondent would promote scientific and technical advances because (a) Respondent intends to grow marijuana indoors, which would provide more control over environmental factors (b) Respondent seeks to grow marijuana in order to research development of a vaporizer as an alternative to smoked marijuana, (c) an alternative source to the National Center's marijuana would provide an opportunity to validate and replicate Dr. ElSohly's discoveries and techniques, and (d) registering Respondent would enable research into possible clinical uses of marijuana for which NIDA has refused to provide material; (11) Respondent's lack of patents should not weigh against his application inasmuch as the University of Mississippi has been the only registered cultivator of marijuana for thirty years; (12) Respondent has no prior conviction relating to controlled substances; (13) although Respondent does not have past experience in manufacturing controlled substances, Dr. ElSohly is the only person in the country with relevant experience in the legal manufacture of marijuana, and the FDA has only recently issued guidelines for

developing medicinal botanical products: there are thus few if any applicants with the expertise in botanicals who would also have experience in chemical manufacture, and Respondent has significant experience in cultivating and propagating plants; and (14) all other considerations relevant to the public health and safety weigh in favor of granting Respondent's application, asserting that this factor cannot be used to reconsider evidence related to another of the § 823(a) factors, and further contending that (a) the support of various members of Congress for Respondent's application weighs in favor of granting it, (b) Dr. Robert's testimony establishes that there is real political opposition in the government to the development of botanical marijuana and that this opposition constricts medical research by restricting the amount of marijuana available for it, and (c) Respondent's application is not premature and seeking the registration before lining up researchers is prudent, especially in light of the length of time that has elapsed since Respondent filed the instant application.

Respondent further asserts that granting him a registration would be consistent with all laws, treaties and conventions. With respect to the Single Convention, Respondent asserts that the Single Convention repeatedly refers to "cultivators" as plural, and nowhere suggests that the number of cultivators be limited to one; although it is unclear whether the United States agency contemplated by the Single Convention is NIDA or the DEA, it is clear that there is an agency that fills that role; if it is acceptable for Dr. ElSohly to not deliver his non-NIDA marijuana to a government agency it is acceptable for Respondent to act likewise, inasmuch as he would be processing the plant into a form acceptable for medical use; and England, a signatory to the Single Convention, has created a system of constructive possession for all licensed manufacturers, and the Government does not contend that this system violates the Single Convention.

DISCUSSION

As noted above, the Deputy Administrator is to register an applicant to manufacture a Schedule I controlled substance if she determines that such registration is consistent with the public interest and with the United States' obligations under international treaties.

I. The Single Convention

As discussed above, the Single Convention specifies that signatory parties have certain responsibilities with respect to marijuana and that such parties are to establish a single government agency to discharge those responsibilities. As Respondent asserts in his brief, it is not clear whether the DEA or NIDA is that agency.[138] The DEA, through its registration process, performs the licensing function, and, through its quota-setting process, determines the total amount of marijuana the National Center is permitted to produce, but NIDA determines how much marijuana the National Center produces for it. It is noteworthy that no government agency takes physical possession of the National Center's crop; it appears, however, from the United Kingdom's regulatory scheme described above that the parties to the Single Convention are free to construe the term "physical possession" as they see fit.

It also appears, although it is not entirely clear, that the marijuana grown by the National Center or by any other registrant for utilization in research would qualify as either "medicinal" within the meaning of Article 1, Paragraph (1)(o),[139] or as "special stocks" within the meaning of Article 1, Paragraph (1)(x),[140] and that therefore the government monopoly on importing, exporting, wholesale trading, and maintaining stocks would not apply. I therefore find that the Single Convention does not preclude registering Respondent.

II. The Statutory Factors

A. Section 823(a)(1)

21 U.S.C. § 823(a)(1) requires consideration of maintaining effective controls against diversion by limiting the manufacturing of Schedule I or II controlled substances "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." Respondent emphasizes that in *Noramco of Delaware v. DEA*, 375 F.3d 1148 (D.C. Cir. 2004), the United States Court of Appeals for the District of Columbia Circuit found that "The stated purpose of section 823(a)(1) is

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[138] Respondent's Proposed Findings of Fact, Conclusions of Law and Argument, p. 66.
[139] Single Convention, art. 1, para. 1(o).
[140] Single Convention, art. 1, para. 1(x).

to effectively control against diversion and it expressly directs the DEA to limit competition only as a means to achieve 'maintenance' of such control."[141] I note, however, that in the same opinion the court apparently found that it was not improper for the Deputy Administrator to consider the adequacy of competition;[142] I therefore address both issues.

1. Controls Against Diversion

Respondent testified that he would grow marijuana in a climate-controlled room that had one wall in the earth and had only one door, that the drying area would be connected to the cultivation room, and that the DEA personnel who visited the University of Massachusetts to inspect the proposed cultivation and drying area said that they thought the area could be made secure. There is no evidence or contention that either Respondent or anyone working with him would be likely to divert the marijuana from the growing or drying or storage areas. I also note that in his August 2002 answers to the DEA's questions, Respondent stated that he intended to grow about twenty-five pounds (dry weight) of marijuana in the first year of cultivation if his application is granted, and there is no evidence – nor does the Government contend – that his intentions are otherwise. I therefore find that it is unlikely that the marijuana that Respondent would grow would be diverted from the University of Massachusetts' facility.

There remains the question of whether marijuana would be diverted after it left the University of Massachusetts. In this respect, the Government emphasizes that Dr. Doblin believes that marijuana should be available as medicine and for non-medical purposes as well, and that the incident in which Dr. Doblin arranged for marijuana from a user in the compassionate use program to be sent to the Drug Detection Laboratory and then to Chemic demonstrates that he would not be averse to operating outside of the DEA's regulatory framework.

The record in this proceeding demonstrates that Dr. Doblin disagrees with the DEA's position on the dangers of marijuana use, and it also demonstrates, as the Government asserts, that Dr. Doblin and MAPS are the sponsors of Respondent's application and would determine the recipients of the marijuana that Respondent would

[141] *Noramco*, 375 F.3d at 1153.
[142] *Id.* at 1154, 1157.

grow if he becomes registered to do so. However, the record also establishes that MAPS and Dr. Doblin would not at any time have physical possession of that marijuana and, perhaps most importantly, that Respondent would send marijuana only to researchers who hold DEA registrations and, therefore, have the requisite approval from the Department of Health and Human Services, including findings that the researcher is qualified and competent, that the research protocol is meritorious, and that the research project has procedures in place to adequately protect against diversion of the marijuana. In these circumstances, I conclude that there is minimal risk that the marijuana that Respondent would cultivate would be diverted.

2. Competition

a. Adequacy of Supply

Although the record contains evidence that there have been some problems with the marijuana that the National Center produces, I find that a preponderance of the record establishes that the quality is generally adequate. I further find that there is no evidence that researchers whom NIDA approves to obtain marijuana have experienced difficulties in obtaining marijuana from the National Center when they need it.

The record does establish, however, that NIDA's system for evaluating requests for marijuana for research has resulted in some researchers who hold DEA registrations and requisite approval from the Department of Health and Human Services being unable to conduct their research because NIDA has refused to provide them with marijuana. I therefore find that the existing supply of marijuana is not adequate.

b. The Policy Against "Shelf Registrations"

As discussed above, the Government contends that registering Respondent would violate the DEA's policy against contingent registrations because Respondent has not shown that his registration would result in a pharmaceutical company developing a drug product from plant marijuana.

I disagree. Respondent is not obligated to show that his registration will lead to a pharmaceutical product but, rather, that he will use his registration to produce marijuana that will be used in legitimate research. That, Respondent has done.

c. Competition via the Process for Awarding NIDA's Contract

The Government also asserts that the process by which NIDA awards the contract to grow marijuana for research provides adequate competition inasmuch as the demand for licit marijuana is extremely limited and marijuana is the most commonly abused drug in the United States. The question is not, however, whether the NIDA process addresses that agency's needs, but whether marijuana is made available to all researchers who have a legitimate need for it in their research. As discussed above, I answer that question in the negative.

It is also undisputed that the NIDA contract requires the contractor to analyze samples of marijuana supplied by law enforcement agencies, a separate activity from cultivating marijuana for research purposes and a requirement that a qualified cultivator may not be able to fulfill.

I find that the NIDA contractual process does not, in the context of this case, render competition in the manufacture of marijuana adequate.

3. Conclusions with respect to Section 823(a)(1)

I find that if Respondent's application is granted, the risk that the marijuana that he would cultivate would be diverted is minimal and that competition in the manufacture of marijuana for research purposes is inadequate. I therefore find that this factor weighs in favor of granting Respondent's application.

B. Section 823(a)(2)

Section 823(a)(2) requires consideration of the applicant's compliance with applicable law. There is neither evidence nor contention that Respondent has not complied with applicable laws and I therefore find that this factor weighs in favor of granting Respondent's application.

C. Section 823(a)(3)

Section 823(a)(3) calls for consideration of the promotion of technical advances in the art of manufacturing controlled substances and in developing new substances. It is undisputed that Respondent has no experience in manufacturing or otherwise handling controlled substances. He does have considerable experience in cultivating medicinal plants, which might promote technical advances in the cultivation of marijuana or in

developing new medications from it. I find, however, that there is not sufficient evidence in the record on which to base a finding as to whether granting Respondent's registration would promote technical advances.

D. Section 823(a)(4)

Section 823(a)(4) requires consideration of the applicant's prior conviction record under laws relating to the manufacture, distribution, or dispensing of controlled substances. It is undisputed that Respondent has never been convicted of any violation of any law pertaining to controlled substances, and I therefore find that this factor weighs in favor of granting the application.

E. Section 823(a)(5)

Section 823(a)(5) requires consideration of the applicant's past experience in manufacturing controlled substances and the existence of effective controls against diversion. As discussed above, Respondent has no experience in manufacturing controlled substances, but does have experience in growing medicinal plants. As also discussed above, I find that the risk of diversion that would result from granting Respondent's application is minimal. I therefore find that this factor weighs in favor of granting the application.

F. Section 823(a)(6)

Section 823(a)(6) requires consideration of other factors relevant to public health and safety. I have discussed Dr. Doblin's use of marijuana and his attitude toward the regulation of marijuana above, and need not repeat that discussion here.

The Government contends that granting Respondent's application would amount to circumventing the Department of Health and Human Services' policy with respect to providing marijuana to researchers, and that the DEA has no legal authority to do so. But as quoted above, the NIH Guidance by its own terms applies to marijuana that the Department of Health and Human Services makes available, not marijuana that might be available from some other legitimate source. I therefore find that the NIH Guidance is not a factor in determining whether Respondent's application should be granted.

CONCLUSIONS

I conclude that granting Respondent's application would not be inconsistent with the Single Convention, that there would be minimal risk of diversion of marijuana resulting from Respondent's registration, that there is currently an inadequate supply of marijuana available for research purposes, that competition in the provision of marijuana for such purposes is inadequate, and that Respondent has complied with applicable laws and has never been convicted of any violation of any law pertaining to controlled substances. I therefore find that Respondent's registration to cultivate marijuana would be in the public interest.

RECOMMENDED DECISION

I recommend that Respondent's application be granted.

Dated: February 12, 2007

Mary Ellen Bittner

Mary Ellen Bittner
Administrative Law Judge

JLS

CERTIFICATE OF SERVICE

This is to hand certify that the undersigned on February 12, 2007, caused a copy of the foregoing to be delivered ~~via interoffice mail~~ to counsel for the Government, Brian Bayly, Esq., Office of Chief Counsel, Drug Enforcement Administration, Washington, D.C. 20537, and a copy to be ~~mailed, postage paid~~, to counsel for Respondent, Julie M. Carpenter, Esq., Jenner & Block, 601 Thirteenth Street, N.W., Suite 1200 South, Washington, D.C. 20005.

hand delivered JLS

Janice Lee Stuell for

Patricia A. Medico
Secretary to Mary Ellen Bittner
Administrative Law Judge

$4.25 (25 cents per page reproduction cost) payable to the U.S. Treasury.

Maureen M. Katz,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. E9–592 Filed 1–13–09; 8:45 am]

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DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Clean Water Act

Notice is hereby given that on December 31, 2008, a proposed consent decree (the ''Decree'') in *United States and State of Oregon* v. *Pacific Northern Environmental Corp., dba Dedicated Fuels, Inc.,* Civil Action No. 3:08–cv–01513–HU, was lodged with the United States District Court for the District of Oregon.

In this action the United States and State of Oregon sought civil penalties for Pacific Northern Environmental Corp.'s (''PNE'') violation of the Clean Water Act's spill prohibition. PNE owns and operates a heating oil business located in North Bend, Oregon, as well as several gas stations in the area. On July 8, 2006, a tanker truck owned and operated by Dedicated carrying several hundred barrels of diesel fuel overturned while traveling on Highway 38, near Milepost 17, just east of Scottsburg, Oregon. Approximately 197 barrels of diesel fuel spilled. Diesel fuel that did not ignite in the ensuing fire migrated to the Umpqua River. PNE's discharge to the Umpqua River violated the Clean Water Act and Oregon law. Under the consent decree, PNE will pay the United States and the State of Oregon civil penalties of $74,272 and $20,000, respectively. Additionally, PNE agrees to perform a supplemental environmental project (''SEP''), the cost of which shall be not less than $47,640.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States and State of Oregon* v. *Pacific Environmental Corp., dba Dedicated Fuels, Inc.*, Civil Action No. 3:08–cv–01513–HU, D.J. Ref. 90–5–1–1–09175.

The consent decree may be examined at the Office of the United States Attorney, Mark O. Hatfield U.S. Courthouse, 1000 SW. Third Avenue, Suite 600, Portland, OR, 97204, and at U.S. EPA Region 10, 1200 Sixth Avenue, Seattle, WA, 98101. During the public comment period, the consent decree may also be examined on the following Department of Justice Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the consent decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $5.75 (25 cents per page reproduction cost) payable to the U.S. Treasury or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address.

Robert E. Maher, Jr.,

Assistant Section Chief, Environmental Enforcement Section.

[FR Doc. E9–579 Filed 1–13–09; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging Proposed Consent Decree

In accordance with Departmental Policy, 28 CFR 50.7, notice is hereby given that a proposed Consent Decree in *United States* v. *Savoy Senior Housing Corp., et al.*, No. 6:06–cv–31 (W.D. Va.), was lodged with the United States District Court for the Western District of Virginia, Lynchburg Division, on January 7, 2009.

The proposed Consent Decree concerns a complaint filed by the United States against Savoy Senior Housing Corporation, Savoy Liberty Village, LLC, SDB Construction, Inc., Jacob A. Frydman, Best G.C., Inc. (a/k/a Best Grading), and Acres of Virginia, Inc., for alleged violations of Section 301(a) of the Clean Water Act (CWA), 33 U.S.C. 1311(a). The proposed Consent Decree resolves all allegations against the defendants for discharging dredged or fill material, and/or controlling and directing such discharges, into waters of the United States at a 140-acre property located in Campbell County, Virginia, without a permit issued by the United States Army Corps of Engineers. The proposed Consent Decree also resolves all allegations against the defendants for discharging sediment in stormwater, and/or controlling and directing such discharges, into waters of the United States on or from the same property, both without a CWA permit and in violation of such a permit once it was obtained.

The proposed Consent Decree requires Savoy Senior Housing Corporation, Savoy Liberty Village, LLC, SDB Construction, Inc., Best G.C., Inc., and Acres of Virginia, Inc., to pay to the United States a civil penalty. The proposed Consent Decree also requires these defendants to restore certain areas on and adjacent to the 140-acre site, and also to fund off-site mitigation through the purchase of credits from stream and wetland restoration banks in the region.

The Department of Justice will accept written comments relating to the proposed Consent Decree for thirty (30) days from the date of publication of this Notice. Please address comments to Kenneth C. Amaditz, Trial Attorney, Environmental Defense Section, P.O. Box 23986, Washington, DC 20026–3986, and refer to *United States* v. *Savoy Senior Housing Corp., et al.*, DJ # 90–5–1–1–17868.

The proposed Consent Decree may be examined at the Clerk's Office, United States District Court for the Western District of Virginia in Lynchburg, Virginia. In addition, the proposed Consent Decree may be viewed at *http://www.usdoj.gov/enrd/Consent_Decrees.html.*

Russell M. Young,

Assistant Chief, Environmental Defense Section, Environment & Natural Resources Division.

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DEPARMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 05–16]

Lyle E. Craker; Denial of Application

On December 10, 2004, the Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause to Lyle E. Craker, Ph.D. (Respondent), of Amherst, Massachusetts. The Show Cause Order proposed the denial of Respondent's pending application for a registration as a bulk manufacturer of marijuana on two grounds. Show Cause Order at 1.

First, the Show Cause Order alleged that Respondent's ''registration would not be consistent with the public interest as that term is used in 21 U.S.C. 823(a).'' Show Cause Order at 1. Second, the Show Cause Order alleged that the Respondent's registration would be inconsistent ''with the United States'

obligations under the Single Convention on Narcotic Drugs (Single Convention), March 30, 1961, 18 U.S.T. 1407.'' *Id.*

With respect to both of these contentions, noting that Respondent sought registration ''to supply analytical, pre-clinical and clinical researchers with marijuana,'' the Show Cause Order emphasized that the ''National Institute on Drug Abuse (NIDA), a component [of] the National Institutes of Health (NIH)'' and ''the United States Department of Health and Human Services [HHS], oversees the cultivation, production and distribution of research-grade marijuana on behalf of the United States Government.'' *Id.* at 2.

With respect to the contention that Respondent's proposed registration is inconsistent with the public interest, the Show Cause Order stated that, under 21 U.S.C. 823(a), ''DEA must limit the number of producers of research-grade marijuana to that which can provide an adequate and uninterrupted supply under adequately competitive conditions.'' *Id.* at 4. The Show Cause Order then stated: ''For the past 36 years, the University of Mississippi has provided such supply under the foregoing criteria, and there is no indication that this registrant will fail to do so throughout the duration of its current registration. While the University of Massachusetts is free to compete with the University of Mississippi to obtain the next NIDA contract to produce research-grade marijuana, there is no basis under Section 823(a) to add an additional producer.'' *Id.*

With respect to the contention of Respondent's sponsor, the Multidisciplinary Association for Psychedelic Studies (MAPS), that marijuana provided by NIDA to researchers was both qualitatively and quantitatively inadequate, the Show Cause Order alleged that marijuana provided by NIDA was ''of sufficient quantity and quality to meet'' the needs of ''legitimate and authorized research[ers].'' *Id.* at 3.

The Show Cause Order also noted MAPS's contentions that ''NIDA is limited to supplying marijuana for research purposes and cannot supply marijuana on a prescription basis,'' that ''this limitation effectively prohibits a sponsor * * * from expending the necessary large amounts of funds to conduct drug development studies resulting in [a] marijuana prescription product,'' and that granting Respondent a registration would resolve this problem. *Id.* In response to these contentions, the Show Cause Order alleged that to obtain approval for the marketing of a new drug under the Food, Drug, and Cosmetic Act (FDCA), the safety and effectiveness of the drug must be demonstrated through three phases of clinical trials, and that clinical trials involving marijuana had not progressed beyond the first phase (phase 1). *Id.* at 2–4.

The Show Cause Order further noted that the policy of HHS for approving the distribution of marijuana to researchers ''has not unduly limited clinical research with marijuana.'' *Id.* at 5. More specifically, the Show Cause Order alleged that ''[s]ince the year 2000, there have been or are eleven approved clinical trials utilizing smoked marijuana,'' and that approved ''marijuana researchers administer marijuana to almost 500 human subjects.'' *Id.* The Show Cause Order also alleged that since 2000, there were ''four approved pre-clinical trials in laboratory and animal modes.'' *Id.* at 5. Relatedly, the Show Cause Order also asserted that ''DEA has no statutory authority to overturn HHS' policy.'' *Id.*

With respect to the contention that Respondent's registration would be inconsistent with the United States' obligations under the Single Convention, the Show Cause Order again referenced that HHS, through NIDA, oversees the cultivation, production and distribution of research-grade marijuana on behalf of the United States Government and alleged that ''[i]n accordance with the Single Convention, the Federal Government [is required] to limit marijuana available for clinical research to [this] source.'' *Id.* at 4.

Respondent timely requested a hearing. The matter was assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner, who conducted a hearing on August 22–26 and December 12–14 and 16, 2005. At the hearing, the parties put on testimonial evidence and introduced documentary evidence. Following the hearing, the parties submitted briefs containing their proposed findings of fact, conclusions of law, and argument.

On February 12, 2007, the ALJ issued her recommended decision. Therein, the ALJ rejected the Government's contention that the Single Convention precluded Respondent's registration. In so holding, the ALJ acknowledged that the Convention requires that its signatories maintain a ''government monopoly on importing, exporting, wholesale trading, and maintaining stocks.'' ALJ at 82. The ALJ reasoned, however, that ''[i]t also appears, although it is not entirely clear, that the marijuana grown by the National Center [1] or by any other registrant for utilization in research would qualify as either 'medicinal' * * * or as 'special stocks' within the meaning of'' the Convention. *Id.* at 82 (citing Single Convention, art. 1, para. (1)(o) & (x)).

The ALJ then turned to whether Respondent had established that his registration would be consistent with the public interest when considering the six enumerated factors of 21 U.S.C. 823(a). With respect to the first factor, 21 U.S.C. 823(a)(1), the ALJ first recited the relevant text of this provision, which requires DEA to consider maintenance of effective controls against diversion by limiting the manufacturing of schedule I or II controlled substances ''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.'' ALJ at 82 (quoting § 823(a)(1)). Noting that there is precedent for the agency to interpret this provision in two distinct ways regarding the issue of adequacy of competition (either by considering or not considering the issue),[2] the ALJ stated that she would evaluate the issue in both ways. *Id.* at 83.

Under the first approach of interpreting 21 U.S.C. 823(a)(1) to allow DEA to disregard the issue of adequacy of competition as long as the agency finds that the applicant for registration would provide effective controls against diversion, the ALJ concluded that ''there is no evidence or contention that either Respondent or anyone working with him would be likely to divert the marijuana from the growing or drying or storage areas.'' *Id.*

The ALJ next rejected the Government's contention that there was a risk of diversion because Mr. Rick Doblin, the Director of MAPS, would determine who was to receive the marijuana. In so holding, the ALJ reasoned that Mr. Doblin would not have physical possession of the marijuana and that Respondent would only send marijuana to researchers with DEA registrations and the requisite approval of HHS. ALJ at 84. The ALJ thus concluded that ''the research project has procedures in place to adequately protect against diversion of the marijuana'' and that ''there is minimal risk of diversion.'' *Id.*

[1] The National Center is an entity of the University of Mississippi which currently holds the contract with NIDA for growing marijuana to supply United States researchers.

[2] The meaning of 21 U.S.C. 823(a)(1) and the competition issue are discussed in detail in part C of the discussion section of this final order.

Under the second approach of interpreting 21 U.S.C. 823(a)(1) to require DEA to consider whether competition is inadequate, the ALJ first turned to whether the supply of marijuana currently available to researchers through HHS is adequate. In this regard, the ALJ found that while ''there have been some problems with the marijuana that the National Center produces, * * * a preponderance of the evidence establishes that the quality is generally adequate.'' *Id.* The ALJ further found, however, that ''NIDA's system for evaluating requests for marijuana for research has resulted in some researchers who hold DEA registrations and requisite approval from [HHS] being unable to conduct their research because NIDA has refused to provide them with marijuana.'' *Id.* The ALJ thus concluded ''that the existing supply of marijuana is not adequate.'' *Id.* The ALJ also concluded that competition is inadequate within the meaning of 21 U.S.C. 823(a)(1). *Id.*[3] The ALJ thus held that the first public interest factor, 21 U.S.C. 823(a)(1), supported granting Respondent's application.

Under the second public interest factor, 21 U.S.C. 823(a)(2), the ALJ found that there was ''neither evidence nor contention that Respondent has not complied with applicable laws'' and thus concluded that this factor supported the granting of Respondent's application. *See id.*

Under the third public interest factor, 21 U.S.C. 823(a)(3), as to whether granting Respondent's application would promote technical advances in the art of manufacturing controlled substances, the ALJ found that Respondent has ''considerable experience in cultivating medicinal plants, which might promote technical advances in the cultivation of marijuana or developing new medications from it.'' ALJ at 85–86. The ALJ nonetheless found that ''there is not sufficient evidence in the record on which to base a finding as to whether granting Respondent's registration would promote technical advances.'' *Id.* at 86.

Under the fourth public interest factor, 21 U.S.C. 823(a)(4), the ALJ found that it was ''undisputed that Respondent has never been convicted of any violation of any law pertaining to controlled substances'' and therefore this factor weighed in favor of granting the application. *Id.*

Under the fifth public interest factor, 21 U.S.C. 823(a)(5), the ALJ considered Respondent's ''past experience in manufacturing controlled substances and the existence of effective controls against diversion.'' *Id.* The ALJ acknowledged that ''Respondent has no experience in manufacturing controlled substances.'' *Id.* Noting that Respondent ''does have experience in growing medicinal plants'' and that ''the risk of diversion is minimal,'' the ALJ concluded that this factor supported granted the application. *Id.*

Finally, under the sixth public interest factor, 21 U.S.C. 823(a)(6), in analyzing such other factors as are relevant to and consistent with public health and safety, the ALJ rejected the Government's contention that granting the application would ''circumvent[]'' HHS's policy with respect to the provision of marijuana to researchers. *Id.* Reasoning that ''the NIH Guidance by its own terms applies to marijuana that [HHS] makes available, [and] not [to] marijuana that might be available from some other legitimate source[,]'' the ALJ concluded that ''the NIH Guidance is not a factor in determining whether Respondent's application should be granted.'' *Id.* The ALJ thus concluded that granting Respondent's application ''would be in the public interest,'' and recommended that I grant his application. *Id.* at 87.

The Government excepted to the ALJ's decision on numerous grounds, and Respondent filed a response to the Government's exceptions. Thereafter, the record was forwarded to me for final agency action.

Having considered the record as a whole, I hereby issue this Decision and Final Order. For reasons explained more fully below, I reject the ALJ's legal conclusion ''that the Single Convention does not preclude registering Respondent.'' *Id.* at 82. Moreover, I reject the ALJ's finding that the proposed registration is consistent with the public interest when considering the six factors enumerated in 21 U.S.C. 823(a). *Id.* at 82–86. I therefore reject the ALJ's recommendation that the application be granted. *See id.* at 87.

Findings

Under Federal Law, marijuana and tetrahydrocannabinols (THC) are schedule I controlled substances. 21 U.S.C. 812(c), Schedule I(c)(10) & (17). Congress placed marijuana and THC in schedule I because the substances have ''a high potential for abuse,'' ''no current accepted medical use in treatment in the United States,'' and ''a lack of accepted safety for use * * * under medical supervision.'' 21 U.S.C. 812(b)(1). *See also* 66 FR 20038 (2001) (denying petition to reschedule marijuana from schedule I), *petition for review dismissed*, *Gettman* v. *DEA*, 290 F.3d 430 (D.C. Cir. 2002).[4]

Marijuana is cultivated from the cannabis plant, which is recognized as ''a very adaptive plant [whose] characteristics are even more variable than most plants.'' GX 25, at 7. Marijuana, which consists primarily of the dried flowering tops and leaves of the cannabis plant,[5] ''is a variable and complex mixture of biologically active compounds.'' *Id.* As of 2001, 483 different chemical constituents had been identified in marijuana, including approximately 66 cannabinoids.[6] 66 FR at 20041; Tr. 1142, 1147. ''THC[7] is the main psychoactive cannabinoid in marijuana''; the plant, however, also contains ''[v]arying proportions of other cannabinoids, mainly cannabidiol (CBD) and cannabinol (CBN),'' which ''sometimes [exist] in quantities that might modify the pharmacology of THC or cause effects of their own.'' *Id.* at 7–8.

[3] In so finding, the ALJ rejected the Government's contention that because the NIDA contract is open to competitive bidding, adequate competition exists. According to the ALJ, ''[t]he question is not * * * whether the NIDA process addresses that agency's needs, but whether marijuana is made available to all researchers who have a legitimate need for it in their research. As discussed above, I answer that question in the negative.'' *Id.* at 85.

As further support for her conclusion, the ALJ reasoned that ''the NIDA contract requires the contractor to analyze'' marijuana seized by law enforcement agencies, and that ''a qualified cultivator may not be able to fulfill'' this requirement.''*Id.*

[4] As related in the Notice, the FDA recommended that marijuana be maintained in schedule I of the CSA. The FDA based its finding on, *inter alia,* the extensive evidence that marijuana has a history and pattern of abuse, that it is ''[t]he most frequently used illicit drug,'' and that it ''has a high potential for abuse.'' 66 FR at 20047 & 20051. The FDA also found that ''[t]here are not FDA-approved medical products,'' ''marijuana does not have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions,'' and ''that, even under medical supervision, marijuana has not been shown to have an acceptable level of safety.'' 66 FR at 20052.

[5] The legal definition of marijuana, as set forth in the CSA, 21 U.S.C. 802(16), is as follows: The term ''marihuana'' means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

[6] Cannabinoids are chemical compounds that are unique to the cannabis plant (not found in any other plant). Tr. 1140–41.

[7] While there are numerous isomers of THC (all of which fall within the listing of ''Tetrahydrocannabinols'' in schedule I of the CSA and many of which are found in the cannabis plant), delta-9-THC is the isomer that is recognized as the primary psychoactive component in marijuana and, for this reason the term ''THC'' is often used to refer to delta-9-THC. *See* 66 FR at 20045; Tr. 1146–47.

The National Center and NIDA's Drug Supply Program

Since 1968, the National Center for Natural Products Research (National Center), a division of the University of Mississippi, has held a contract with the Federal Government to grow marijuana for research purposes and held the requisite registrations under the Controlled Substances Act (CSA), as well as the federal law that preceded the CSA, authorizing the University to conduct such activity.[8] Tr. 1152–53, 1350–51. *See also* 21 CFR 1301.13. The contract, which is open for competitive bidding at periodic intervals, *see* GX 15, is administered by NIDA, a component of NIH (which is part of HHS), pursuant to its Drug Supply Program. RX 1, at 231. Since 1999, the term of the contract has been five years. *See* GXs 13 & 15; Tr. 1156.

Under the NIDA contract, the National Center ''[g]row[s], harvest[s], store[s], ship[s] and analyze[s] cannabis of different varieties, as required.'' GX 13, at 6. The contract requires that the National Center ''shall serve as NIDA's cannabis drug repository,'' as well as ''develop and produce standardized marijuana cigarettes within a range of specified THC content, and placebos for use in pre-clinical and clinical research programs,'' and maintain minimum stocks of both bulk marijuana and marijuana cigarettes of various THC contents, and store them in a DEA approved facility. *Id.* at 6–7.

Marijuana potency is primarily based on the concentration (percentage by weight) of THC in the plant material. Tr. 1148–49. As of August 25, 2005, the National Center held on behalf of NIDA approximately 1055 kilograms (kg) of marijuana with THC contents ranging up to 12.26 percent. *See* RX 53. This inventory includes six batches of marijuana with THC contents ranging from 9.02 to 9.89 percent,[9] one batch (of nearly 19 kg) with a THC content of 10 percent, nearly 25 kg with a THC content of 11.34 percent, and approximately 27 kg with a THC content of 12.26 percent.[10] *See id.* In his testimony, Mahmoud ElSohly, Ph.D., who is the Principal Investigator under the NIDA contract, and who has overseen the National Center's work with marijuana since 1980, stated that the Center is capable of producing marijuana with a THC content of 20 percent or more.[11] Tr. 1130–31, 1152, 1203, 1254–55.

The contract also requires the National Center to ''ship to research investigators as authorized by the [NIDA] Project Officer upon receipt of a shipment order.'' GX 13, at 7. While the NIDA ''Project Officer may pre-authorize any normal recurring requests that the contractor will then fill once it has received'' various assurances,[12] the contract further states that ''[a]ll other requests should be submitted to the NIDA Project Officer for approval.'' *Id.* at 8. Moreover, ''[i]f there is a reason to question a particular request, the Contractor shall inform the NIDA Project Officer who will make a final decision on providing the material and quantity requested.'' *Id.* As these provisions make clear, the National Center has no authority to distribute any of the marijuana it produces pursuant to the NIDA contract without NIDA's approval.[13]

In 1997, the White House Office of National Drug Control Policy asked the Institute of Medicine (IOM), a component of the National Academy of Sciences, to conduct a review of the scientific evidence regarding the potential health benefits and risks of marijuana and its constituent cannabinoids. RX 1, at 7. In 1999, the IOM published its report. The IOM found, among other things, that ''[d]efined substances, such as purified cannabinoid compounds, are preferable to plant products, which are of variable and uncertain composition. Use of defined cannabinoids permits a more precise evaluation of their effects, whether in combination or alone.'' RX 1, at 22. With respect to this issue, the IOM reached the following conclusion: ''Scientific data indicate the potential therapeutic value of cannabinoid drugs, primarily THC, for pain relief, control of nausea and vomiting, and appetite stimulation; smoked marijuana, however, is a crude THC delivery system that also delivers harmful substances.'' Id. The report further stated:

> The therapeutic effects of cannabinoids are most well established for THC, which is the primary psychoactive ingredient of marijuana. But it does not follow from this that smoking marijuana is good medicine.
>
> Although marijuana smoke delivers THC and other cannabinoids to the body, it also delivers harmful substances, including most of those found in tobacco smoke. In addition, plants contain a variable mixture of biologically active compounds and cannot be expected to provide a precisely defined drug effect. For those reasons there is little future in smoked marijuana as a medically approved medication. If there is any future in cannabinoid drugs, it lies with agents of more certain, not less certain, composition.'' [14]

[8] Initially, the National Center obtained a researcher's registration; it now also holds a manufacturer's registration.

[9] These batches range from approximately 12 to 15 kg in size.

[10] As of the date of the hearing, more than 920,000 marijuana cigarettes of various THC concentrations including placebo had been manufactured pursuant to the NIDA contracts between 1974 and 2003. GX 27.

[11] 11 As Dr. ElSohly explained, he has grown numerous strains of marijuana from seeds that have been obtained from a variety of countries and has used them to do ''genetic selection to have genetic material of high potency.'' Tr. 1255.

[12] These include that the researcher have the appropriate DEA registration and FDA/IND approvals, provide assurance that the marijuana ''will not be resold'' and ''will be used only for research or patient purposes,'' that the use of the marijuana will adhere to the appropriate Safety Standards for research,'' and that the researcher agree ''to comply with all Federal, State and Local Safety requirements for use of the materials.'' *See* GX 13, at 8.

[13] Independent of its contract with NIDA, the National Center holds an additional registration to manufacture marijuana and THC. GXs 75 & 78. The National Center was granted this registration under the terms of a Memorandum of Agreement (MOA) entered into with DEA in 1999. GX 78. As set forth in the MOA, the purpose of the registration was ''to allow the Center to develop a new product formulation for effecting delivery of [THC] in a pharmaceutically acceptable dosage form suppository * * * and to provide crude THC extract to a DEA-registered manufacturer of THC for further purification.'' *Id.* at 2. The MOA further stated that, under the terms thereof, the Center would ''manufacture marijuana for the purpose of extracting THC therefrom.'' *Id.* Subsequently, the Center submitted a new application for a registration to bulk manufacture marijuana and THC ''to prepare marihuana extract for further purification into bulk active [THC] for use in launching FDA-approved pharmaceutical products.'' 70 FR 47232 (2005). DEA has not yet issued a final order as to this application. (DEA publishes in the **Federal Register** all final orders on applications for registration to bulk manufacture schedule I and II controlled substances.)

The MOA further provided that ''[i]n accordance with articles 23 and 28 of the Single Convention on Narcotic Drugs * * * private trade in 'cannabis' is strictly prohibited. Therefore, the Center shall not distribute any quantity of marijuana to any person other than an authorized DEA employee.'' GX 78, at 2. Continuing, the MOA explained that ''[t]he Single Convention does not prohibit private trade in 'cannabis preparations,' '' and noted that this term, ''within the meaning of the Single Convention, is a mixture, solid or liquid containing cannabis, cannabis resin, or extracts or tinctures of cannabis.'' *Id.* Because ''[t]he THC that the Center will extract from marijuana [is] considered such a 'cannabis preparation[,]' * * * the Center may, in accordance with the Single Convention, distribute the crude THC extract to private entities'' provided the Center otherwise complies with the CSA and DEA regulations. *Id.* at 2–3. The MOA also set forth a detailed series of controls to maintain accountability of the marijuana from acquisition of the seeds through the extraction of THC from the harvested material. *Id.* at 3–7.

[14] To similar effect, an ad hoc group of experts, who were selected by NIH and convened in 1997 as part of a workshop to assess the potential medical uses of marijuana, issued a report to the Director of NIH, which noted:

> As with any smoked drug (e.g., nicotine or cocaine), characterizing the pharmacokinetics of THC and other cannabinoids from smoked marijuana is a challenge. A person's smoking behavior during an experiment is difficult for a researcher to control. People differ. Smoking behavior is not easily quantified. An experienced marijuana smoker can titrate and regulate doses to obtain the desired acute psychological effects and

Id. at 195–96. *See also* GX 53 (letter from Alice P. Mead, GW Pharmaceuticals, P.L.C., to Christine V. Beato, Acting Asst. Sec. for Health, HHS (Apr. 12, 2005)) (''[H]erbal cannabis should comprise only the starting material from which a *bona fide* medical product is ultimately derived. * * * [S]tandardizing herbal starting material represents only the first of many steps necessary to create a modern medicine that is safe and effective for use in specific medical conditions. * * * [A] final medical product * * * must also be delivered in a dosage form that is consistent in composition and that allows the patient to obtain an identifiable and reliable amount of medication.'') (emphasis in original).

Accordingly, the IOM recommended that clinical trials using cannabinoid drugs should be conducted with ''the goal of developing rapid-onset, reliable, and safe delivery systems.'' *Id.* at 197. The IOM also advised that clinical trials involving smoked marijuana ''should involve only short-term marijuana use (less than six months), should be conducted in patients with conditions for which there is a reasonable expectation of efficacy, should be approved by institutional review boards, and should collect data about efficacy.'' *Id.*

Also in 1999, due in part to an increased interest in marijuana research and taking into account the IOM report, HHS decided to change the procedures by which it would supply marijuana to researchers. Tr. 1632–33; GX 24. The new procedures were announced in a document released by NIH on May 21, 1999. GX 24, at 1. In the announcement, ''HHS recognize[d] the need for objective evaluations of the potential merits of cannabinoids for medical uses[,]'' and that ''[i]f a positive benefit is found, * * * the need to stimulate development of alternative, safer dosage forms.'' *Id.* at 2. Toward this end, NIH explained that the new procedures were designed to increase the availability of marijuana for research purposes by, among other things, making such marijuana ''available on a cost-reimbursable basis.'' *Id.* This new procedure allowed researchers who were privately funded to obtain marijuana from HHS by reimbursing the NIDA contractor for the cost of the marijuana. Tr. 1633; *see also* GX 31, at 3. This was a departure from the prior practice (pre-1999), whereby HHS only made marijuana available to persons who received NIH funding. *Id.* The new procedures implemented by HHS in 1999 remain in effect today. Tr. 1629.

HHS further stated in 1999 that it intended through the new procedures ''to make available a sufficient amount of research-grade marijuana to support those studies that are the most likely to yield usable, essential data.'' GX 24, at 2. With respect to those researchers who do not have NIH funding, HHS explained that ''the scientific merits of each protocol will be evaluated through a Public Health Service interdisciplinary review process [which] will take into consideration a number of factors, including the scientific quality of the proposed study, the quality of the organization's peer-review process, and the objective of the proposed research.'' *Id.*

HHS then identified the criteria it would apply in evaluating requests for marijuana:

> The extent to which the protocol incorporates the elements of good clinical and laboratory research;
>
> The extent to which the protocol describes an adequate and well-controlled clinical study to evaluate the safety and effectiveness of marijuana and its constituent cannabinoids in the treatment of a serious or life threatening condition;
>
> The extent to which the protocol describes an adequate and well-controlled clinical study to evaluate the safety and effectiveness of marijuana and its constituent cannabinoids for a use for which there are no alternative therapies;
>
> The extent to which the protocol describes a biopharmaceutical study designed to support the development of a dosage form alternative to smoking; [and]
>
> The extent to which the protocol describes high-quality research designed to address basic, unanswered scientific questions about the effects of marijuana and its constituent cannabinoids or about the safety or toxicity of smoked marijuana.

Id. at 3.

HHS further noted that ''[a] clinical study involving marijuana should include certain core elements,'' and that ''[a] study that incorporates the [1997] NIH Workshop recommendations will be expected to yield useful data and therefore, will be more likely to receive marijuana under the HHS program.'' *Id.*

Finally, HHS explained that the ''proposed protocols must be determined to be acceptable under FDA's standards for authorizing the clinical study of investigational new drugs.'' *Id.* Relatedly, HHS stated that ''although FDA's review of Phase 1 submissions will focus on assessing the safety of Phase 1 investigations, FDA's review of Phases 2 & 3 submissions will also include an assessment of the scientific quality of the clinical investigations and the likelihood that the investigations will yield data capable of meeting statutory standards for marketing approval.'' *Id.* HHS further made clear that if a protocol is approved, ''NIDA will provide the researcher with authorization to reference NIDA's marijuana Drug Master File.'' *Id.* at 4.

At the administrative hearing in this case, Steven Gust, Ph.D., Special Assistant to the Director of NIDA, explained that, in addition to seeking to facilitate research into the possible medical utility of marijuana, the new procedures implemented by HHS in 1999 were intended ''to make the process more standardized, and to * * * provide some expertise that did not really exist at NIDA in terms of reviewing applications that involved * * * the use of marijuana * * * for treatment of diseases.'' Tr. 1632–33. Accordingly, HHS ''established a separate peer review process that * * * moved the review into the Public Health Service [a component of HHS] * * * where additional expertise from other NIH Institutes and other Federal agencies'' could be utilized in reviewing the scientific merit of the applications. *Id.* at 1633–34. Dr. Gust further explained that the members of the review committee are drawn from the various specialty institutes of NIH, and the Substance Abuse and Mental Health Services Administration (SAMHSA). *Id.* at 1692; 1713–15.[15] Dr. Gust also testified that the ''scientific bar has been set very low, [so] that any project that has scientific merit is approved,'' and that ''anything that gets approved gets NIDA marijuana.'' *Id.* at 1700–01. As of April 2004, HHS had approved at least seventeen pre-clinical or clinical studies of marijuana, which were sponsored by the California Center for Medical Cannabis Research (CMCR).[16] GX 31, at

to avoid overdose and/or minimize undesired effects. Each puff delivers a discrete dose of THC to the body. Puff and inhalation volume changes with phase of smoking, tending to be highest at the beginning and lowest at the end of smoking a cigarette. * * * During smoking, as the cigarette length shortens, the concentration of THC in the remaining marijuana increases; thus, each successive puff contains an increasing concentration of THC.

One consequence of this complicated process is that an experienced marijuana smoker can regulate almost on a puff-by-puff basis the dose of THC delivered to lungs and thence to brain. A less experienced smoker is more likely to overdose or underdose. Thus a marijuana researcher attempting to control or specify dose in a pharmacologic experiment with smoked marijuana has only partial control over the drug dose actually delivered.

See GX 25, at 9–10 (Workshop on the Medical Utility of Marijuana).

[15] Dr. Gust initially testified that someone from FDA sits on the committee but later stated that he was not exactly sure if this was so. Tr. 1712.

[16] The California research studies were conducted pursuant to a law enacted by California in 1999 known as the Marijuana Research Act of 1999. Cal.

Continued

3. According to one witness who testified on behalf of Respondent, all of the CMCR-sponsored researchers who applied to NIDA for marijuana did in fact receive marijuana from NIDA. Tr. 694–95.

Respondent's Application and Contentions

Respondent is a Professor in the Department of Plant, Soil and Insect Sciences at the University of Massachusetts Amherst. Tr. 13. On June 28, 2001, Respondent submitted an application to bulk manufacture the schedule I controlled substances marijuana and tetrahydrocannabinols.[17] GXs 1 & 3; 21 CFR 1308.11(d). Respondent's application is sponsored by the Multidisciplinary Associations for Psychedelic Studies (MAPS). GX 3, at 1.

Because Respondent seeks a registration to manufacture a schedule I controlled substance, DEA required that he complete a questionnaire.[18] In response to the question regarding the purpose for which he sought registration, Respondent stated that ''[t]he plant material will be grown for federally-approved uses only, including analytical, pre-clinical, and clinical research,'' and that ''no material is intended for illegal use or for medical marijuana patients whose use may be legal under state, but not federal law.'' GX 3, at 1.[19]

Respondent added that ''[t]he production costs * * * would be underwritten by a grant'' from MAPS. *Id.* According to Respondent, ''MAPS is seeking to develop the marijuana plant into an FDA-approved prescription medicine,'' and that ''[t]he growth of plants at [UMASS] is a necessary step for supplying quality marijuana for use in MAPS' drug development process.'' *Id.* Respondent also advised that ''MAPS will sponsor research at other institutions using smoked marijuana and marijuana delivered through a vaporizer device that heats, but does not burn the plant material, thus reducing the products of combustion normally found in smoked marijuana.'' *Id.*

Respondent further stated that his ''[c]ustomers would include both MAPS-sponsored research and research sponsored by other organizations.'' *Id.* at 3. Relatedly, Respondent explained that ''[r]esearchers conducting MAPS sponsored research would receive supplies of the plant material free, while other researchers would either receive the marijuana free or through a donation to MAPS.'' *Id.* at 1. *See also* Tr. 225 (''I may very well be approached by other people with approved studies who need a source also.'').

At the hearing, Mr. Rick Doblin, the President of MAPS,[20] also testified regarding the purpose of Respondent's application. Mr. Doblin, who admitted that he engages in recreational use of marijuana on a weekly basis, explained that ''[t]he reason we need a supply from Dr. Craker is that we are engaged in trying to make marijuana into an FDA-approved prescription medicine, and * * * we need to establish a drug master file for a particular product, and * * * we need to conduct research with that product, and have that product available to us for potential marketing should we get FDA approval.'' Tr. 603, 718–19. Mr. Doblin testified as to his ''belie[f] that smoked marijuana or vaporized marijuana in plant form will successfully compete with marijuana extracts on price.'' *Id.* at 605. He also testified as to his belief that the ''efficacy and safety'' of vaporized plant-form marijuana ''will be similar'' to drugs containing cannabinoid extracts and that ''the efficacy will be similar and safety slightly different with smoked'' marijuana than with drugs containing cannabinoid extracts. *Id.*

Mr. Doblin further testified that he ''disagree[d]'' with the Institute of Medicine's conclusion that defined and purified cannabinoid compounds ''are preferable to plant products, which are of variable and uncertain composition.'' *Id.* at 654. Mr. Doblin also testified that ''what we're trying to do is get the Public Health Service and NIDA out of the picture; they're only in the picture just for marijuana only because they have a monopoly. And that is what is so obstructing the system.'' *Id.* at 666.

Finally, Mr. Doblin testified that MAPS would only need between $5 to $10 million ''to make marijuana into a medicine'' through the various stages of the FDA new drug approval (NDA) process.[21] *Id.* at 701; *see also id.* at 703. In his testimony, Mr. Doblin did not, however, identify a single instance in which an entity (whether for-profit or nonprofit) had taken a drug—let alone a botanical substance with known safety issues, *See*, *e.g.*, GX 43, at 9—through the multi-faceted NDA process for a similar cost.[22] Moreover, while Mr.

Health & Safety Code § 11362.9. This state law established the ''California Marijuana Research Program'' to develop and conduct studies on the potential medical utility of marijuana. *Id.* (The program is also referred to as the ''Center for Medicinal Cannabis Research'' (CMCR). Tr. 396.) The state legislature appropriated a total of $9 million for the marijuana research studies. Tr. 397. The state law was enacted following the passage of Proposition 215, a ballot initiative otherwise known as the Compassionate Use Act of 1996. Tr. 395–96; *see also United States* v. *Oakland Cannabis Buyers' Cooperative* (''*OCBC*''), 532 U.S. 483, 486 (2001).

[17] On his application for registration (GX 1), Respondent incorrectly checked the box for ''dosage form'' manufacturing when, in fact (based on the activity in which he proposes to engage), he is seeking to become registered as a ''bulk'' manufacturer. In written questions DEA submitted to Respondent as a follow-up to the application, DEA properly characterized the activity as ''bulk manufacture,'' and Respondent, in his written answers to these questions, gave no indication that he disagreed. *See* GX 3. Also, in his testimony at the hearing, Respondent acknowledged that his plan was to send marijuana ''in bulk'' to others, who would roll it into cigarettes. Tr. at 243. Respondent also testified that MAPS President Rick Doblin ''assisted in the response to the *bulk* manufacturer's questions.'' Tr. 352 (emphasis added). Cf. 32 CFR 1300.02(b)(32) (defining ''drug product'' as ''an active ingredient in dosage form that has been approved or otherwise may be lawfully marketed under the Food, Drug, and Cosmetic Act for distribution in the United States''); 21 CFR 1301.72(a) & 1304.22(a) (listing ''bulk materials awaiting further processing'' separately from ''finished products'').

[18] As set forth in 21 CFR 1301.15: ''The Administrator may require an applicant to submit such documents or written statements of fact relevant to the application as he/she deems necessary to determine whether the application should be granted.''

[19] Respondent further testified that it was his intention to simply send bulk marijuana to researchers who would then roll their own cigarettes. Tr. at 243.

[20] When asked during the hearing about the title of his organization (Multidisciplinary Association for Psychedelic Studies) and, in particular the term ''Psychedelic,'' Mr. Doblin explained, in part, ''it's about tools and procedures that bring to the surface people's subconscious and unconscious and, you know, deeper emotions.'' Tr. 474.

[21] In a recent Supreme Court decision, Justice Ginsberg, in a dissenting opinion, summarized the process by which FDA approves new drugs for marketing as follows:

The process for approving a new drug begins with preclinical laboratory and animal testing. The sponsor of the new drug then submits an investigational new drug application seeking FDA approval to test the drug on humans. *See* 21 U.S.C. 355(i); 21 CFR 312.1 *et seq.* (2007). Clinical trials generally proceed in three phases involving successively larger groups of patients: 20 to 80 subjects in phase I; no more than several hundred subjects in phase II; and several hundred to several thousand subjects in phase III. 21 CFR 312.21. After completing the clinical trials, the sponsor files a new drug application containing, *inter alia*, ''full reports of investigations'' showing whether the ''drug is safe for use and * * * effective''; the drug's composition; a description of the drug's manufacturing, processing, and packaging; and the proposed labeling for the drug. 21 U.S.C. 355(b)(1).

Riegel v. *Medtronic, Inc.*, 128 S.Ct. 999, 1018–19 n.15 (2008) (Ginsburg, J., dissenting).

[22] While Respondent produced evidence establishing that the $800–880 million costs of bringing a new drug to market includes research and development costs incurred for drugs that are not approved, as well as opportunity costs (the cost of investing in research rather than something else), *see* Tr. 161, 734–36, Respondent has not shown a single instance in which an entity has obtained FDA approval of a drug through the NDA process for the cost range which Mr. Doblin claimed would be sufficient to obtain approval of plant-form marijuana.

Moreover, the IOM Report states that the average cost of a Supplemental New Drug Application (SNDA), which is used when a company seeks to obtain FDA approval to market a drug (which has already gone through the three phases of clinical

Doblin testified that ''the mission statement [of MAPS] is to develop psychedelics and marijuana into FDA-approved medicines and then to educate the public about that'' (Tr. 478), the vagaries of his testimony prevent a clear determination of how far along in that goal he envisions MAPS to be.[23]

Correspondence Pertaining to the Application

Subsequent to Respondent's submission of his application for a DEA registration, on March 4, 2003, the Chief of DEA's Drug and Chemical Evaluation Section wrote to Respondent noting that ''it appears that the basis for your application is the purported need for a higher potency and higher 'quality' marijuana product than that currently available from the National Institute on Drug Abuse.'' GX 29, at 1. The DEA letter further explained that the Agency had ''contacted NIDA, the Department of Health and Human Services * * * and some current researchers'' and had ''determined that * * * the quality of marijuana available from NIDA is acceptable,'' that a high potency product with a THC content of 7 to 8 percent was currently ''available to bona fide research protocols,'' and that if ''[i]n the future, should federally approved research protocols require a higher potency marijuana (*i.e.* 15 percent THC), all believe that it could be supplied by NIDA.'' *Id.*

Thereafter, on June 2, 2003, Respondent wrote to DEA acknowledging that during a visit with several agency Diversion Investigators, the discussion had ''primarily focused[ed] on the need for an alternative source of plant material to that grown at the University of Mississippi under contract to the National Institute of Drug Abuse (NIDA).'' GX 30. Continuing, Respondent stated that ''[a] second source of plant material is needed to facilitate privately-funded, FDA-approved research into medical uses of marijuana, ensuring a choice of sources and an adequate supply of quality, research-grade marijuana for medicinal applications.'' *Id.* Consistent with these statements, Respondent has declined to bid on the NIDA contract. Tr. 252–53.

Respondent further asserted that while ''the primary researchers now receiving plant material may openly state to you that they are satisfied with the current source, * * * in private conversations these same researchers indicate a fear of having the current supply eliminated if they complain about the available source material.'' GX 30. As support for his contention regarding the level of researcher's satisfaction with NIDA's marijuana, Respondent attached two items: a reprint of a newspaper article and a letter from a Dr. Ethan Russo to the then-Chief of DEA's Drug and Chemical Evaluation Section. *See* GX 30a & 30b.

At the hearing, Respondent testified that at the time he filed his application, he had become concerned, based on conversations he had with ''other people,'' that the marijuana provided by the National Center ''may have been of relatively low quality, and that [it] was not readily available to run the clinical trials which some people wanted to run.'' Tr. 215. When asked to provide the names of these ''other people'' who had told him this, Respondent said he did not recall. *Id.*

Respondent's Contentions Regarding the Inadequacy of NIDA Marijuana

Respondent makes three principal claims in support of his contention that the supply of marijuana currently available through NIDA is inadequate. First, he claims that ''NIDA does not provide medical marijuana to all legitimate researchers'' and that ''NIDA has refused to provide marijuana to at least three legitimate researchers.'' Resp. Prop. Findings at 12. Second, he claims that ''the quality of the NIDA marijuana raises concerns for researchers and patients.'' *Id.* at 16. Third, he claims that ''the NIDA supply was inadequate because a pharmaceutical developer could not reasonably rely on NIDA marijuana to take marijuana through the FDA new drug approval process.'' Respondent's Response to Govt.'s Exceptions (hereafter, ''Respondent's Resp.'') at 16.

HHS's Denials of Researcher's Requests for NIDA Marijuana

Respondent's first claim is based on three incidents over a decade-long time period in which he alleges that researchers were improperly denied access to NIDA's marijuana. The first incident, which occurred in 1995, involved an application submitted by Donald Abrams, M.D., who sought

trials and been approved for marketing) for a new indication, was $10 to 40 million. RX 1, at 214. It should be noted, however, that in taking a drug through the three phases, its sponsor will have obtained extensive data regarding the drug's safety including ''adverse effects of the drug [and] clinically significant drug/drug interactions.'' 21 CFR 314.50(d)(5)(vi).

In support of his assertion that MAPS could obtain FDA approval for only $5 to $10 million, Mr. Doblin testified that marijuana is different than other drugs that go through the FDA approval process. Mr. Doblin based this assertion on his contentions that: marijuana has been used by ''tens of millions of people'' while others drugs going though the NDA process are only used by a few thousand; there is ''an enormous body of evidence about [marijuana's] safety * * * that we don't need to replicate;'' and sufficient data to satisfy the FDA as to marijuana's safety and efficacy could be obtained by testing only 500 to 600 people. *Id.* at 737–38.

The FDA's guidance document for botanical drug products makes plain that ''[a] botanical drug product that is not generally recognized as safe and effective for its therapeutic claims is considered a new drug under § 201(p) of the [Food, Drug, and Cosmetic] Act,[]'' and that ''any person wishing to market a botanical drug product that is a new drug is required to obtain FDA approval of an NDA * * * for that product.'' GX 92A, at 7. Moreover, ''an NDA must contain substantial evidence of effectiveness derived from adequate and well-controlled clinical studies, evidence of safety, and adequate CMC [chemistry, manufacturing, and controls] information.'' *Id. See also* GX 92A, at 27–38 (specifying the information that must be provided to FDA for phase 3 clinical studies of a botanical product to meet the requirements of the FDA regulations governing the contents of INDs). Finally, with respect to the nonclinical safety assessment required to support phase 3 clinical trials, the FDA guidance states:

To support safety for expanded clinical studies or to support marketing approval of a botanical drug product, toxicity data from standard toxicology studies in animals may be needed * * * . A botanical product submitted for marketing approval as a drug will be treated like any other new drug under development. Safety data from previous clinical trials conducted in foreign countries will be considered in determining the need for nonclinical studies. However, previous human experience may be insufficient to demonstrate the safety of a botanical product, especially when it is indicated for chronic therapy. Systematic toxicological evaluations could be needed to supplement available knowledge on the general toxicity, teratogenicity, mutagenecity, and carcinogenicity of the final drug product.

Id. at 34. While Mr. Doblin asserted that MAPS would not ''need to replicate all those studies about the genetics, * * * the effect on reproduction, the effect in all sorts of bodily systems,'' Tr. 737, he did not identify any specific studies performed in other countries that establish the safety of marijuana for testing in phase 3 clinical studies. While millions of people have undoubtedly used marijuana, few have done so subject to the scientific rigor of a controlled clinical trial. Nor did Respondent produce any credible evidence establishing that the various types of animal studies which FDA usually requires to support phase 3 clinical trials would not have to be performed. GX 92A, at 35–37.

[23] As indicated above, based on the record, no clinical trials involving marijuana have advanced beyond phase 1. Moreover, each sponsor must submit to FDA his/her own IND to be authorized to conduct clinical investigation with a new drug (such as marijuana). *See* 21 CFR 312.20, 312.23. Again, given the vagaries of Mr. Doblin's testimony, it cannot be determined whether there is sufficient existing preclinical laboratory and animal studies data to support a submission of an IND for whatever proposed indications that Mr. Doblin has in mind for his envisioned FDA-approved marijuana medicine. But even assuming, *arguendo*, that MAPS could successfully submit an IND based on existing data, it would still have to proceed through extensive clinical trials (*see* 21 CFR 312.21), and then—assuming that such trials are fully successful at demonstrating the basis for safety and efficacy (which often is not the case with clinical trials)—MAPS would still have to submit and obtain approval of an NDA. All of these steps, and the uncertainties as to the outcomes of each step, further call into question Mr. Doblin's estimate of being able to obtain FDA approval of marijuana for only $5 to $10 million.

marijuana from NIDA to study its effects on persons with HIV-related wasting syndrome. RX 15, at 1. NIDA rejected Dr. Abrams's application ''based upon issues of design, scientific merit and rationale.'' [24] Dr. Abrams subsequently submitted a revised research protocol that NIDA found to be scientifically meritorious and for which NIDA supplied marijuana in 1997.[25] *See* GX 21, at 1. NIDA also supplied Dr. Abrams with marijuana for subsequent studies. *Id.;* Tr. 689. In any event, for purposes of determining the relevance of the 1995 incident in which Dr. Abrams' original protocol was rejected by NIDA, it is notable that this occurred before HHS adopted its new guidelines for the provision of marijuana for research purposes. As Dr. Gust testified, in 1995, HHS's practice was to provide marijuana only to researchers who obtained NIH funding—a practice that was abandoned by HHS in 1999 when the agency adopted its new procedures for facilitating marijuana research (allowing privately funded researchers to also obtain marijuana). Tr. 1749.

The second incident involved an application by Dr. Ethan Russo, a neurologist, who sought funding from NIDA to study the use of marijuana to treat migraine headaches beginning around 1996. Tr. 527–28. The precise dates of the events related to Dr. Russo are somewhat unclear as Respondent presented these events through the testimony of Mr. Doblin. (Dr. Russo did not testify.) *Id.* Based on Mr. Doblin's testimony, it appears that during 1996–97, NIDA twice rejected Dr. Russo's protocol for reasons which are not clearly established by the record. *Id.* at 527, 691–92. However, according to Mr. Doblin, Dr. Russo conceded that, on both of these two occasions when NIDA rejected his protocol, NIDA's bases for doing so did include ''some valid critiques.'' Tr. 692. Mr. Doblin testified that Dr. Russo subsequently attempted for a third time to obtain marijuana from NIDA, but on this third occasion he decided not to seek government funding but to seek private funding to purchase the marijuana from NIDA. *Id.* at 692. According to Mr. Doblin, this third protocol submitted by Dr. Russo was approved by both the FDA and Dr. Russo's institutional review board, but NIDA again refused to supply marijuana. *Id.* at 692–93. When asked when this last denial by NIDA occurred, Mr. Doblin testified: ''I think it was 1999.'' *Id.* at 693.

As noted above, NIH announced on May 21, 1999, HHS's new procedures for making marijuana available to researchers. Bearing in mind that Respondent had the burden of proving any proposition of fact that he asserted in the hearing, 21 CFR 1301.44(a), nothing in Mr. Doblin's testimony, or any other evidence presented by Respondent, established that HHS denied Dr. Russo's request for marijuana under the new procedures implemented by the agency in 1999. Indeed, Respondent produced no evidence showing that HHS has denied marijuana to any clinical researcher with an FDA-approved protocol subsequent to the adoption of the 1999 guidelines.

The third incident involved an application by Chemic Laboratories (Chemic), which—at the request of Mr. Doblin—sought marijuana from NIDA in 2004 [26] for a proposed study involving a device known as the ''Volcano Vaporizer'' (hereafter ''Volcano''). RX 49 & 52B. To understand the nature and purpose of this proposed study, some earlier facts that were disclosed at the hearing need to be considered. According to Mr. Doblin's testimony, prior to this incident (*i.e.*, before Chemic applied to NIDA for marijuana in 2004), Mr. Doblin had devised an elaborate arrangement whereby Chemic received marijuana to conduct an earlier study with the Volcano using marijuana obtained outside of the HHS process and without the knowledge or approval of HHS or DEA. Specifically, Mr. Doblin admitted that he encouraged persons who obtained marijuana from ''buyers' clubs'' in California as well as persons who obtained their marijuana from NIDA under HHS's ''compassionate use program'' [27] to anonymously send their marijuana to a DEA-registered drug testing laboratory so that MAPS could compare the potency of the ''buyers' clubs'' marijuana with that supplied by NIDA.[28] Tr. 668–82. Acting at the behest of Mr. Doblin, once the drug testing laboratory completed its analysis of the marijuana it received through these sources, it delivered the ''extra'' marijuana to Chemic, so that Chemic could conduct testing on the Volcano. *Id.* Chemic did conduct such testing,[29]

[24] That the above-quoted grounds were the bases upon which NIDA denied Dr. Abrams' original application is implicit from the letter that Dr. Abrams submitted to NIDA in response to the denial (RX 15). These bases are explicitly stated in NIDA's April 19, 1995, letter to Dr. Abrams, which appears on MAPS' Web site (at *http://www.maps.org/mmj/leshner.html*) and of which I take official notice. This letter from NIDA stated, among other things, the following:

Our decision here is based upon issues of design, scientific merit and rationale. We believe that your study will not adequately answer the question posed.

Although the study propose[d] seeks to make a dose-effect comparison of smoked marijuana to delta-9-tetrahydrocannabinol (THC), there is no real dosing control. The marijuana is to be taken home and there is no requirement and way to ensure that the subjects smoke all available materials on any fixed schedule. Additionally, that they are given a two-week supply of marijuana at one time further confounds the study design. Thus, we believe the dose-effect component is confounded since the study cannot correlate variability in weight gain with dosage.

We also believe the study lacks adequate sample size to make any inferences regarding the dose-effect relationship. . . . Another confounding variable not adequately controlled for in your proposed study is diet. Neither the total daily caloric intake nor the percentages of the composition of the foodstuffs is assessed.

In accordance with the Administrative Procedure Act (APA), an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' U.S. Dept. of Justice, *Attorney General's Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is ''entitled on timely request to an opportunity to show to the contrary.'' 5 U.S.C. 556(e); *see also* 21 CFR 1316.59(e). To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within fifteen days of service of this order which shall commence with the mailing of the order.

[25] Following the 1996 passage of proposition 215, NIDA contacted Dr. Abrams and asked him if he would redesign his study to determine whether marijuana usage by persons who were HIV-positive (but who did not have AIDS-wasting syndrome) increased viral load as well as the interaction of marijuana with protease inhibitors. Tr. 523–24. Dr. Abrams agreed to do so and NIDA provided him with a $1 million grant to fund the study.

[26] It appears from the record that Chemic initially applied to HHS for marijuana in 2003 but, at HHS's request, Chemic submitted a revised protocol, which HHS considered to be submitted in 2004. *See* GXs 49 & 52B.

[27] *See Kuromiya* v. *United States,* 78 F.Supp.2d 367 (E.D. Pa. 1999) (describing compassionate use program under which less than 10 persons currently receive marijuana from HHS).

[28] Because marijuana is a schedule I controlled substance, human use is limited to ''Government-approved research'' in accordance with 21 U.S.C. 823(f). *See OCBC,* 532 U.S. at 491–492 and n.5. In accordance with § 823(f) and the DEA regulations, where a schedule I controlled substance is used in research—including the HHS compassionate use program—the activities involving the substance must be limited to those authorized in the research protocol. *See* 21 CFR 1301.13(e)(1)(v), 1301.18. Research activities beyond those specified in the protocol are prohibited absent the submission and approval of a supplemental protocol. 21 CFR 1301.18(d). Respondent made no attempt to assert that any of the research protocols associated with the compassionate use program allow for the distribution of marijuana to a drug testing laboratory, as there is no basis for such an assertion. The CSA prohibits the distribution of any controlled substance except as authorized by the Act, 21 U.S.C. 841(a)(1), and the Act makes no allowance for ultimate users (including research subjects) to distribute their controlled substances to others.

[29] Chemic was not registered with DEA under 21 U.S.C. 823(f) to conduct research with marijuana and when DEA later learned that Chemic was seeking to conduct a second marijuana study (when Chemic subsequently sought to obtain marijuana directly from NIDA and sought DEA's authorization for doing so), the agency so advised Chemic that this activity required a research registration. *See* RX 49, at 2. DEA registrants are only authorized to conduct activities with controlled substances ''to

which was funded by MAPS and the California National Organization for the Reform of Marijuana Laws (CaNORML), and Chemic published its results in two reports, one of which was co-authored by CaNORML.[30] *See id.*

Thus, this ''third incident'' to which Respondent points involved an effort by MAPS to expand upon the research that Chemic had conducted on the Volcano—this time using marijuana directly obtained from NIDA rather than using marijuana obtained without the knowledge or approval of HHS or DEA. Id. Under MAPS sponsorship and oversight, Chemic so applied to NIDA in 2004. Id.; RX 52B. The protocol submitted by Chemic proposed to heat marijuana obtained from NIDA and from a Dutch ''medical marijuana'' program to three different temperature levels below its combustion temperature and to then ''compare the quality and relative percentage of available cannabinoids'' in the material obtained from each source. RX 52B, at 2–3.

By letter dated July 27, 2005, a U.S. Public Health Service (PHS) committee of scientists, which evaluated Chemic's protocol pursuant to the 1999 Guidance, rejected it on the grounds that the ''project does not add to the scientific knowledge base in a significant way.'' [31] Id. at 4. With respect to the protocol's purpose of comparing the cannibinoid content of NIDA and Dutch marijuana, the PHS committee found that ''[m]arijuana varies in THC content and [that] simply demonstrating that this device can measure those differences is of little scientific value.'' *Id.* at 3. The PHS committee also found that the protocol's other purposes (''to conduct a reliability study of the device by analyzing multiple vapor collections'' and to ''determine the 'precision, accuracy, robustness and efficacy' of the vaporizing device'') did ''not appear to be a hypothesis driven research project,'' but rather, ''analogous to a process that is used to 'validate' an analytical method.'' *Id.* The PHS committee thus concluded that the ''overall aims of the project appear to be descriptions of work that would need to be conducted as part of good standard laboratory procedure prior to a clinical study.'' *Id.*

The PHS Committee further noted that, at that time (2005), a separate, HHS-approved clinical trial involving marijuana and the Volcano was already underway. *Id.* This then-ongoing clinical trial was being conducted by Dr. Abrams and was sponsored by the CMCR, using NIDA-supplied marijuana. *Id.*; Tr. 689. Moreover, as the letter from the PHS Committee indicates, one of the documents that Dr. Abrams had previously submitted in support of his then-ongoing clinical trial was a report that Chemic itself had prepared regarding its prior study of marijuana and the Volcano.[32] GX 52B, at 3. Given that Dr. Abrams' clinical trial was ''underway and is examining the pharmacodynamics and pharmacokinetics of several different potencies of marijuana in human volunteers using the Volcano(c) device,'' the Committee concluded that ''[i]t is difficult to see what additional scientific knowledge will be provided by the current protocol, considering the prior work done by the applicant, as described in the above report, and the ongoing clinical trial at CMCR.'' *Id.*

Respondent also introduced into evidence a letter from the President of Chemic to HHS responding to several points raised by the PHS Committee in denying Chemic's application. *See* RX 55. Respondent's letter does not, however, establish that HHS impermissibly denied Chemic's application for marijuana.[33] To the contrary, the evidence supports the conclusion that HHS (acting through the PHS Committee) made its determination not to supply marijuana on this occasion based on scientific considerations, finding that Chemic's then-latest proposed study was duplicative of prior and ongoing research and not likely to provide useful data.

Respondent's Contention That NIDA's Marijuana Is of Poor Quality

Respondent also contends that ''[t]he quality of the NIDA marijuana raises concerns for researchers and patients.'' Resp. Prop. Findings at 16. In this regard, Respondent asserts that various researchers have complained that NIDA's marijuana is of inconsistent potency, that NIDA's marijuana is harsh, that NIDA's marijuana is frequently several years old and not fresh, that the available product is of low potency, and that NIDA's product includes stems and seeds. *See id.* at 16–27. Contrary to Respondent's view, the evidence does not ''demonstrate[] serious concerns about the quality of NIDA's'' marijuana products. *Id.* at 27. As explained below, Respondent's contentions are largely based on snippets from questionnaires in which the researchers generally indicated their overall satisfaction with the quality of NIDA's marijuana. As the ALJ found, ''a preponderance of the record establishes that the quality is generally adequate.'' ALJ at 84.

With respect to the contention that NIDA's marijuana is of inconsistent potency or inadequate potency, Respondent relies on comments contained on three questionnaires that were completed by researchers at DEA's request. Resp. Prop. Findings at 17–18. One of the questions asked: ''Have you ever had any difficulty obtaining marijuana from NIDA for all strengths of cigarettes to meet research requirements?'' GX 16, at 8. While Dr. Grant of the CMCR answered affirmatively and added that ''having consistency of 6% -8% [THC] content have been difficult,'' he further stated that NIDA ''ha[s] been *accommodating* by trying to produce the high % products in a timely manner.'' *Id.* at 9 (emphasis in original). In response to another question regarding the adequacy of NIDA's products, Dr. Grant noted that ''NIDA has been reliable[,]'' and ''they have been easy to work with and amenable to accommodating for the requirements of the study.'' *Id.* at 6.

It is true that Dr. Grant, in answering this question, noted the problems with the range of potency in the higher potency material. Dr. Grant explained, however, that the problems he found regarding the range of potency were attributable to the cigarettes being ''handrolled and thus difficult to prepare.'' *Id.* Moreover, Dr. Grant answered ''yes'' to the question of whether NIDA's current products were ''adequate for your research purposes

the extent authorized by their registration and in conformity with other provisions of [the CSA].'' 21 U.S.C. 822(b).

[30] The first report, which was submitted by Chemic in 2003 to MAPS and CaNORML, is titled ''Evaluation of Volcano(r) Vaporizer for the Efficient Emission of THC, CBD, CBN and the Significant Reduction and/or Elimination of Polynuclear-Aromatic (PNA) Analytes Resultant of Pyrolisis,'' and is available on MAPS' Web site at *http://www.maps.org/mmj/vaporizerstudy4.15.03.* The second report, titled ''Cannabis Vaporizer Combines Efficient Delivery of THC with Effective Suppression of Pyrolitic Compounds,'' also appears on MAPS' Web site at *http://www.maps.org/mmj/Gieringer-vaporizer.pdf.* I take official notice of both documents. *See also http://www.maps.org/news-letters/v13n1/13111gie.pdf* (2003 MAPS news letter discussing Vaporizer studies sponsored by MAPS and NORML and the Marijuana Policy Project), of which I take official notice.

[31] HHS also noted that there were ''a number of technical concerns'' with Chemic's proposal. RX 52B, at 4.

[32] The report, titled ''Evaluation of Volcano® Vaporizer for the efficient emission of THC, CBD, CBN and the significant reduction and/or elimination of polynuclear-aromatic (PNA) analytes resultant of pyrolysis,'' appears on MAPS Web site as discussed in note 30.

[33] If Chemic had a valid basis to challenge HHS's denial of its request for marijuana, it presumably had remedies available to challenge that agency action either within HHS or in the courts. *See, e.g.*, 5 U.S.C. 702 (''A person suffering legal wrong because of agency action * * * is entitled to judicial review thereof.''). Respondent produced no evidence showing that Chemic has pursued any such remedies.

with regard to potency?'' *Id.* at 15. Also, in response to the question of whether ''these problems [have] ever compromised the study?,'' Dr. Grant indicated: ''N/A.'' *Id.* at 6.

Dr. Grant further indicated that he had ''no'' information that ''would lead [him] to believe that the future supply of marihuana required for research would be insufficient or unavailable through NIDA,'' *id.* at 8, and that he had ''no'' concerns regarding ''the availability of research-grade marijuana from NIDA'' to meet CMCR's future needs. *Id.* at 9. While Dr. Grant also indicated that it would be clinically important to evaluate a higher potency product than the 7–8 percent THC content marijuana CMCR was currently using, he also indicated that CMCR had not sought a higher potency product but had only discussed with NIDA the feasibility of such a product. *Id.* at 16.

On his questionnaire, Ronald Ellis, M.D., of the University of California, San Diego, noted that in ''[a]t least two shipments, [there] was some variability on stated THC content and the actual [content] measured.'' GX 17, at 6. Dr. Ellis further noted, however, that NIDA personnel ''have been very responsive.'' *Id.* Apparently, Dr. Ellis's clinical trial received some marijuana which was supposed to have a THC content of 8 percent, but only had a content of approximately 7 percent. *Id.* at 9. Dr. Ellis indicated, however, that the potency of NIDA's current product was adequate for research purposes. *Id.*

Respondent also relies on Dr. Donald Abrams' ''no'' answer regarding the consistency of the potency of NIDA's product. Resp. Prop. Findings at 18 (citing GX 21, at 6). Dr. Abrams further noted that ''[o]riginally approved for 3.9% THC content, midway through the 'Short-term effects * * *' protocol, NIDA informed [us] that the potency had been downgraded to 3.5%. Everything since is said to be at 3.5%.'' GX 21, at 6. Notably, the ''Short-term effects'' study occurred more than a decade ago, and Dr. Abrams did not indicate that there had been further problems with the consistency of the potency of the marijuana supplied by NIDA for several later studies he conducted.

Nor does the evidence support Respondent's contention that the marijuana available through NIDA is of insufficient potency to satisfy the needs of legitimate researchers. In his brief, Respondent relies on the statements of Drs. Grant and Abrams that it would be beneficial to evaluate the efficacy of marijuana cigarettes with a higher THC content than what was currently being supplied by NIDA. Resp. Prop. Findings at 22–23 (citing GX 16 & 21). Respondent, however, produced no evidence establishing that any researcher has obtained approval of FDA and other reviewing authorities to conduct clinical trials using higher THC content marijuana. As Dr. Abrams explained, he ''wanted to use a higher potency product but there were questions from the [scientific review board] and the funding agency [CMCR].'' GX 21, at 9.

Moreover, as Dr. ElSohly testified, the National Center has in inventory substantial quantities of bulk marijuana material with THC contents of ten to eleven percent and has some material with a THC content of fourteen percent.[34] Tr. 1203. Dr. ElSohly also testified that the National Center could produce marijuana with a THC content of up to 20 percent. *Id.* He further testified that he had informed ''some of the investigators that if they want to, they can order material of a certain potency'' and ''roll their own cigarettes.'' *Id.* at 1204–05.

Respondent also maintains that NIDA's marijuana is harsh and that some patients have complained that it was ''inferior in sensory qualities (taste, harshness) [to] the marijuana they smoke outside the laboratory,'' and that ''it was the worst marijuana they had ever sampled.'' Resp. Prop. Findings at 19–21. Yet, as the questionnaires completed by the researchers indicate, only a small percentage of study subjects have complained about the harshness of NIDA's marijuana. See GX 18, at 7 (one of ten patients complained); GX 21, at 8 (four out of fifty dropped out because of quality); GX 22, at 7 (''Out of 100 plus subjects, no more than [three] may have commented that the product was harsh.'').[35] Moreover, as one of the researchers noted, it was unclear whether the harshness was related to the actual marijuana cigarettes or the placebo material.[36] As for Respondent's further contention that some patients complained that NIDA's marijuana ''was the worst they had ever sampled,'' this evidence does not establish that the taste of the products rendered them unsuitable for their intended use.[37] Furthermore, Respondent provides no scientific basis for his suggestion that the research subjects' description of the degree of their subjective satisfaction with the experience of smoking marijuana in a research setting should be a criterion for judging the adequacy of the quality of marijuana for research purposes.[38]

Finally, Respondent contends that NIDA's marijuana is frequently ''not fresh'' and that it includes stems and seeds. Resp. Prop. Findings at 21–22; 25–27. While the record contains some evidence that older marijuana loses some if its potency, all but one of the researchers indicated that neither the lack of freshness nor the existence of plant parts (stems and seeds) had adversely impacted their research. *See* GX 16, at 13 (CMCR); GX 17, at 7 (Dr. Ellis); GX 18, at 7 (Dr. Corey-Bloom); GX 19, at 7 (Dr. Israelski); [39] GX 20, at 7 (Dr. Wallace); GX 22, at 7 (Dr. Polich); GX 28, at 7 (Prof. Lichtman); *but see* GX 21, at 7–8 (Dr. Abrams) (indicating that four

[34] Respondent also cites the questionnaire of Prof. Aron Lichtman, of the Department of Pharmacology, Virginia Commonwealth University, who conducted research in animals. Resp. Proposed Findings at 23 (citing GX 28). On his questionnaire, Prof. Lichtman indicated that he ''would [have] prefer[red] something at a higher potency, but at the time, 3–4% was the highest potency available.'' GX 28, at 9. Prof. Lichtman's questionnaire indicated, however, that his study had last obtained marijuana in 1999. Prof. Lichtman's answer is thus not probative of whether NIDA is currently capable of providing marijuana of adequate potency to support legitimate research needs.

Respondent's evidence regarding the potency of marijuana distributed by NIDA for patients in the former Compassionate Investigational New Drug program likewise dates back to 1999. See Resp. Prop. Findings at 24 (citing RX 19, at 47–48). As such, the evidence is not probative of whether NIDA is currently capable of supplying marijuana of adequate potency.

[35] Dr. ElSohly testified: ''I think you had like 50 subjects, and only three or four complained of the harshness. That's a very small percentage. You are going to get that regardless of what you administer.'' Tr. at 1589.

[36] As Dr. Cory-Bloom noted, it was unclear whether the harshness was attributable to actual marijuana cigarettes or placebo cigarettes. GX 18, at 7. Relatedly, Dr. ElSohly testified that the complaints of harshness were likely attributable to the placebo because ''all of the components have been extracted out . . . [s]o this will be just like smoking * * * grass or * * * hay or something like that or just paper that might have this harshness, and there's no soothing effect of the other components in the plant material.'' Tr. 1289–90.

[37] Respondent also cites to hearsay evidence regarding the experience of a single patient who had previously used non-NIDA marijuana (illegally obtained from California ''buyers'' clubs'') without problems but then purportedly developed bronchitis upon smoking NIDA marijuana. Resp. Prop. Findings at 21; Tr. 570. Even if I were to credit this testimony, the record as a whole establishes that NIDA's marijuana was well tolerated in the great majority of the various studies' subjects.

[38] Marijuana is known to cause, among other things, ''a distortion in the sense of time associated with deficits in short-term memory and learning,'' ''difficulty carrying on an intelligible conversation,'' anxiety, paranoia, panic, depression, dysphoria, delusions, illusions, and hallucinations. RX 1 (IOM report), at 101–102. These effects impact the determination of what, if any, weight to attach to research subjects' descriptions of their satisfaction with the marijuana they have smoked.

[39] Dr. Israelski did not recall any complaints about the ''freshness'' of NIDA's marijuana.

out of fifty patients had ''dropped out due to quality'').

Moreover, with respect to the existence of stems and seeds in NIDA's marijuana, Dr. ElSohly acknowledged that prior to 2001, there may have some stems and seeds in the marijuana it sent to the Research Triangle Institute (the contractor for the manufacture of the cigarettes). Tr. 1300–01. Dr. ElSohly further testified, however, that in 2001, the National Center acquired a special de-seeding machine which removes all the seeds and stems from the marijuana that is used to manufacture cigarettes. *Id.* at 1301. Respondent produced no evidence showing that the marijuana which the National Center has since supplied has contained stems and seeds.[40]

Respondent's Contention That NIDA's Marijuana Is Inadequate To Support The Development of Plant-Form Marijuana Into an FDA-Approved Prescription Drug

Respondent further contends that the existing supply of NIDA marijuana is inadequate because ''MAPS seeks to develop botanical marijuana as an FDA-approved prescription drug.'' Resp. Prop. Findings at 8. In support of this contention, Respondent makes two primary factual assertions. First, he claims that ''to develop a pharmaceutical product, a developer must have assured access to a reliable, dependable source of the particular formulation of the product the developer needs, both for research, and for distribution if the product is approved,'' and that ''[w]ithout such a source, there is no development.'' *Id.* at 9. Second, he claims that ''even before the Phase [1] and Phase [2] studies on a product, the developer must generally submit a Drug Master File,''[41] and that the Drug Master File (DMF) for NIDA's marijuana contains proprietary information which NIDA controls. *Id.*

As for Respondent's contentions regarding the need to submit a DMF, Respondent asserts that ''there is no procedure to force [the DMF's] owner to make a Drug Master File, or the information in it, available to a drug developer.'' Resp. Prop. Findings at 10 (citing Tr. 447–49; testimony of Dale Gieringer). While Respondent concedes that NIDA ''has allowed the researchers whom it chooses to supply with marijuana to rely on that file,'' and that FDA has approved several Phase 1 studies using NIDA marijuana and the information contained in the DMF, *id.* at 10, it contends that because NIDA's mission is to study drug abuse, it is not likely that ''NIDA would authorize MAPS to rely on the NIDA marijuana [DMF] currently on file with the FDA.'' *Id.* at 45.

The 1999 HHS Guidance makes clear, however, that if a proposed research project meets the Department's criteria for the provision of research-grade marijuana, ''NIDA will provide the researcher with authorization to reference NIDA's marijuana Drug Master File.'' GX 24, at 4. Moreover, as the FDA has explained, ''the submission of a DMF is not required by law or regulation,'' but rather, ''is submitted solely at the discretion of the holder.'' *Guideline For Master Drug Files*, at 2. The FDA regulations provide: ''FDA ordinarily neither independently reviews drug master files nor approves or disapproves submissions to a drug master file. Instead, the agency customarily reviews the information only in the context of an application under part 312 or part [314].'' 21 CFR 314.420(a). Accordingly, as the FDA Guidelines explain, while ''the information contained in [a] DMF may be used to support an Investigational New Drug Application (IND), [or] a New Drug application (NDA) * * * [a] DMF is NOT a substitute for an IND [or] NDA.'' *Guideline For Master Drug Files,* at 3.

Relatedly, David Auslander, M.D., the Government's expert witness in pharmaceutical development, testified that ''not all companies do Drug Master Files'' and that ''FDA does not necessarily require a Drug Master File to do a Phase [1] and Phase [2] study in all cases if the Drug Master File * * * comes from a producer that's different from the sponsor itself.'' Tr. 2024. Dr. Auslander also explained that a drug developer may not even have a Drug Master File at the time it applies to conduct Phase 1 or Phase 2 studies. *Id.* As Dr. Auslander further testified, the necessary information can be submitted in an IND or an NDA. *Id.* at 2024–25.

As for the contention that NIDA is not a reliable source of supply, it is undisputed that a for-profit drug developer would be unlikely to take a drug through the FDA approval process unless it was ''assured that they would have a drug supply that is unchanging and reliable.'' Tr. 117 (testimony of Irwin Martin, Ph.D.). Dr. Martin also testified that ''[o]ne of the biggest problems in drug development is the unfortunate need sometimes to repeat studies. If you have a new formulation or your drug source has changed, you many need to repeat years worth of data because you can no longer assure that the data you developed with this earlier version of [the] drug will actually be the same drug as you now have.'' *Id.* at 118. Dr. Martin further testified that while ''no reasonably business-oriented company would ever develop a product'' if it did not have a reliable and consistent supply source, he also noted that if a company had to change its supply source, a company could try to show that the new product was pharmcokinetically equivalent to the old product. Tr. 120–21; *see also* Tr. 2027.

Also on this issue, Dr. Auslander testified further on behalf of the Government that if the developer's source changed, it ''would not necessarily repeat the Phase [1] and [2] clinical studies over again, but * * * would do additional chemical studies, stability [studies] * * * to show that the quality of material from source A and the quality of material acquired from source B are equivalent.'' Tr. 2027–28. Both Respondent's and the Government's experts agreed, however, that if the developer could not establish equivalence between the two products, ''it would not be a trivial experience'' for the developer. *Id.* at 2029; *see also id.* at 121 (testimony of Dr. Martin that developer would have to start over).

Relatedly, Respondent further asserts that there is ''overwhelming'' evidence that NIDA ''would not be likely to choose to serve as the supplier to a medical marijuana pharmaceutical product developer even if it were authorized to so.'' Resp. Prop. Findings at 10. In support of this assertion, Respondent extracts two sentences from a letter in which Nora Volkow, M.D., NIDA's director, responded to Mr. Doblin's letter accusing NIDA/HHS of ''seriously obstructing'' Chemic's research involving the Volcano which MAPS was sponsoring (and whose application HHS ultimately denied).[42] *See id.* (quoting RX 13; ''It is

[40] In support of its contention that NIDA marijuana contains stems and seeds which renders the product's quality inadequate, Respondent also cites an article, ''Chronic Cannabis Use in the Compassionate Investigational New Drug Program.'' Resp. Prop. Findings at 26 (citing RX 19, at 49–50). Respondent particularly notes two photographs of marijuana that was manufactured in April 1999. *See id.* This evidence thus predates the National Center's 2001 acquisition of a de-seeding machine.

[41] I also take official notice of the FDA's *Guideline For Drug Master Files* (Sept. 1989) (available at *http://www.fda.gov/cder/guidance/dmf.htm/*).

According to this FDA guideline (at 2), ''[a] Drug Master File (DMF) is a submission to the [FDA] that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.''

[42] In that letter, Mr. Doblin also mentioned that DEA had indicated that it would not review Chemic's application to import ten grams of Dutch marijuana until NIDA/HHS completed its review of Chemic's protocol. RX 14. Mr. Doblin also

Continued

not NIDA's role to set policy in this area or to contribute to the DEA licensing procedures. Moreover, it is also not NIDA's mission to study the medicinal use of marijuana or to advocate for the establishment of facilities to support this research.''). *See also* RX 14 (letter of Mr. Doblin; ''NIDA/HHS is seriously obstructing a privately-funded drug development program aimed at evaluating marijuana's potential use as an FDA-approved medication.'').

In that letter, Dr. Volkow declined to intervene explaining that:

> * * * NIDA is just one of the participants on the HHS review panel and continues, on behalf of the U.S. Government, to provide supplies of well-characterized cannabis for both NIH and non-NIH-funded research. The latter is conducted according to the procedure established in 1999 by HHS for obtaining access to marijuana for research purposes. It is not NIDA's role to set policy in this area or to contribute to the DEA licensing procedures. Moreover, it is not NIDA's mission to study the medicinal uses of marijuana or to advocate for the establishment of facilities to support this research. Therefore, I am sorry but I do not believe that we can be of help to you in resolving these concerns.

RX 13. As both this letter and the 1999 Guidance make plain, HHS—and not NIDA—is the policymaker regarding the criteria for determining who can obtain research-grade marijuana from NIDA. As NIDA does not independently control to whom it may supply marijuana for legitimate research, the letter is not indicative of whether NIDA would be a reliable source of marijuana for an entity which sought to develop plant-form marijuana into an FDA-approved prescription medicine.

Respondent also points to the 1999 Guidance document's statement that ''[t]he goal of this program must be to determine whether cannabinoid components of marijuana administered through an alternative delivery system can meet the standards enumerated under the Federal Food, Drug, and Cosmetic Act for commercial marketing of a medical product. As the IOM report stated, 'Therefore, the purpose of clinical trials of smoked marijuana would not be to develop marijuana as a licensed drug, but such trials could be a first step towards the development of rapid-onset, nonsmoked cannabinoid delivery systems.' '' [43] GX 24, at 2.

As found above, the IOM's recommendation was based on its conclusion that ''[a]lthough marijuana smoke delivers THC and other cannabinoids to the body, it also delivers harmful substances, including most of those found in tobacco smoke. In addition, plants contain a variable mixture of biologically active compounds and cannot be expected to provide a precisely defined drug effect. For those reasons there is little future in smoked marijuana as a medically approved medication.'' RX 1, at 195–96.

Moreover, the HHS Guidance does not address what the Secretary's response would be were the current clinical trials to show that the efficacy/safety profile of smoked marijuana supported FDA approval of it as a prescription medicine for particular indications or patient populations. Nor does it address what the Secretary's response would be if clinical trials were to show that the efficacy/safety of vaporized plant form marijuana for particular indications supported its approval as a prescription drug.

Dr. Gust testified that notwithstanding the stated goal of the 1999 Guidance, a researcher who ''had an IND from FDA * * * would not have a problem getting marijuana.'' Tr. 1718. Further, in response to the ALJ's question as to whether a researcher whose goal was to obtain FDA approval of plant-form marijuana would have more difficulty obtaining marijuana from HHS than a researcher who sought to produce an extract-based product, Dr. Gust testified: ''I don't believe so.'' *Id.* at 1719–20.

Dr. Gust also explained that whether plant-form marijuana should be approved as a prescription medicine is ''not a question for the'' PHS committee that reviews requests for NIDA marijuana. *Id.* at 1720. Rather, ''it's a question for the regulation and approval process that goes on through FDA.'' *Id.* Finally, while Dr. Gust acknowledged that ''HHS would strongly endorse'' the IOM's view that ''if there's going to be an approved medication, it's going to be a purified constituent of marijuana that will be delivered in a non-smokable form,'' he further testified that in his experience, there was no bias against ''the concept of approving marijuana as a medication'' at the level of PHS review. *Id.* at 1722.[44]

Respondent further asserts that ''it is not at all clear that NIDA *could* serve as a source for a pharmaceutical product.'' Resp. Prop. Findings at 11 (emphasis in original). Notwithstanding Mr. Doblin's beliefs regarding the likely safety/efficacy profiles of smoked and vaporized marijuana, *see* Tr. at 605, it is highly speculative whether clinical trials will ultimately support FDA approval of plant-form marijuana through either delivery system.[45]

As further support for this contention, Respondent references that Dr. ElSohly answered ''That's correct'' when asked the following question by Respondent's counsel: ''So if somebody wants to develop a commercial product with marijuana, they could not use the NIDA marijuana; is that fair?'' Resp. Prop. Findings at 11 (quoting Tr. 1463). It is not clear exactly what to make of Dr. ElSohly's answer to this question.[46] In

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referenced DEA's handling of Respondent's application.

[43] In discussing the content of the HHS Guidance, Respondent asserts: ''And it expressly states that 'the purpose of clinical trials of smoked marijuana would not be to develop marijuana as a licensed drug.' '' Resp. Proposed Findings at 11 (quoting GX 24, at 2). Notably, Respondent's quotation edits out the Guideline's reference to the IOM Report. The complete text of the Guidance shows, however, HHS did not come to this conclusion without evidentiary support, but rather, relied on the extensive findings of the IOM.

[44] In discussing this testimony, the ALJ noted that Dr. Gust had acknowledged that a researcher with an FDA-approved protocol might nonetheless be denied marijuana by the PHS committee under the criteria set forth in the guidance. ALJ at 51 (citing Tr. 1694). There is, of course, no evidence that any researcher with an FDA-approved protocol has been denied marijuana subsequent to the 1999 guidelines. Dr. Gust's answer was based on a hypothetical question. Accordingly, this portion of Dr. Gust's testimony provides no basis to question his credibility as to whether in his experience, HHS (and the PHS review committees) are biased against researchers who seek to obtain FDA approval for plant-form marijuana.

[45] Given that, as indicated above, marijuana has been found to contain hundreds of different chemicals, including a variable mixture of biologically active compounds that cannot be expected to provide a precisely defined drug effect, IOM has expressed the view that, ''if there is any future in cannabinoid drugs, it lies with agents of more certain, not less certain, composition.'' RX 1, at 195–96.

[46] Based on the questions that led up to the above-quoted question, it appears that, in answering ''That's correct,'' Dr. ElSohly was confirming that the marijuana he grows pursuant to the NIDA contract may not be taken by the University of Mississippi (without prior authorization from NIDA) for use in the commercial development of a THC extract product where such commercial activity was not authorized by NIDA. *See* Tr. at 1462–63. Indeed, the following subsequent exchange between Respondent's counsel and Dr. ElSohly suggests that Dr. ElSohly correctly understood that there was no prohibition on the use of NIDA marijuana for the development of commercial products:

> Q: Dr. ElSohly, if an organization like MAPS, for example, a nonprofit or pharmaceutical organization, wanted to try to develop smoked marijuana into an FDA-approved medicine, could it use the marijuana that you grow to the preclinical and clinical testing if NIDA agreed?
>
> A: I would say yes.

Tr. 1562–63. Moreover, even if Dr. ElSohly was of the mistaken view that the marijuana he grew for NIDA could never be used by anyone for commercial product development, such a misunderstanding on Dr. ElSohly's part would not be controlling for purposes of this proceeding. The record is clear that it is HHS—not Dr. ElSohly—that determines the terms of his contract, including to whom and under what circumstances he may supply marijuana; and the record is also clear that Dr. ElSohly follows the instructions he receives from NIDA as to whom to deliver the marijuana. Further, as explained above, the record reveals that HHS's policy contains no prohibition on the use of

any event, 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. While Article H.13 states that ''contract funds shall not be used to support activities that promote the legalization of any drug or other substance included in schedule I'' of the CSA, it further provides that ''[t]his limitation shall not apply when the contractor makes known to the contracting officer that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage.'' GX 13, at 20 (citing Pub. L. 108–447, § 510, 108 Stat. 2809 (2005)). Likewise, the 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. GX 24. To the contrary, by adopting a new procedure whereby privately funded researchers could obtain marijuana from NIDA at cost, HHS made it possible starting in 1999 for a commercially sponsored researcher to develop a drug product using NIDA-supplied marijuana. *See id.* at 2. Finally, Respondent cites no provision of law that prohibits NIDA from serving as a supply source for a prescription drug approval process.[47]

Evidence Regarding the Remaining Statutory Factors

There is no evidence that Respondent has not complied with applicable state or local laws. *See* Gov. Proposed Findings at 139 (discussing 21 U.S.C. 823(a)(2)). Moreover, Respondent has never been convicted of any controlled-substance related offense. Tr. 78; *see* 21 U.S.C. 823(a)(4).

As for factor five, on the questionnaire, Respondent acknowledged that he ''has no current or previous registrations and is unaware of any registration [having] previously [been] granted to the university.'' GX 3, at 3. While Respondent testified that he would meet all ''appropriate security conditions,'' he also acknowledged that ''I've never grown marijuana or any other controlled substance.'' Tr. 79. He further testified that ''We have not—I have no experience in the control against diversion.'' *Id.* Relatedly, Respondent testified that he had no personal experience in providing security for plants, *id.* at 255, and that both graduate students and technicians would be used to perform the various tasks associated with the project. *Id.* at 254 (''I usually don't go down and water the plants in the greenhouse; I usually have a technician that does that.''); *id.* at 254–55 (''They [the graduate students and technicians] would probably do the transplanting[,]'' and ''a daily check on any environmental controls we have.''). Respondent presented no evidence that any person who would be involved in the daily operation of the project would have experience in the lawful manufacture or distribution of schedule I and II controlled substances.[48]

Finally, Respondent testified that he believed that granting his application would promote technical advances in the art of manufacturing controlled substances and the development of new substances. *Id.* at 74–76. More specifically, Respondent asserted that granting his application would advance ''the understanding [of] any possible clinical use of marijuana if we were able to supply this to investigators to run trials.'' *Id.* at 75–76. Respondent also testified that ''we would learn more about how the environment affects the constituents in the plant material which would enable'' a potential manufacturer, were marijuana to become approved by the FDA as a drug, to ''know the environment it needs to be grown under to produce a clinical marijuana.'' *Id.* at 76. Respondent further opined that granting his registration would promote technical advances because part of the purpose of growing the marijuana was to allow MAPS to test its vaporizer. *Id.* at 77–78. Respondent acknowledged, however, that he would not personally be working on MAPS's vaporizer device or on any other delivery device. *Id.* at 230. He also acknowledged that he has no patents regarding the growing of any medicinal plants. *Id.* at 238.

Discussion

Pursuant to 21 U.S.C. 823(a), ''[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 the United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971.'' 21 U.S.C. 823(a). ''In determining the public interest,'' § 823(a) directs the Attorney General to consider the following factors:

(1) Maintenance of effective controls against diversion of particular controlled substances and any controlled substances in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances 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;

(2) Compliance with applicable State and local law;

(3) Promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) Prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) Past experience in the manufacture of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) Such other factors as may be relevant to and consistent with public health and safety.

Id. This Agency's regulations further provide that ''[a]t any hearing on an application to manufacture any controlled substance listed in Schedule I or II, the applicant shall have the burden of proving that the requirements for such registration pursuant to [§ 823(a)] are satisfied.'' 21 CFR 1301.44(a).

As § 823(a) makes plain, even if an applicant satisfies its burden of proof with respect to the public interest inquiry, it cannot be granted a registration unless its proposed activities are consistent with the United States' obligations under international treaties. The United States is a party to

the marijuana grown pursuant to the NIDA contract for commercial development purposes.

[47] As for Respondent's contention that the Government did not ''introduce any evidence that NIDA could or would [serve as a supply source] to support its claim that NIDA's supply is adequate to meet all legitimate medical and scientific purposes,'' Resp. Prop. Findings at 11, Respondent, and not the Government, has the burden of proof on the issue of whether supply is inadequate within the meaning of 21 U.S.C. 823(a)(1). *See* 21 CFR 1301.44(a).

[48] Respondent testified that he had performed classified work on plants for the U.S. Army and that ''there were security systems in place similar to the security systems you have in this building'' (referring to DEA Headquarters, where the hearing took place), and he answered ''Yes'' when asked by his counsel whether he recognized ''the importance of that sort of security in a situation like this registration application.'' Tr. 367. It is unclear what Respondent meant by ''the security systems you have in this building,'' since the only security to which he would have been exposed in entering DEA Headquarters to testify were the requirements of passing through a metal detector, being accompanied by a DEA employee, and wearing a visitor's badge. These DEA Headquarters security measures have nothing to do with the security measures required of DEA registrants who handle controlled substances, which are set forth in 21 CFR 1301.71 through 1301.76. Thus, this portion of Respondent's testimony was ambiguous and did not establish, for purposes of 21 U.S.C. 823(a)(5) that, if his application were granted, there would exist in his establishment effective controls against diversion.

the Single Convention. Accordingly, whether Respondent's proposed activities are consistent with this Nation's obligations under the Convention is a threshold question.

A. Whether Respondent's Proposed Registration Is Consistent With the Single Convention

The Single Convention imposes a comprehensive series of measures to control narcotic drugs and other substances including marijuana (which is referred to in the Single Convention as ''cannabis'').[49] Under the Convention, cannabis is both a Schedule I and Schedule IV[50] drug and is subject to the control measures applicable to each schedule. Single Convention, art. 2, para. 5; *see also* Secretary-General of the United Nations, *Commentary on the Single Convention on Narcotic Drugs, 1961,* 65 (1973) (hereinafter, Commentary). Moreover, under article 28, ''[i]f a Party permits the cultivation of the cannabis plant for the production of cannabis or cannabis resin, it shall apply thereto the system of controls as provided in article 23 respecting the opium poppy.'' Single Convention, art. 28, Para. 1. As the Commentary further explains:

> The system of control over all stages of the drug economy which the Single Convention provides has two basic features: limitation of narcotic supplies of each country * * * to the quantities that it needs for medical and scientific purposes, and authorization of each form of participation in the drug economy, that is, licensing of producers, manufacturers and traders. * * * In the case of the production of opium, coca leaves, cannabis and cannabis resin, this regime is supplemented by the requirement of maintaining government monopolies for the wholesale and international trade in these drugs in countries which produce them. * * *

Commentary at 263.

Amongthese controls is the requirement that ''[t]he Agency shall * * * have the exclusive right of importing, exporting, wholesale trading and maintaining stocks other than those held by manufacturers of opium alkaloids, medicinal opium or opium preparations.'' Single Convention art. 23, para. 2(e). The Convention further provides, however, that the ''Parties need not extend this exclusive right to medicinal opium and opium preparations.''[51] *Id.*

The Commentary to article 28 thus explains that ''[a] Party permitting the cultivation of the cannabis plant for cannabis and cannabis resin must, pursuant to article 23, paragraph [2(e)(2)] in connexion with article 28, paragraph 1, grant its national cannabis agency *the exclusive right of wholesale * * * trade in these drugs.*'' Commentary at 314 (emphasis added). The Commentary further explains that the Government ''need not extend this exclusive right to extracts and tinctures of cannabis.'' *Id.*

Respondent raises several arguments as to why his registration would be consistent with the Single Convention. First, he argues that ''the Convention clearly contemplates that more than one cultivator or bulk manufacturer may be licensed by the member nation's licensing agency.'' Resp. Prop. Findings at 66. Second, he argues that because his ''crop would be medical marijuana, grown and processed to be adapted for medicinal use, it is not subject to the agency's 'exclusive right' for 'maintaining stocks.' '' *Id.* at 67.

Relatedly, Respondent argues that because DEA has granted Dr. ElSohly a registration to ''grow marijuana for private purposes'' and does not require him to ''turn[] over those stocks to any government agency,'' granting his application will likewise conform with the Single Convention. Respondent further contends that Dr. ElSohly has been able to grow marijuana outside of the NIDA contract and that ''DEA would not have issued those licenses had they violated the Single Convention.'' *Id.* at 68. Respondent also argues that the United Kingdom, which is also Party to the Convention, has allowed marijuana to be grown by a private entity (GW Pharmaceuticals) without its government taking physical possession. *Id.* Likewise, in his Response to the Government's exceptions to the ALJ's recommended decision, Respondent argues that the ALJ ''correctly held that Article 23 [para.] 2(d) does not require the government to take physical possession of [his] crop.'' Respondent's Resp. at 9.

In concluding that the ''Single Convention does not preclude registering Respondent,'' the ALJ offered three reasons. First, based on the United Kingdom's regulatory scheme, she reasoned that ''it appears * * * that the parties to the Single Convention are free to construe the term 'physical possession' as they see fit.'' ALJ 82. As for the remaining two reasons, the ALJ explained that ''[i]t also appears, although it is not entirely clear, that the marijuana grown by the National Center or by any other registrant for utilization in research would qualify as either 'medicinal' within the meaning of article 1, paragraph (1)(o), or a 'special stocks' within the meaning of article 1, paragraph (1)(x), and that therefore the government monopoly on importing, exporting, wholesale trading, and maintain stocks would not apply.'' *Id.*

Neither the ALJ's rationales nor Respondent's arguments are persuasive. As for the argument that the Single Convention does not require that the Government take physical possession, the argument provides no comfort to Respondent for two reasons. First, the argument ignores that taking possession and engaging in wholesale distribution are two separate activities under the Convention. Notably, in his briefs, Respondent does not even acknowledge the distinction. *See* Resp. Proposed Findings and Conclusion of Law at 64–70; Respondent's Resp. at 9–12.

Second, as Respondent's evidence makes clear, his purpose for seeking a registration is not simply to grow marijuana, but to distribute it outside of the HHS system. Mr. Doblin's testimony

[49] Under the Single Convention, '' 'cannabis plant' means any plant of the genus Cannabis.'' Article 1(c). The Single Convention defines ''cannabis'' to include ''the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated.'' Article 1(b). This definition of ''cannabis'' under the Single Convention is less inclusive than the CSA definition of ''marihuana.'' *See* 21 U.S.C. 802(16). However, this distinction in inconsequential for purposes of the matters at issue in this proceeding.

[50] The Single Convention's use of the term ''Schedule IV'' is not to be confused with the CSA's use of the same term. Under the Convention, the terms ''Schedule I, Schedule II, Schedule III and Schedule IV mean the correspondingly numbered list of drugs or preparations annexed to this Convention.'' Single Convention, art. 1, para. 1(u). As the Convention further explains, ''[t]he drugs in Schedule IV shall also be included in Schedule I and subject to all measures of control applicable to drugs in the latter Schedule'' as well as the additional measures contained in article 2, paragraph 5. *Id.* art. 2, para. 5.

Under Article 2, paragraph 5, the Convention requires that [a] Party shall adopt any special measures of control which in its opinion are necessary having regard to the particularly dangerous properties of a drug so included. *Id.* art. 2, para. 5(a). The Convention further directs that:

> A Party shall, if in its opinion the prevailing conditions in its country render it the most appropriate means of protecting the public health and welfare, prohibit the production, manufacture, export and import of, trade in, possession or use of any such drug except for amounts which may be necessary for medical and scientific research only, including clinical trials therewith to be conducted under or subject to the direct supervision and control of the Party.

Id. art. 2, para. 5(b).

[51] Article 23 of the Convention further provides that ''[a] Party that permits the cultivation of the opium poppy for the production of opium shall establish, if it has not already done so, and maintain, one or more government agencies * * * to carry out the functions required under this article.'' Single Convention art. 23, para. 1. Moreover, ''[a]ll cultivators of the opium poppy shall be required to deliver their total crops of opium to the Agency. The Agency shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest.'' *Id.* para. 2(d).

that ''what we're trying to do is get the [PHS] and NIDA out of the picture,'' Tr. 666, makes this plain. *See also* Tr. 225 (testimony of Respondent; ''I may very well be approached by other people with approved studies who need a source also.''). Thus, Respondent's contention that the Single Convention does not prohibit multiple cultivators is beside the point, since his proposed purpose for gaining authorization to grow marijuana (so that MAPS—rather than HHS/NIDA—can control distribution of the marijuana) would defy one of the central control provisions of the Single Convention with respect to cannabis cultivation. As the Commentary to the Single Convention states:

> Countries * * * which produce * * * cannabis * * *, [i]n so far as they permit private farmers to cultivate the plants * * *, cannot establish with sufficient exactitude the quantities harvested by individual producers. If they allowed the sale of the 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 régime would thus be considerably weakened. In fact, experience has shown that permitting licensed private traders to purchase the crops results in diversion of large quantities of drugs into illicit channels. * * * [T]he acquisition of the crops and the wholesale and international trade in these agricultural products cannot be entrusted to private traders, but must be undertaken by governmental authorities in the producing countries. Article 23 * * * and article 28 * * * therefore require a government monopoly of the wholesale and international trade in the agricultural product in question in the country which authorizes its production.

Commentary at 278. Indeed, the central theme of Respondent's argument—starting with the opening sentence of his Proposed Findings and Conclusion of Law and repeated throughout the document—is that the very Government monopoly over the wholesale distribution of marijuana that the Single Convention demands is the primary evil that Respondent seeks to defeat through obtaining a DEA registration. Thus, from the outset of the analysis, Respondent's proposed registration cannot be reconciled with United States obligations under the treaty.

Respondent offers no argument that his proposed distributions would not constitute wholesale trading under the Convention. *See, e.g.*, GX 3, at 3 (''customers would include both MAPS-sponsored research and research sponsored by other organizations.''). Respondent's proposed activity in distributing to researchers does not constitute retail trading because his customers are not the ultimate users of the marijuana, but rather researchers, who would then dispense the drugs to ultimate users. *See* Commentary at 329 (A manufacturer's ''license does not in any event * * * include the retail trade in drugs.'').[52]

In construing the meaning of ''United States obligations under [the Single Convention]'' in the context of 21 U.S.C. 823(a), any reliance by the ALJ or Respondent on the United Kingdom's practice is misplaced.[53] For one, as set forth in § 823(a), Congress assigned to the Attorney General sole authority to determine whether a proposed registration under this provision is consistent with United States obligations under the Single Convention. Nowhere in the CSA does Congress call upon the Attorney General to rely on—or even consider—how other nations interpret the Single Convention as a basis for the Attorney General's determination of what are the United States obligations under the treaty.[54] Second, the Single Convention contains provisions that call upon each nation that is a party to the treaty to determine, in its own opinion, whether and how to tailor its control measures commensurate with the circumstances particularized to that country. For example, article 2, paragraph 5, of the Single Convention states the following with respect to drugs included in Schedule IV (including cannabis):

> (a) A Party shall adopt any special measures of control which in its opinion are necessary having regard to the particularly dangerous properties of a drug so included; and
>
> (b) A Party shall, if in its opinion the prevailing conditions in its country render it the most appropriate means of protecting the public health and welfare, prohibit the production, manufacture, export and import of, trade in, possession or use of any such drug except for amounts which may be necessary for medical and scientific research only, including clinical trials therewith to be conducted under or subject to the direct supervision and control of the Party.

Thus, what the United Kingdom might, in its opinion, deem to be appropriate control measures to meet its obligations under the Single Convention given the circumstances involving cannabis in Britain might be distinct from what the United States finds, in its opinion, to be the appropriate control measures to fit the circumstances involving cannabis in the United States.[55]

If the United States were to look to any outside entity for guidance on compliance with the Single Convention, that entity would be the International Narcotics Control Board (INCB), which is the United Nations organ created by the Single Convention to implement, and monitor compliance with, the Convention. *See* Single Convention, articles 5, 9–15, 19–20. In its 2005 Annual Report, the INCB reiterated: ''Articles 23 and 28 of the [Single] Convention provide for a national cannabis agency to be established in countries where the cannabis plant is cultivated licitly for the production of cannabis, even if the cannabis produced is used for research purposes only.'' [56] Similarly, the INCB issued a statement in 2008 stating, with respect to the standards under the Single Convention

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[52] Under the CSA and DEA regulations, wholesale distribution and dispensing (retail distribution) are independent activities and require separate registrations. *See* 21 U.S.C. 802(11) (definition of ''distribute'' excludes dispensing); *compare* 21 U.S.C. 823(b) *with* 823(f) (separate registration required for distributor versus dispenser); *see also* 21 CFR 1301.13(e) (listing categories of registration and authorized activities). Only a practitioner (and not a manufacturer or distributor) can dispense a controlled substance to a patient. *See id.* at 1301.13(e)(1).

Moreover, the Single Convention is a drug-control regime. The precise economic arrangements between Respondent, MAPS, and any other potential customers, are therefore irrelevant in determining whether his proposed activity would constitute wholesale trading.

[53] There was a dispute between the parties as to the admissibility of the document Respondent submitted (attached to RX 26) purporting to set forth the United Kingdom's explanation of how it carried out its obligation under the Single Convention to establish a national cannabis agency. Tr. 1812. After having the parties brief the issue, the ALJ noted, in a ''Memorandum to Counsel and Ruling,'' that one of the Government's objections was that Respondent did ''not explain how exhibit 26 was issued or under what authority.'' The ALJ concluded that ''although the circumstances under which exhibit 26 came to be promulgated are not clear, it appears that the document is in effect in the United Kingdom.'' *Id.* The ALJ did not explain her basis for this conclusion. *See id.* It is unnecessary to determine whether this ruling by the ALJ was proper because, even assuming, *arguendo,* that the document accurately represented the official position of the United Kingdom and was issued by the appropriate representative of the British Government, for the reasons explained above, reliance on this document for determining how to interpret the Single Convention for purposes of 21 U.S.C. 823(a) is inappropriate.

[54] For this reason, it is unnecessary to expressly reject the interpretation contained in the document submitted by Respondent (attached to RX 26) titled ''United Kingdom National Cannabis Agency: Protocol.''

[55] In any event, there is no evidence that the British Government has allowed GW to engage in the type of activity for which Respondent seeks to become registered—the wholesale distribution of plant-form marijuana. Rather, as DEA has done with respect to the National Center and its project to supply THC extract to Mallinckrodt (GX 78), the British Government has granted GW a license to grow marijuana for the limited purpose of producing extract for a pharmaceutical product. Rx 26, Ex. A at 2.

[56] The above-quoted statement appears on page 16, in paragraph 81, of the 2005 INCB Annual Report, which is available at *http://www.incb.org/pdf/e/ar/2005/incb_report_2005_2.pdf.* I take official notice of the report.

relating to the control of cannabis, that ''[s]uch standards require, inter alia, the control of cultivation and production of cannabis by a national cannabis agency.'' [57] As explained above, it is this control of the cultivation and production of cannabis by a national agency of the United States to which Respondent is fundamentally opposed, thereby demonstrating the inconsistency between his application and the Single Convention.

The ALJ further reasoned that ''although it is not entirely clear,'' the marijuana Respondent seeks to grow would be exempt from the Government's exclusive right to engage in wholesale trading because it would qualify as either ''medicinal'' or ''special stocks.'' ALJ at 82. As explained below, the ALJ erred on both counts.

In his response to the Government's exceptions, Respondent contends that the ''[t]he Single Convention defines 'medicinal' marijuana as that 'which has undergone the process necessary to adapt it for medicinal use.' '' Respondent Resp. at 10 (quoting art I. para 1 (o)). The Single Convention, however, contains no such term.

Rather, the Convention defines only the term ''[m]edicinal opium.'' Single Convention art 1, para.1(o) (defining ''medicinal opium'' as ''opium which has undergone the processes necessary to adapt it for medicinal use.''). Accordingly, Respondent's argument rests solely on an analogy to the term ''medicinal opium.'' Respondent's reliance is misplaced as it ignores several critical distinctions between what was formerly known as ''medicinal opium'' and what it contends is ''medicinal marijuana.''

As the Commentary explains: ''The Single Convention follows earlier narcotics treaties in defining 'medicinal opium' as a special form of opium in which that drug is used in medical treatment.'' Commentary at 21–22. The Commentary goes on to state that ''medicinal opium'' is a form of opium powder to which lactose has been added ''to reduce its morphine content *to the standard* of about 10 percent prescribed for 'medicinal opium.' '' *Id.* (emphasis added).

In a footnote, the Commentary further explains that ''[t]he fifth edition of the *Pharmacopœa Helvetica* (1949) * * * defines 'medicinal opium' as opium powder reduced to a content of 9.2 to 10.2 per cent of anhydrous morphine by the addition of lactose. This pharmacopœa calls 'medicinal opium' also 'powdered opium.' '' Commentary at 22 n.8. The Commentary then notes that ''[t]he term 'medicinal opium' ha[d] been abandoned in'' in favor of the terms ''powdered opium'' and ''standardized powered opium'' in several pharmacopœas which had been published in the late 1960s. *Id.* (citing *British Pharmacopœa* 686 (1968), and *Pharmacopœa Internationalis* 403 (2d ed. 1967)). Of further note, the term is not used at all in more recent pharmacopœas.[58] *See, e.g., The United States Pharmacopeia 2008,* at 2860–61 (31st Rev. 2007); *British Pharmacopoeia 2008,* at 1599–1601 (2007).

Thus, the term ''medicinal opium'' is now obsolete. The term's obsolescence itself provides ample reason to disregard it in determining the scope of the United States' obligations with respect to marijuana. But even if the term is still relevant, Respondent ignores that the term referred to a product which had not only been extracted from the opium poppy but had also undergone several further processes (including the addition of another substance, lactose) to prepare it for use in other drugs and to obtain a specific and *standardized* content of morphine, its primary active ingredient. *See British Pharmacopoeia 2008,* at 1599 (''Raw opium is intended only as a starting material for the manufacture of galenical preparations. It is not dispensed as such.''); GX 53, at 3 (letter of GW Pharmaceuticals) (''[O]pium is a Schedule II substance, but it merely provides the starting material for a number of pharmaceutical dosage forms that are lawfully marketed in the U.S. Herbal opium is not itself used directly by patients.'').

Indeed, the inclusion of ''medicinal opium'' in the various older Pharmacopœas indicates that there were recognized standards for the substance's manufacture and composition and that the drug had an accepted medical use in humans. *See, e.g., The United States Pharmacopeia* (17th Rev. ed. 1965), at xxv (noting that federal law ''designate[s] the Pharmacopeia as establishing the standards of strength, quality, and purity of medicinal products recognized therein when sold in interstate commerce for medicinal use'');[59] *see also The United States Pharmacopeia 2008,* at v (''*USP 31* * * * contains science-based standards for drugs, biologics, dietary, and excipients used in dosage forms and products. With few exceptions, all articles for which monographs are provided in *USP 31* * * * are legally marketed in the United States or are contained in legally marketed articles.''); *British Pharmacopoeia 2008,* at 4 (''The requirements stated in the monographs of the Pharmacopoeia apply to articles that are intended for medicinal use. * * * An article intended for medicinal use that is described by means of an official title must comply with the requirements of the relevant monograph.'').

In contrast, there are no recognized standards with respect to herbal marijuana. And consistent with the recognition in almost every country that marijuana has no accepted medical use, neither marijuana, cannabis, nor THC is listed in the various pharmacopeias. *See The United States Pharmacopeia 2008,* at 1620, 2588–2589, 3366–3367; *British Pharmacopoeia 2008,* at 375–376, 1373–1374, 2111–2112; *European Pharmacopoeia,* at 777, 1495, 1997. *Cf. James Everard's Breweries* v. *Day,* 265 U.S. 545, 562 (1924) (rejecting contention that Congress arbitrarily determined that ''intoxicating malt liquors possessed no substantial and essential medicinal properties''; ''Neither beer nor any other intoxicating malt liquor is listed as a medicinal remedy in the United States Pharmacopeia. They are not generally recognized as medicinal agents. There is no consensus of opinion among physicians and medical authorities that they have any substantial value as medical agents. * * * '').

Moreover, it is beyond question that, in the United States, marijuana has no currently accepted medical use and there are no FDA-approved medical products consisting of marijuana. *See OCBC,* 532 U.S. at 491 (''for purposes of the [CSA], marijuana has 'no currently accepted medical use' at all.''); 66 FR at 20052 (as stated by the FDA, ''[t]here are no FDA-approved marijuana products.''). Thus, by any plausible application of the term ''medicinal opium'' to cannabis, as a factual matter, there is currently no such thing in the United States as ''medicinal cannabis.'' Respondent effectively concedes this point, by describing the purpose of his proposed registration as being ''to *develop* the marijuana plant into an

[57] This statement was made in an INCB press release issued on February 8, 2008, which is available at *http://www.unis.unisvienna.org/unis/pressrles/2008/usinar1023.html*, and of which I take official notice.

[58] There is also no listing of any opium-containing product in the latest edition (2008) of FDA's ''Orange Book,'' which lists each drug product currently approved for marketing under the FDCA based on a determination by the FDA that the drug is safe and effective. *See http://www.fda.gov/cder/orange/obannual.pdf.*

[59] *See also European Pharmacopoeia* 1, § 1.1 (4th ed. 2001) (General Statements) (''The active ingredients (medicinal substances), excipients (auxiliary substances), pharmaceutical preparations and other articles described in monographs are intended for human consumption and veterinary use (unless explicitly restricted to one of these uses)'').

FDA-approved prescription medicine.'' GX 3, at 1 (emphasis added).

Finally, even if all the foregoing considerations were ignored and DEA were to treat the marijuana that Respondent seeks to grow as akin to ''medicinal opium'' for purposes of the Single Convention, Respondent's proposed activity would still be inconsistent with the Convention for the following reason. As the Commentary explains: ''Opium-producing countries may thus authorize private manufacture of, and private international and domestic wholesale trade in, medicinal opium and opium preparations. *The opium other than medicinal opium needed for such manufacture must however be procured from the national opium agency.*'' Commentary at 284 (emphasis added). Thus, under the Convention, even if ''medicinal cannabis'' may be privately traded, the treaty requires that the raw material needed to produce the ''medicinal cannabis'' (i.e., the marijuana plant material) must be obtained from the national cannabis agency. This again reflects the central theme of cannabis control under the Single Convention—that the national agency must control the production and distribution of the raw marijuana material used for research or any other permissible purpose. Respondent's unwillingness to accept this principle illustrates how his proposed registration is fundamentally at odds with the treaty.

The ALJ also reasoned that the marijuana Respondent seeks to grow would qualify under the Convention as ''special stocks'' and thereby be exempt from the ''exclusive government's right to maintain stocks.'' ALJ at 82. Even Respondent acknowledges the ALJ's error on this point. *See* Respondent's Resp. at 12 (''[I]t is evident that [the ALJ] simply inadvertently referenced the wrong term from Article 1.''). The term ''special stocks'' under the Convention refers to ''drugs held in a country or territory by the Government of such country or territory for special government purposes and to meet exceptional circumstances.'' Single Convention, Art. 1, para. 1(w). Neither party is suggesting, and there is no basis to conclude, that the marijuana Respondent seeks to produce fits into this definition.[60]

While recognizing that the ALJ misread the term ''special stocks,'' Respondent argues that the marijuana he seeks to produce nonetheless qualifies as retail ''stocks,'' because it is marijuana that will be held '' 'by institutions or qualified persons in the duly authorized exercise of therapeutic or scientific functions.' '' *Id.* (quoting Single Convention, art. 1, para. 1(x)). Respondent thus contends that the marijuana he seeks to produce is exempt from the government monopoly provisions of article 23, paragraph 2, subparagraph (e).

Respondent is mistaken. The entire text of the relevant provision explains that the marijuana Respondent would maintain does not fall within the exception to the definition of ''stocks.'' What is excluded under the treaty from the definition of ''stocks'' are those drugs held ''[b]y retail pharmacists or other authorized retail distributors and by institutions or qualified persons in the duly authorized exercise of therapeutic or scientific functions.'' Single Convention, art. 1, para. 1(x)(iv). As this provision makes plain, the exemption applies only to the drugs held by those persons or entities who are authorized to dispense to ultimate users.

Respondent is not, however, a licensed pharmacist or physician and obviously cannot legally seek a practitioner's registration, which is required to dispense. *See* 21 U.S.C. 823(f). Rather, he is seeking to produce raw cannabis plant material to supply researchers. His proposed activity thus does not fall within the exemption for ''qualified persons in the duly authorized exercise of therapeutic or scientific functions'' within the meaning of the Single Convention.

Moreover, even with respect to cannabis material acquired for retail purposes that does fit within the exception of article 1, paragraph (x)(iv), the treaty still requires that such material be obtained via the national agency. As the Commentary explains with respect to opium (and therefore also with respect to cannabis, by virtue of article 28), while ''[t]he retail trade in, and other retail distribution of, opium * * * need not be in the hands of the monopoly[,] [r]etail traders or distributors must, however, acquire their opium from the'' Government. Commentary at 284. Respondent's arguments repeatedly fail to acknowledge or accept this concept that lies at the core of the Single Convention. Yet, there is no escaping that, by seeking through his application to dismantle the existing Government control over the distribution of cannabis produced by growers and turn a share of that control over to MAPS, Respondent's goal is antithetical to the treaty. For the foregoing reasons, the provision of article 1, paragraph (x)(iv) exempting certain material from the definition of ''stocks'' does not support Respondent.

As for Respondent's point that DEA has previously allowed the University of Mississippi to grow marijuana to produce ''marijuana extracts that the University then sells to pharmaceutical companies to develop products'' (Resp. Prop. Findings at 68), it is true that DEA has previously allowed such activity under a Memorandum of Agreement (MOA) that was entered into in 1999. GX 78. However, that MOA expressly states:

> In accordance with articles 23 and 28 of the Single Convention on Narcotic Drugs, 1961 (''Single Convention''), private trade in ''cannabis'' is strictly prohibited. Therefore, the Center shall not distribute any quantity of marijuana to any person other than an authorized DEA employee.
>
> The Single Convention does not prohibit private trade in ''cannabis preparations,'' however. A ''cannabis preparation,'' within the meaning of the Single Convention, is a mixture, solid or liquid containing cannabis, cannabis resin, or extracts or tinctures of cannabis. The THC that the Center will extract from marijuana would be considered such a ''cannabis preparation.'' Therefore, the Center may, in accordance with the Single Convention, distribute the crude THC extract to private entities (provided such distributions of THC by the Center comply with all requirements set forth in the CSA and DEA regulations).

Id. at 2–3 (footnote explaining treaty definition of cannabis omitted). Thus, the MOA was specifically designed to ensure that the University of Mississippi would not be distributing cannabis outside of the Government-controlled system required by the Single Convention. *See* Single Convention, art. 23, para. 1(e) (exempting ''preparations'' from government monopoly on wholesale distribution). In contrast, Respondent does *not* seek to distribute a cannabis extract or any other processed cannabis material that constitutes a ''preparation'' within the meaning of the Single Convention. Instead, Respondent seeks to grow and distribute marijuana plant material that has undergone no processing other than drying (and therefore does not come within the Single Convention definition of ''preparation'').[61]

[60] The term ''special stocks'' is operative in the Single Convention only in ways that have no bearing on this adjudication. *See* art. 19, paras. 1(d) & 2(d) (requiring parties to furnish the INCB with annual estimates of, among other things, ''[q]uantities of drugs necessary for addition to special stocks'' and amounts taken therefrom); art. 20, para. 3 (parties' statistical returns to INCB need not address those relating to special stocks); art. 21, para. 2 (explaining how to take into account special stocks for purposes of countries' limitations on manufacture and importation).

[61] The above-quoted 1999 MOA was issued with respect to the University of Mississippi's 1998

Continued

As the foregoing demonstrates, while the Single Convention does not necessarily prohibit the registration of an additional manufacturer, what it does prohibit is the wholesale distribution of plant-form marijuana by any entity other than the United States Government. Respondent is not under contract with HHS to supply it with marijuana and has made clear that the purpose of his registration is to distribute marijuana outside of the HHS system. Because it is clear that Respondent's proposed activity is not within one of the exemptions from the obligatory government monopoly imposed by the Convention, he has failed to show that his proposed activities would be consistent with the Single Convention.[62] *See* 21 U.S.C. 823(a). Accordingly, his proposed registration is precluded under Federal law.

B. Whether Respondent's Proposed Registration Is Consistent With the Public Interest

As explained in the preceding section, Respondent's registration is clearly inconsistent with the United States' obligations under the Single Convention. While this ground alone compels DEA to deny the application, as explained below, an analysis of the public interest criteria of 21 U.S.C. 823(a) leads to the conclusion that Respondent's registration is inconsistent with the public interest. This provides a separate basis—independent of the treaty consideration—on which the application must be denied.

As stated above, under § 823(a), there are six factors that must be evaluated in determining whether a proposed registration is consistent with the public interest. The public interest factors ''are considered in the disjunctive.'' *Southwood Pharmaceuticals, Inc.,* 72 FR 36487, 36497 (2007). I may rely on any one or a combination of factors and give each factor the weight I deem appropriate in determining whether to deny an application for a registration. *See Green Acre Farms, Inc.,* 72 FR 24607, 24608 (2007); *ALRA Laboratories, Inc.,* 59 FR 50620, 50621 (1994). Moreover, I am ''not required to make findings as to all of the factors.'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005).

1. Public Interest Factor One

The first public interest factor is the:

maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, *by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate an uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes.*

21 U.S.C. 823(a)(1) (emphasis added).

As the ALJ observed, DEA has construed paragraph 823(a)(1) in two different ways in prior final orders, both of which were simultaneously upheld in a case that was reviewed by a United States Court of Appeals. ALJ at 82–83. Because of this, I have undertaken an extensive analysis of this provision, which is found in part C of this discussion.[63] For the reasons explained therein, I believe that the most sound reading of the text of paragraph 823(a)(1) requires DEA to consider limiting the number of bulk manufacturers and importers of a given schedule I or II controlled substance to that which can produce an adequate and uninterrupted supply under adequately competitive conditions. The Government so asserted in the Show Cause Order and throughout the proceedings. Although Respondent offered a different interpretation of paragraph 823(a)(1),[64] he asserted that, under any interpretation, this factor weighed in favor of finding the proposed registration consistent with the public interest.[65]

As discussed at length in part C of this discussion, *infra,* to properly construe paragraph 823(a)(1), it must be viewed in comparison with § 823(d)(1). Whereas § 823(d)(1) contains no requirement that DEA consider limiting in any way the total number of registered manufacturers of controlled substances in schedules III, IV, and V, paragraph 823(a)(1) does require DEA to consider limiting the total number of bulk manufacturers of schedule I and II controlled substances. Specifically, paragraph 823(a)(1) calls upon DEA to consider ''limiting'' (i.e., placing an *upper boundary* on) the number of registered bulk manufacturers of a given schedule I or II controlled substance to that ''which can produce an adequate

application to become registered to manufacture marijuana for the purposes of product development. GX 78, at 1–2. In 2005, the University of Mississippi applied for a new registration to manufacture marijuana ''to prepare marihuana extract for further purification into bulk active [THC] for use in launching FDA-approved pharmaceutical products.'' 70 FR 47232; *see also* Tr. 1521. DEA has not yet issued a final order as to this application and the University therefore does not currently have DEA authorization to undertake such activity. As with Respondent's application, DEA may only grant the pending University of Mississippi application if the agency determines that the University has demonstrated that the registration would be consistent with United States treaty obligations and the public interest. *See* GX 79, at 3. In making such determinations, DEA will not simply rely on the prior issuance of registration under the 1999 MOA but will consider the application anew, in view of the current circumstances and consistent with this final order. Among other things that must be considered with respect to the pending University of Mississippi application, I note that the Commentary to the Single Convention states the following with respect to the exemption for ''opium preparations'' under Article 23, paragraph (e): ''Opium-producing countries may thus authorize private manufacture of, and private international and domestic wholesale trade in, medicinal opium and opium preparations. *The opium other than medicinal opium needed for such manufacture must however be procured from the national opium agency.*'' Commentary at 284 (emphasis added). Whether the University of Mississippi's proposed registration would be consistent with this aspect of the treaty has not yet been determined by DEA and is not the subject of this adjudication.

[62] Though the above discussion provides ample basis on which to conclude that Respondent has failed to meet his burden of proving that his proposed registration is consistent with United States obligations under the Single Convention, I also note briefly the following statement in the Commentary regarding the obligation of the United States under article 23, paragraph 2(a) to designate the areas in which cultivation takes place: ''It is also suggested that [such areas] should to the greatest extent possible be located in the same part of the country, and be contiguous, in order to facilitate more effective control.'' Commentary at 280. Thus, in a situation in which a country that is a party to the treaty allows for multiple growers of opium or cannabis with the national agency maintaining control over the distribution of such material in accordance with the Single Convention, the Commentary suggests that proper adherence to the treaty would result in that country keeping the growers located as near as possible to one another.

[63] For ease of exposition, the detailed analysis of the meaning of paragraph 823(a)(1) appears in a separate section of this discussion (part C), due to its length.

[64] *See* note 65, *infra,* regarding Respondent's proposed interpretation of paragraph 823(a)(1).

[65] Because I have concluded, for the reasons set forth in part C of the discussion, that DEA is obligated under the text of paragraph 823(a)(1) to consider limiting the number of bulk manufacturers and importers of a given schedule I or II controlled substance to that which can produce an adequate and uninterrupted supply under adequately competitive conditions, I reject Respondent's alternative reading of paragraph 823(a)(1). Specifically, I reject the interpretation of paragraph 823(a)(1) under which ''the registration should be granted without regard to'' adequacy of competition and supply so long as the ''registration would not interfere with DEA's maintenance of effective diversion controls.'' *See* Respondent's Resp. at 13. Respondent cites *Noramco* v. *DEA,* 375 F.3d 1148 (D.C. Cir. 2004) in support of this interpretation. *Id.*; Resp. Proposed Findings and Conclusion of Law at 36. The *Noramco* decision is examined at length in part C of this discussion. Because I interpret paragraph 823(a)(1) to require consideration of the adequacy of supply and competition, I decline to undertake an analysis of the facts of this case whereby the adequacy of competition and supply is disregarded. However, as indicated above, Respondent has alternatively argued that there is a sufficient basis to grant his application when construing paragraph 823(a)(1) as requiring a showing of inadequate competition or supply, and that argument is addressed at length in this final order.

and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes.''

Thus, an applicant seeking to become registered to bulk manufacture a schedule I or II controlled substance bears the burden of demonstrating that the existing registered bulk manufacturers of a given schedule I or II controlled substance are unable to produce an adequate and uninterrupted supply of that substance under adequately competitive conditions. As a threshold matter, Respondent misconstrues this provision as placing the burden on *DEA,* whenever someone applies for registration under 21 U.S.C. 823(a), to demonstrate that competition is already adequate within the meaning of paragraph 823(a)(1). *See* Resp. Proposed Findings and Conclusion of Law at 47 (in which Respondent contends that the ''requirement'' of ''adequately competitive conditions'' ''is not met by the by the current NIDA monopoly''). In fact, the DEA regulations plainly state that every applicant seeking registration under § 823(a) has ''the burden of proving that the requirements for such registration pursuant to [this section] are satisfied.'' 21 CFR 1301.44(a).

Accordingly, the analysis under paragraph 823(a)(1) (and Respondent's burdens thereunder) must be divided into the following parts: (a) an analysis of the adequacy of supply and (b) an analysis of the adequacy of competition. If Respondent can demonstrate by a preponderance of the evidence that either supply or competition is inadequate within the meaning paragraph 823(a)(1), this weighs heavily in favor of granting the registration. If, however, Respondent fails to meet his burden with respect to both supply and competition, this weighs heavily against granting the registration. (See part C of this discussion.)

(a) Adequacy of Supply Within the Meaning of Paragraph 823(a)(1)

The first question under paragraph 823(a)(1) is whether Respondent has demonstrated that the existing supply of marijuana is inadequate to meet the legitimate needs of the United States. As the parties essentially agree, the adequacy of supply of marijuana must be evaluated in two respects: (i) quantity and (ii) quality.

(i) Adequacy of the Quantity of the Existing Supply

With respect to the adequacy of the *quantity* of supply, the record establishes that as of the date of the hearing, there were approximately 1055 kg of marijuana of various potencies in the NIDA vault. RX 53. Moreover, some of this marijuana apparently had been harvested as early as 1997, and it appears that as of the date of the hearing, no marijuana had been grown since 2001. *Id.* For the following reasons, this amount of existing supply far exceeds any present demand for research-grade marijuana as well as any reasonably anticipated demand for such marijuana in the foreseeable future.

Lawful research involving marijuana can be divided into two categories: NIH-funded and privately funded. *See* GX 31, at 3. With respect to NIH-funded research, Respondent does not contend, and there is no basis in the record to conclude, that NIDA has failed to provide, or is incapable of providing, an adequate quantity of marijuana. Rather, to the extent Respondent is claiming that NIDA is unable to provide an adequate quantity of marijuana,[66] this claim relates to privately funded researchers. Yet, even as to this claim, the evidence indicates otherwise.

The record reflects that since HHS changed its policies in 1999 to make marijuana more readily available to researchers (by, among other things, allowing privately funded researchers to obtain marijuana), every one of the 17 CMCR-sponsored pre-clinical or clinical studies that requested marijuana from NIDA was provided with marijuana. GX 31, at 3; Tr. 694–95. Significantly, according to one of the witnesses who testified on behalf of Respondent, CMCR funding of research involving marijuana has currently ended and it appears doubtful that a resumption of such funding is ''on the horizon.'' Tr. at 397–402, 441. Thus, the witness testified, once the research projects sponsored by CMCR that utilize NIDA marijuana reach their conclusion, ''[i]t's likely that the [CMCR] research is done.'' *Id.* at 401–02. Other than the CMCR-sponsored research, the record reveals only one other instance in which a privately funded researcher sought marijuana from NIDA after HHS changed its policies in 1999 to make marijuana more readily available to researchers. That one other instance was the MAPS-sponsored request submitted by Chemic to obtain marijuana to conduct research on the Volcano. *See* RX 52B. According to Mr. Doblin, Chemic ''applied to NIDA to purchase ten grams'' of marijuana. Tr. 531; RX 14. Although, as discussed above, HHS denied that request on scientific grounds (*see* RX 52B), there is no basis to conclude that NIDA was incapable of providing Chemic with the quantity of marijuana it was seeking. Indeed, the ten grams of marijuana that Chemic requested is less then one 100,000th of the amount of marijuana that NIDA has available to supply researchers. *See* RX 53.

Accordingly, the evidence overwhelmingly establishes that NIDA is capable of providing an adequate quantity of marijuana to meet all current and foreseeable research needs of the United States. And while NIDA's existing system for supplying marijuana is quantitatively adequate regardless of how much or how little additional marijuana Respondent seeks to produce, it is notable that the approximately 1055 kg of marijuana currently on hand is more than 90 times the amount of marijuana that Respondent proposes to grow.

Respondent nonetheless contends that the process by which HHS provides marijuana to researchers—which involves a peer review of the scientific merits of the research proposal [67]—results in a barrier to research that effectively renders the supply of marijuana inadequate. Respondent points to three prior incidents to support his contention that the HHS scientific review process impedes research. As discussed above, the first two of these incidents (those involving Dr. Abrams and Dr. Russo) are irrelevant as they occurred before HHS adopted its new procedures in 1999 for making marijuana more widely available to researchers.[68] The third incident involved the application of Chemic to obtain marijuana to conduct research on the Volcano. As discussed above, HHS

[66] Respondent appears to challenge the process by which NIDA supplies marijuana to researchers and the quality of the marijuana, rather than the quantity. *See, e.g.*, Respondent's Resp. at 15–16. The ALJ's recommendation regarding the adequacy of supply also focused on the process by which NIDA supplies marijuana, and she was not of the opinion actual quantity of marijuana supplied by NIDA was inadequate. *See* ALJ at 84. Nonetheless, for the sake of completeness, and in accordance with 21 U.S.C. 823(a)(1), I am addressing the adequacy of supply from a quantitative perspective.

[67] Tr. at 1626–28, 1635. In his testimony, Dr. Gust explained the term ''peer review'' as follows: ''Peer review is a process that has been used, certainly by NIH, and I think in other agencies in the Department of Health and Human Services, and probably the Federal Government, where outside expertise is acquired and outside opinions on the scientific merit of specific research proposals.'' *Id.* at 1627. Dr. Gust added that the NIH peer review committees ''review proposals three times a year for the NIH, and there are—occasionally a Federal employee participates in one of those reviews, but probably 90 percent or more of the participants are researchers who are in the private sector, for the most part in academic institutions.'' *Id.* at 1627–28.

[68] Further, as discussed above, the evidence indicates that the denials involving of Dr. Abrams and Dr. Russo were based on HHS finding their protocols to be lacking in scientific merit.

declined to supply Chemic with marijuana in 2005 based on scientific considerations, finding that Chemic's then-latest proposed study was duplicative of prior and ongoing research and not likely to provide useful data. Thus, the success of Respondent's claim that the HHS scientific review process renders the existing supply of marijuana inadequate depends on whether one accepts Respondent's assumption that anyone in the United States who has a proposed research project involving marijuana should be entitled to obtain marijuana—regardless of whether the competent Government authority finds the research to be lacking in scientific merit.[69]

Respondent's assumption about who is entitled to conduct research with marijuana is directly undercut by the text of the CSA. As set forth in 21 U.S.C. 823(f), persons seeking to conduct research with schedule I controlled substances (such as marijuana) may only obtain a DEA registration ''for the purpose of *bona fide* research'' (emphasis added), with the Secretary of HHS being responsible for determining ''the qualifications and competency'' of the applicant ''as well as the merits of the research protocol.'' The process HHS has established to assess the scientific merit of proposed research studies involving marijuana is that described in the 1999 HHS announcement of its new procedures.[70] GXs 24 & 31; Tr. at 1626–35. That Respondent finds this process to be scientifically rigorous[71]—and thereby not automatically accepting of any proposed study sponsored by MAPS—provides no basis for any valid objection or any contention that the HHS supply of marijuana is inadequate.[72]

(ii) Adequacy of the Quality of the Existing Supply

As for Respondent's contention that the *quality* of marijuana supplied by NIDA is unsatisfactory and that this renders the supply of marijuana inadequate within the meaning of 21 U.S.C. 823(a)(1), the ALJ rejected this contention, finding that a preponderance of the evidence established that ''the quality is generally adequate.'' ALJ at 84. In this regard, Respondent contended that NIDA's marijuana was of inconsistent potency, that it was of too low a potency, that it included stems and seeds, that it was not fresh, and that some of the patients had complained that it ''was the worst marijuana they had ever sampled.'' Resp. Proposed Findings at 16–27 & 49.

As found above, Respondent's contentions rest largely on snippets taken from questionnaires which were completed by a number of researchers. On balance, however, the researchers indicated their overall satisfaction with NIDA's marijuana and noted that the agency had been accommodating and responsive to their concerns. *See, e.g.*, GX 16, at 6 & 19. Moreover, most of the researchers indicated that the potency of NIDA's product was adequate and had not compromised their research. *See, e.g.*, GX 16, at 6 & 15; GX 17, at 9. Furthermore, while Respondent notes that several researchers stated that it would be beneficial to evaluate a higher potency product, he produced no evidence that any researcher had obtained approval from FDA and other reviewing authorities to conduct clinic trials with such a product. *See* GX 21, at 9 (researcher explaining that he ''wanted to use a higher potency product but there were questions from the [scientific review board] and the'' CMCR). In any event, the evidence establishes that NIDA's stock includes substantial quantities of high THC content marijuana and that its contractor is capable of producing marijuana with a THC content of up to twenty percent.[73] Tr. 1203–05.

Related to this argument, Respondent also contends that NIDA's marijuana has stems and seeds and that some patients complained that ''that the marijuana is inferior in sensory qualities (taste, harshness) than the marijuana they smoke outside the laboratory. Some have stated it was the worst marijuana they had ever sampled.'' Resp. Proposed Findings at 20 (other citation omitted); *see also id.* at 49. The evidence establishes, however, that the contractor has rectified the problem with respect to the stems and seeds. Tr. 1301.

As for the complaints regarding the sensory qualities of NIDA's products, only a small percentage of the numerous studies' subjects complained about the harshness of NIDA's marijuana, and as one researcher explained, it is not clear whether it was placebo or actual marijuana that was the cause of the complaints. GX 18, at 7. Relatedly, it seems a strained argument for Respondent to make that experienced

[69] It is not even clear whether Respondent continues to cite the Chemic situation of an example of supposedly ''legitimate research'' for which HHS declined to provide marijuana. While Respondent did so characterize the Chemic situation in his proposed findings of fact and conclusions of law (at 14), in his subsequently filed response to the Government's exceptions to the ALJ recommendation, he listed only Dr. Abrams and Dr. Russo as examples of ''legitimate research'' for which marijuana was not supplied. Respondent's Resp. at 16. As noted, the incidents involving Dr. Abrams and Dr. Russo occurred prior to HHS's promulgation of the 1999 guidelines. As such, these incidents are not probative of the current availability of research-grade marijuana from HHS.

[70] Respondent points out that the Secretary of HHS has delegated to the FDA Commissioner the Secretary's functions under 21 U.S.C. 823(f) relating to research with controlled substances in schedule I. Respondent's Resp. at 4–5 (citing FDA Staff Manual Guides 1410.10). While this is correct as a general matter for schedule I controlled substances, the record plainly indicates that with specific regard to research involving marijuana, HHS has retained its authority to determine the qualifications and competency of the researcher, as well as the merits of the research protocol, for purposes of § 823(f). *See* GX 24. Indeed, the 1999 HHS announcement of its policies for providing marijuana to researchers expressly states: ''To receive such a registration [under § 823(f)], a researcher must first be determined *by HHS* to be qualified and competent, and the proposed research must be determined *by HHS* to have merit.'' *Id.* at 1 (emphasis added). Dr. Gust's testimony confirms that, in fact, HHS—through its peer review process—does make these determinations for persons seeking to conduct research with marijuana. Tr. 1626–35.

Moreover, as discussed above, Respondent produced no evidence showing that HHS has denied marijuana to any clinical researcher with an FDA-approved protocol subsequent to the adoption of the 1999 guidelines. The lone applicant whose post-1999 request for marijuana was denied (Chemic) submitted its request to, and had it reviewed by HHS—not FDA. *See* GXs 49 & 52B. For all these reasons, it is unfounded for Respondent to suggest that the supply of marijuana is somehow inadequate because HHS has not assigned FDA sole responsibility for determining what research proposals involving marijuana are scientifically meritorious.

[71] Any suggestion that the HHS scientific review process is unduly rigorous is belied by the testimony of Dr. Gust that the ''scientific bar has been set very low, [so] that any project that has scientific merit is approved,'' and that ''anything that gets approved gets NIDA marijuana'' (Tr. at 1700–01) as well as the uncontroverted evidence that every one of the 17 CMCR-sponsored research protocols submitted to HHS was deemed scientifically meritorious by HHS and was supplied with marijuana (GX 31, at 3; Tr. 694–95).

[72] For the same reasons, I find wholly unpersuasive the ALJ's recommended finding that the supply of marijuana is inadequate because of the HHS scientific review process.

[73] Despite Respondent's suggestion that human research subjects should be given marijuana of higher potencies than that supplied by NIDA (*see, e.g.*, Tr. 552, 567 (testimony of Mr. Doblin)), there is no basis in the record to conclude that it would be medically or scientifically appropriate to do so. To the contrary, Dr. ElSohly testified that he was told by CMCR researchers that they did *not* want Dr. ElSohly to supply them with marijuana with a THC content as high as eight percent because, based on their prior observations of research subjects being given NIDA marijuana containing eight percent THC, ''the subject couldn't tolerate that, and if we can make a six percent, that would be more appropriate.'' Tr. 1280. Dr. ElSohly also testified that other scientists expressed the same opinion that six percent THC content was preferable because the research subjects ''would not tolerate'' marijuana with eight percent THC. Tr. 1295. Large doses of marijuana (in terms of the amount of THC administered) have been found to cause adverse mood reactions, including anxiety, paranoia, panic, depression, dysphoria, depersonalization, delusions, illusions, and hallucinations. RX 1, at 102. A primary reason that researchers are required to submit an IND to FDA prior to engaging in research with human subjects is ''to assure the safety and rights of subjects.'' 21 CFR 312.22(a).

marijuana smokers reported, after consuming a hallucinogenic substance, that they found NIDA's marijuana to be less pleasing to their senses than the marijuana they had illegally obtained and used. People generally take medicines—which marijuana is not—for their therapeutic benefits and not their taste. And in any event, Respondent has not established that NIDA's products were unsuitable for their intended use.[74]

For these reasons, I accept the ALJ's recommended finding that Respondent did not meet his burden of demonstrating that NIDA is incapable of providing marijuana of sufficient quality to meet the legitimate research needs of the United States.

Thus, I conclude that the evidence does not support Respondent's contention that the supply of marijuana is inadequate—in terms of quantity or quality—within the meaning of paragraph 823(a)(1).

(b) Adequacy of Competition Within the Meaning of Paragraph 823(a)(1)

The second question under paragraph 823(a)(1) is whether Respondent has demonstrated that the existing supply of marijuana is not being produced under adequately competitive conditions to meet the legitimate needs of the United States. Again, as explained below in part C of this discussion, paragraph 823(a)(1) does *not* require DEA simply to register as many bulk manufacturers of a given schedule I or II controlled substance as the market will bear. Nor does paragraph 823(a)(1) require the registration of an additional bulk manufacturer based merely on the assertion the additional registration will result in some vague, theoretical incremental increase in competition. If such a theoretical assertion would suffice, then the language of paragraph 823(a)(1) requiring DEA to consider ''limiting'' the number of registered bulk manufacturers would be rendered meaningless. This is because every person seeking to enter the market as a new bulk manufacturer of a given schedule I or II controlled substance could make the theoretical claim that every new registrant increases the overall amount of competition.

Thus, to avoid reading the limiting language of paragraph 823(a)(1) in a superfluous manner, in final orders where DEA has analyzed competition under paragraph 823(a)(1), DEA has looked to empirical data; specifically, DEA has focused on the historical and present prices charged to those who lawfully acquire the controlled substance from the existing registered bulk manufacturers.[75] This approach is consistent with the following statement made by the Department of Justice stated during Congressional hearings leading up to the enactment of the CSA:

> There is no reason to assume that the Attorney General will prejudice his primary objectives of effective control by excessive licensing. Nor will he undertake direct price control. He will be empowered to take cognizance of evidence showing that prices are clearly and persistently excessive. The criteria for determining whether prices far exceed that which is reasonable relate to reasonable costs and reasonable profits. * * * If evidence indicates that additional licensing will result in more reasonable prices with no significant diminution in the effectiveness of drug control, the Attorney General should be able to license the additional manufacturers.[76]

Here, the evidence demonstrates that NIDA has always provided marijuana to researchers at cost or for free—and at no profit to NIDA. Privately funded researchers receive marijuana at NIDA's cost[77] and HHS-funded researchers (who have historically comprised the bulk of the marijuana recipients) receive the marijuana at no cost. GX 24, at 2; GX 31, at 3; Tr. 1212, 1633, 1670–71. Thus, there is no basis to suggest that the cost to any researcher under the existing supply arrangement is unreasonable. Respondent himself does not so contend; nor does he claim that the cost to any researcher of obtaining marijuana would be lower if Respondent became registered to grow marijuana. Respondent hypothesizes that ''if another manufacturer could produce suitable medical marijuana for a lower cost, competitive conditions would, as they usually do, benefit the researcher-consumer.'' Resp. Prop. Findings at 48. However, Respondent provides no evidentiary basis for the proposition that he (or anyone else) could produce marijuana at a lower cost than NIDA. Moreover, Mr. Doblin acknowledged that MAPS would have a ''profit-making'' motivation as part of its ''operation'' to supply marijuana for the purposes of drug development, and that this would impact ''costs.'' Tr. 605–606. In contrast, there is no evidence that HHS or NIDA is driven in any respect by a profit motive in deciding to whom and at what cost to supply marijuana. Even accepting, *arguendo*, Mr. Doblin's testimony that ''we [MAPS] would either provide [marijuana] free or at cost through donations to MAPS to other researchers who are not doing MAPS funded projects'' (Tr. at 589), this would still not demonstrate a lowering of the cost to researchers. This is because, if MAPS were so willing to fund all researchers, they could do so under the existing system by paying NIDA on a cost-reimbursable basis for the marijuana, allowing the researchers to obtain the marijuana at no cost to the researchers. Thus, Respondent has not demonstrated that competition is inadequate in the way that other applicants for registration under § 823(a) have successfully done in prior final orders; i.e., by focusing on prices charged by the existing registrants that supply the market for the schedule I or II controlled substance in question and showing those prices to be unreasonable.[78]

Respondent also claims that the process by which the NIDA contract is awarded is not adequately competitive because the contract requires not only that the contractor manufacture marijuana, but also that it analyze marijuana samples sent in by law enforcement agencies. *Id.* at 48. Respondent further contends that the NIDA process ''does not ensure that researchers pay a competitive price [because] NIDA sets the price and there is no evidence as to how that price is set.'' *Id.* Finally, Respondent rehashes his argument regarding the quality of NIDA's marijuana contending that granting his application would promote competition and improvement in the quality of research marijuana. *Id.* at 49.

The ALJ agreed with Respondent and rejected the Government's contention that the NIDA process provides for adequate competition because demand for research grade marijuana is limited, the contract is periodically put up for

[74] Moreover, Respondent presented no evidence to show that he is capable of producing marijuana with any degree of quality control—let alone the type of evidence that would allow an inference that he could improve upon the quality of marijuana produced at the University of Mississippi. To the contrary, as explained below in the discussion of public interest factor five, Respondent's lack of experience in growing marijuana is in stark contrast to Dr. ElSohly's decades of experience in manufacturing, analyzing, and publishing scientific articles on the subject.

[75] See *Penick Corporation Inc.,* 68 FR 6947 (2003); *Roxane Laboratories, Inc.,* 63 FR 55891 (1998).

[76] *Hearings Before the Subcomm. to Investigate Juvenile Delinquency of the Comm. on the Judiciary, United States Senate,* 91st Cong. 372 (1969) (discussed more fully in part C of this discussion).

[77] According to Dr. ElSohly, where marijuana is supplied to privately funded researchers, ''the researchers would just pay the production costs.'' RX 5, at 2.

[78] *See Penick Corporation, supra; Roxane Laboratories, supra* (both of which are examined in part C of this discussion). As one DEA scientist testified in this proceeding, based on his experience, when the agency has historically considered the adequacy of competition within the meaning of paragraph 823(a)(1), the analyses ''all seem to be geared around the economics.'' Tr. at 945.

competitive bidding, and the Convention requires that the Government maintain a monopoly on the wholesale distribution of the substance. More specifically, the ALJ reasoned that ''[t]he question is not * * * whether the NIDA process addresses that agency's needs, but whether marijuana is made available to all researchers who have a legitimate need for it in their research.'' ALJ at 85. Based on her finding that NIDA denied marijuana to two researchers, the ALJ ''answer[ed] that question in the negative.'' *Id.*

The ALJ also reasoned that analyzing marijuana samples was ''a separate activity from cultivating marijuana for research purposes and a requirement that a qualified cultivator may not be able to fulfill.'' *Id.* The ALJ thus concluded that ''the NIDA contractual process does not * * * render competition in the manufacture of marijuana adequate.'' *Id.*

I reject both the ALJ's legal conclusions and Respondent's arguments. As for the ALJ's (and Respondent's) reasoning that the NIDA contractual process does not render competition adequate because the contract requires the analyzing of marijuana samples, in executing its authority under § 823(a), DEA does not act as a board of contract appeals. In any event, the contract does not prohibit the contractor from subcontracting this function. *See* GX 15, at 4 (Request for Proposal) (''As this procurement may require expertise in several scientific areas, *offerors are encouraged* to solicit subcontractors or expert consultants as appropriate.'') (emphasis added).[79]

Finally, as for the contention that granting his application would provide for competition and thereby promote improvement in the quality of research-grade marijuana,[80] if Respondent believes that he can produce a higher-quality product than the current contractor, he should bid on the contract.[81] If he prevails, and demonstrates that his project will implement effective controls against diversion, he can establish that his registration would be consistent with the public interest. Respondent, however, has not been awarded a contract to supply NIDA, which, consistent with the Single Convention, is the only lawfully authorized wholesale distributor of plant-form marijuana.

Thus, whether viewing the competition aspect of paragraph 823(a)(1) by considering the reasonableness of prices paid by those who lawfully acquire bulk marijuana for research or by considering the adequacy of the competitiveness of the process by which persons may bid to become the grower of marijuana for NIDA, Respondent has failed to meet his burden. This combined with his failure to meet his burden of demonstrating inadequate supply within the meaning of paragraph 823(a)(1) weighs heavily against granting his application. Nonetheless, Respondent raises a host of arguments under the heading of paragraph 823(a)(1) which—though not actually germane to paragraph 823(a)(1)—are addressed below.

(c) Additional Arguments Raised by Respondent Under the Heading of Paragraph 823(a)(1)

In lieu of presenting evidence to show that competition is inadequate by virtue of unreasonable prices for research-grade marijuana or any other economic data, Respondent argues that competition should be deemed inadequate within the meaning of paragraph 823(a)(1) based on his objection to the to ''government monopoly'' whereby HHS distributes marijuana to researchers. In other words, the very monopoly over the wholesale distribution of marijuana that is mandated by the Single Convention (indeed, the element that is at the heart of the structure of cannabis control under the treaty) is the central basis on which Respondent relies in attempting to meet his burden of demonstrating inadequate competition within the meaning of paragraph 823(a)(1). This argument is flawed in the following respects. As explained above and in part C of this discussion, the competition analysis set forth in paragraph 823(a)(1) must be based on actual economic considerations in the existing market—not policy questions about the wisdom of having the Federal Government control the wholesale distribution of marijuana.

In addition, Respondent's suggestion that paragraph 823(a)(1) can be used to defeat the Single Convention's requirement of a government monopoly over wholesale marijuana distribution mistakenly construes the treaty criterion § 823(a) as being in competition with the public interest criterion. In fact, as explained above, an applicant for registration under § 823(a) must demonstrate that the proposed registration is consistent with *both* the Single Convention and the public interest—and neither criterion is at odds with the other. Both the Single Convention and the United States Code are the ''supreme law of the land,'' U.S. Const. art VI, and in enacting the CSA, Congress made clear that § 823(a) should be interpreted in a manner that is consistent with the United States' obligations under the Convention. The Agency's interpretation of paragraph 823(a)(1) must therefore recognize not only the Convention's specific provisions applicable to marijuana, which expressly prohibit competition in the wholesale distribution of the substance, but also the background principles which underlie both the Convention and the CSA. Accordingly, I reject Respondent's invitation to interpret § 823(a) in a manner that would abrogate the United States' obligation under the Convention to maintain a monopoly in the wholesale trade of marijuana.

While § 823(a) was enacted subsequent to the Convention—indeed it implements the Convention[82]—it is a provision of general applicability and contains no explicit reference to marijuana. Under settled principles of statutory construction, while a later enacted law can sometime repeal an earlier provision, '' '[r]epeals by implication are not favored' and will not be presumed unless the 'intention of the legislature to repeal [is] clear and manifest.' '' *National Ass'n of Home Builders* v. *Defenders of Wildlife,* 127 S.Ct. 2518, 2532 (2007) (quoting *Watt* v. *Alaska*, 451 U.S. 259, 267 (1981)). Accordingly, courts ''will not infer a statutory repeal 'unless the later statute expressly contradict[s] the original act' or unless such a construction is 'absolutely necessary * * * in order that [the] words [of the later statute] shall have any meaning at all.' '' *Id.* (quoting *Traynor* v. *Turnage*, 485 U.S. 535, 548 (1988) (int. quotations and other citations omitted)).

[79] The University of Mississippi subcontracts to another entity, Research Triangle Institute (RTI), the responsibilities under the contract to produce the marijuana cigarettes (using marijuana supplied by the University of Mississippi) and deliver them to authorized recipients. Tr. 1162–65, 1168–69; *see also* 72 FR 73369 (notice of registration for RTI).

[80] As discussed above, Respondent failed to put forth any evidence demonstrating that he is capable of any type of quality control relating the manufacture of marijuana and his lack of experience and expertise in this field compared to that of Dr. ElSohly suggests that he is incapable of improving on the quality of marijuana produced by the University of Mississippi.

[81] I also note Respondent's contention that the NIDA process ''does not ensure that researchers pay a competitive price [because] NIDA sets the price and there is no evidence as to how that price is set.'' Resp. Prop. Findings at 48. Even if marijuana were not subject to the Convention's requirement, I would still reject the argument because Respondent had the burden of proving that the prices are excessive.

[82] *See* H.R. Rep. 1444 (91st. Cong., 2d Sess.), *reprinted at* 1970 U.S.C.C.A.N. 4566, 4572.

Here, this rule applies with added force for two reasons. First, Respondent's construction would derogate the sovereign authority of the United States. See, *e.g., E. I. Du Pont de Nemours & Co.* v. *Davis,* 264 U.S. 456, 462 (1924) (noting that in taking over the railroads, ''the United States did so in its sovereign capacity * * * and it may not be held to have waived any sovereign right or privilege unless plainly so provided''); *cf. Federal Power Comm'n* v. *Tuscarora Indian Nation,* 362 U.S. 99, 120 (1960) (quoting *United States* v. *United Mine Workers of America,* 330 U.S. 258, 272 (1947) (''There is an old and well-known rule that statutes which in general terms divest pre-existing rights or privileges will not be applied to the sovereign without express words to that effect.''); *Sea-Land Service, Inc.,* v. *The Alaska R.R.,* 659 F.2d 243, 245 (D.C. Cir. 1981) (holding that ''[t]he Sherman Act * * * does not expose United States instrumentalities to liability, whether legal or equitable in character, for conduct alleged to violate antitrust constraints'').

Second, Respondent's construction would result in the abrogation of the Convention's provision. While Congress may abrogate a treaty, the ''legislation must be clear to ensure that Congress—and the President—have considered the consequences.'' *Roeder* v. *Islamic Republic of Iran,* 333 F.3d 228, 238 (D.C. Cir. 2003). The D.C. Circuit has further explained that ''[t]he 'requirement of [a] clear statement assures that the legislature has in fact faced, and intended to bring into issue, the critical matters involved in the judicial decision.' '' *Id.* (quoting *Gregory* v. *Ashcroft*, 501 U.S. 452, 461 (1991)). *See also Vimar Seguros y Reaserguros, S.A.* v. *M/V Sky Reefer,* 515 U.S. 528, 539 (1995) (''If the United States is to be able to gain the benefits of international accords and have a role as a trusted partner in multilateral endeavors, its courts should be most cautious before interpreting its domestic legislation in such manner as to violate international agreements.''); *George E. Warren Corp.* v. *U.S. E.P.A.,* 159 F.3d 616, 624 (D.C. Cir. 1998) (upholding agency rule which ''avoid[ed] an interpretation that would put a law of the United States into conflict with a treaty obligation of the United States,'' and observing that that ''[s]ince the days of Chief Justice Marshall, the Supreme Court has consistently held that congressional statutes must be construed wherever possible in a manner that will not require the United States to violate the law of nations'') (internal quotations and other citations omitted).

As explained above, § 823(a) is not limited to applicants who seek a registration to manufacture marijuana, but rather is a provision that applies to every person who seeks a registration to manufacture any one of the hundreds of other controlled substances listed in schedules I and II. Paragraph 823(a)(1)'s direction to the Attorney General to consider the adequacy of competition does not provide a clear statement of congressional intent to abrogate the Convention's requirement that the United States Government maintain a monopoly on the wholesale trade in marijuana. Absent the requisite clear statement, I conclude that to the extent the CSA seeks to promote adequate competition in the supply of marijuana, the NIDA process satisfies Congress' purpose by putting the contract up for competitive bidding at periodic intervals then supplying the marijuana to researchers for free or at NIDA's cost.

Respondent also contends that the current NIDA supply is ''inadequate because a pharmaceutical developer could not reasonably rely on NIDA marijuana to take [plant-form] marijuana through the FDA new drug approval process.'' Respondent's Resp. at 16; *see also* Respondent Proposed Findings at 45 (''no rational drug sponsor seeking to develop botanical marijuana as an FDA-approved product could proceed without seeking a source of supply alternative to NIDA's''). Of note in this regard, Mr. Doblin testified that MAPS could take plant-form marijuana through the FDA-approval process for a cost of $5 to $10 million notwithstanding ample evidence that the actual costs would be considerably more, and that he ''disagree[d]'' with the IOM's conclusion that defined and purified cannabinoid compounds ''are preferable to plant products, which are of variable and uncertain composition.'' Tr. 654; RX 1, at 22. *See also* GX 53 (letter of GW Pharmaceuticals; ''[H]erbal cannabis should comprise only the starting material from which a *bona fide* medical product is ultimately derived.''). Mr. Doblin also testified that the safety of smoked marijuana would be only ''slightly different'' from that of drugs containing cannabinoid extracts, Tr. at 605, notwithstanding the IOM's further conclusion that smoking ''is a crude THC delivery system that also delivers harmful substances'' such as those found in tobacco, and that ''there is little future in smoked marijuana as a medically approved medication.'' RX 1, at 195.

Mr. Doblin's testimony hardly suggests that he is a ''rational drug developer.'' But even ignoring his testimony, Respondent's argument is meritless. Respondent's contention that ''MAPS can have no confidence * * * that NIDA would authorize MAPS to rely on'' NIDA's Drug Master File, Resp. Proposed Findings at 44–45, ignores that under the HHS Guidance, NIDA is required to ''provide the researcher with authorization to reference'' it. GX 24, at 4. Moreover, neither Federal law nor FDA's regulations require that a drug developer submit a Drug Master File. FDA, *Guideline for Drug Master Files,* at 2.

Respondent further contends that NIDA would not be willing to serve as supplier to a drug developer because doing so is not part of its mission. It is, however, HHS, and not NIDA (which is only a subcomponent therein) which sets policy on whether to provide marijuana. As for Respondent's insinuation that HHS is biased against research that seeks to develop plant-form marijuana into a prescription medicine, it is true that Dr. Gust testified that HHS ''strongly endorse[s]'' the IOM's view that if marijuana is to provide the basis for a prescription medicine, it will be in a medicine which uses ''a purified constituent'' and a non-smokable delivery system. Tr. 1722. A view based on science is not bias. Moreover, Dr. Gust's testimony made clear that PHS does not have a bias against research that is directed at developing plant-form marijuana, *id.* at 1719–20, 1722; and that whether plant-form marijuana should be approved as a prescription medicine is a question for the FDA-approval process. *Id.* at 1720. Respondent's contention to this effect is therefore rejected.

In sum, under the text of 21 U.S.C. 823(a)(1), to maintain effective controls against diversion, DEA is obligated to consider limiting the number of registered bulk manufacturers of any given schedule I or II controlled substance to that which can produce an adequate and uninterrupted supply of the substance under adequately competitive conditions. Thus, every applicant for registration under § 823(a) bears the burden of demonstrating that either the existing supply or competition is inadequate within the meaning of paragraph 823(a)(1). For the reasons provided above, Respondent has failed to meet this burden. Accordingly, factor one weighs heavily against granting his application.

2. Public Interest Factor Two

The second public interest factor is ''compliance with applicable State and local law.'' 21 U.S.C. 823(a)(2). The ALJ stated: ''There is neither evidence nor

contention that Respondent has not complied with applicable laws and I therefore find that this factor weighs in favor of granting Respondent's application.'' ALJ at 85. In view of this statement, it must be repeated that at any hearing on an application to manufacture a schedule I or II controlled substance, the applicant has the burden of proving that the requirements for registration under 21 U.S.C. 823(a) are satisfied. 21 CFR 1301.44(a). Moreover, the issue under the second public interest factor is not merely whether an applicant has complied in the past with applicable State and local law, but also whether the applicant will do so if he becomes registered. Thus, it was imprecise for the ALJ to suggest that the absence of evidence regarding past compliance with applicable State and local law constitutes a favorable showing on behalf of the applicant for purposes of the second public interest factor. However, the record is not entirely silent with respect to this factor. As the ALJ noted (ALJ at 57), and as Respondent has emphasized (Resp. Prop. Findings at 57), Respondent did testify that he met with ''state investigators'' who told him that ''a state permit would depend on a federal permit being granted.'' Tr. 45. Given that the Government did not contest this part of Respondent's testimony, I will give Respondent the benefit of the doubt by inferring that what he intended to convey was that Massachusetts state officials indicated to him that he would be able to obtain a ''registration'' under Massachusetts law to manufacture marijuana if and when he were to obtain a DEA registration to do so.[83] I do so despite the fact that Respondent did not indicate in his testimony or through the submission of any documentary exhibits whether he had actually filed an application with the state and submitted the appropriate fee for such state registration. Thus, consistent with the ALJ's recommendation, I find Respondent has put forth some evidence which (being unrefuted) allows for a conclusion that his proposed activities would be in compliance with State and local law.

[83] Analogous to federal law, Massachusetts law provides that ''every person who manufactures * * * any controlled substance within the commonwealth shall upon payment of a fee, * * * register with the commissioner of public health, in accordance with his regulations, said registration to be effective for one year from the date of issuance.'' Mass. Gen. Laws Ann. ch. 94C, § 7(a) (West 2008). Massachusetts has adopted the CSA schedules of controlled substances, making marijuana a schedule I controlled substance under state law. *See* Mass. Gen. Laws Ann. ch. 94C, § 2(a).

The Government took exception, however, to the ALJ's recommendation that this factor (paragraph 823(a)(2)) be weighed in favor of granting Respondent's application. Gov. Exceptions at 12–13. The Government argues that this factor ''is most often relevant'' in cases in which practitioners have lost their state controlled substance authorization. *Id.* at 13. Further, the Government contends, ''[w]hile the failure to have a required state or local license would prove fatal to an application, * * * an expectation by Respondent that the required state license will ineluctably follow the granting of a DEA registration and a promise to comply with state and local law in the future simply renders this factor irrelevant and does not weigh in favor of either party.'' *Id.* In response thereto, Respondent asserts that the lack of evidence of noncompliance with state or local law should indeed support a finding that this factor weighs in favor of registration. Respondent's Resp. at 18–19.

It is certainly true, as both parties agree, that the evidence relating to Respondent's proposed activities cannot be deemed as weighing against the pubic interest for purposes of paragraph 823(a)(2). However, whether one characterizes the evidence relevant to this factor as weighing in favor of granting Respondent's application or simply neutral seems somewhat a matter of semantics. Given the nature of the evidence here (Respondent's mere testimony that he anticipates authorization from the state and that he promises to comply with state law), I accept the characterization that the evidence is favorable as to the second public interest factor, with the caveat that this factor is of limited weight commensurate with the nature of the evidence.

3. Public Interest Factor Three

The third public interest factor is ''promotion of technical advances in the art of manufacturing these substances and the development of new substances.'' 21 U.S.C. 823(a)(3). The ALJ found that Respondent has ''considerable experience in cultivating medicinal plants, which might promote technical advances in the cultivation of marijuana or developing new medications from it.'' ALJ at 85–86. The ALJ nonetheless found that ''there is not sufficient evidence in the record on which to base a finding as to whether granting Respondent's registration would promote technical advances.'' Id. at 86. When asked by his own counsel how his registration would promote technical advances, Respondent answered in a vague manner:

> Well, I think there is two answers to that as far as I'm concerned. One is that, yes, it would make an advance in the understanding any possible clinical use of marijuana if we were able to supply this to investigators to run trials, and, secondly, as I've explained to DEA agents that visited, that we would learn more about how the environment affects the constituents in the plant material which would enable, if this does become at some stage down the road here, becomes a useful drug, and that the manufacturer of it has to be controlled under security conditions, they would know the environment it needs to be grown under to produce a clinical marijuana, medical marijuana.

Tr. at 75–76. In the first part of the above answer, it appears that Respondent is simply accepting the word of his sponsor, Mr. Doblin, that his obtaining a DEA registration would result in marijuana being provided to researchers who would not otherwise obtain it. If so, Respondent is relying on a false premise. As discussed at length above, the evidence demonstrates that not one bona fide researcher within the meaning of the CSA (i.e., one whose protocol has been determined by HHS to be scientifically meritorious) has ever been denied marijuana[84] and that, under the new procedures adopted by HHS in 1999, the ''scientific bar'' has been set relatively low, allowing marijuana to be provided to 17 privately funded researchers. As for the second part of his answer, in which Respondent attempted to explain how his registration would result in learning ''more about how the environment affects the constituents in the plant material,'' this explanation is noticeably lacking in detail and without any discernable scientific basis. By his own admission, Respondent is ''not experienced in growing this plant (marijuana).'' Tr. at 40. In comparison, Dr. ElSohly, who has been the principal investigator under the NIDA contract and has overseen the National Center's work with marijuana since 1980 (employing a wide variety of

[84] Even with respect to Dr. Abrams—who MAPS seems to believe was improperly denied marijuana in the pre-1999 era (before HHS changed its policy for providing marijuana to researchers)—Respondent produced no evidence that HHS's denial was lacking in scientific basis. To the contrary, as indicated above, the evidence indicates that NIDA initially denied Dr. Abrams' request based on valid concerns about the design and scientific merit of his protocol. *See* note 24, *supra,* and accompanying text. The record further reflects that Dr. Abrams corrected these deficiencies to NIDA's satisfaction upon submitting a revised protocol and, as a result, received marijuana from NIDA in 1997; NIDA also supplied Dr. Abrams with marijuana for subsequent studies. *Id.*

manufacturing techniques),[85] has at least seven patents relating to the manufacture and identification of marijuana and its derivatives, and has authored numerous articles on these subjects that have been published in scientific journals. Tr. 1136–38, 1331–36; GXs 65–71, 93. Respondent's lack of experience in growing marijuana does not preclude a finding under paragraph 823(a)(3) that his proposed activities would promote technical advances in the art of manufacturing marijuana and developing new substances. Nor does Respondent's lack of expertise in this area compared to that of Dr. ElSohly preclude such a finding as it is conceivable that a newcomer to a field could make scientific discoveries that others have failed to make. However, Respondent's lack of experience and expertise combined with the vagaries of his testimony as to how he would promote technical advances in the art of manufacturing marijuana and developing new substances do not support a finding that he would do so. Thus, I concur with the ALJ's recommendation as to this factor and conclude that Respondent has failed to meet his burden of demonstrating that his proposed activities would promote technical advances in the art of manufacturing marijuana and developing new substances.

4. Public Interest Factor Four

The fourth public interest factor is ''prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances.'' 21 U.S.C. 823(a)(4). I adopt the ALJ's recommended finding that it was ''undisputed that Respondent has never been convicted of any violation of any law pertaining to controlled substances'' and therefore this factor weighs in favor of granting the application. I reject the Government's contention that the historical and ongoing activities of Mr. Doblin and MAPS relating to controlled substances (which the Government asserts are improper but for which there is no evidence in the record of any criminal convictions) should be considered under this factor.

5. Public Interest Factor Five

The fifth public interest factor is ''past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion.'' 21 U.S.C. 823(a)(5). Both parties and the ALJ agree that Respondent has no past experience in the manufacture of controlled substances, and I so find.[86] Consideration of such experience serves two purposes. First, the review of an applicant's track record provides substantial information as to prior violations and the likelihood of its future compliance with the Act and regulations. *See ALRA Laboratories, Inc.* v. *DEA*, 54 F.3d 450, 452 (7th Cir. 1995) (''An agency rationally may conclude that past performance is the best predictor of future performance.''). Second, the experience factor recognizes that the regulatory scheme is complex and that having effective controls against diversion requires more than simply having a secure building and a policy and procedures manual.[87] Rather, having effective controls requires that those controls be properly performed. Thus, Respondent's lack of experience in the manufacture of controlled substances cannot be dismissed as inconsequential.[88] Indeed, there is agency precedent for concluding, in appropriate circumstances, that lack of such experience can be an independent basis for denial of registration.[89] However, I find in this case that Respondent's lack of experience in handling controlled substances—while a factor weighing against granting his application—should not disqualify him from obtaining a registration to bulk manufacture marijuana.

As to whether there would be, within Respondent's establishment, effective control against diversion,[90] Respondent testified that, although he ''did not have a full-blown plan when [he] applied for the [DEA registration],'' when DEA personnel conducted an on-site inspection of his premises, he assured them that he ''understood the need for security'' and that they thought that his proposed room for growing marijuana ''could be made secure with no problems.'' Tr. 44–45, 355–56. Respondent further testified that he

[85] The National Center grows marijuana both indoors and outdoors and has done so using conventional soil planting from seeds and seedlings, as well as using hydroponics (without soil), vegetative propagation (using cuttings to retain the genetic identity of the ''mother plant''), and micropropagation (vegetative propagation using a very small part of plant material rather than a cutting). Tr. 1187–1263, 1328–30. It has also utilized a variety of harvesting, drying, fertilization, and storage methods to affect the THC content of the marijuana, to promote more effective rolling of cigarettes, and to isolate certain cannabinoids. *Id.* It also has in its inventory seeds from different parts of the world, which can produce marijuana of various potencies. *Id.* Respondent did not identify any cultivation, harvesting, or other manufacturing techniques relating to marijuana in which the National Center lacks expertise.

[86] While the ALJ correctly observed that Respondent has no experience in the in the manufacture of controlled substances, she stated that Respondent ''does have experience in growing medicinal plants.'' ALJ at 86. It is unclear whether the ALJ was taking this into account for purposes of factor 5, or simply noting it in passing, because she ultimately recommended that I conclude ''there is not sufficient evidence in the record on which to base a finding as to whether granting Respondent's registration would promote technical advances.'' *Id.* In any event, under the text of paragraph 823(a)(5), experience in the manufacture of anything other than ''controlled substances'' is immaterial for purposes of factor 5.

[87] The CSA and DEA regulations impose a complex and comprehensive scheme to protect against diversion. These include not only requirements pertaining to the physical security of manufacturing facilities, *see* 21 CFR 1301.73, and employee screening procedures, *id.* 1301.90, but also extensive inventory, record keeping, and reporting requirements. *See* 21 CFR 1304.04 (maintenance of records and inventories); id. 1304.11 (inventory requirements); 1304.22(a) (records for manufacturers); 1304.33 (ARCOS reports); 1301.74(c) (reporting of theft).

[88] Respondent notes the Government's argument that '' '[i]n no case involving applications to handle controlled substances, has 'prior experience' with non-controlled substances ever been considered as support for granting an application.' '' Respondent's Resp. at 24. Respondent maintains that ''this argument is simply wrong,'' and that ''[i]n *Chattem Chemicals, Inc.*, 71 FR 9834, 9838 (2006) * * * the applicant had no prior experience in processing opium alkaloids, the controlled substance for which it sought a manufacturer's registration.'' Respondent's Resp. at 24–25. That much is true. Respondent ignores, however, that Chattem already held registrations to manufacture schedule II controlled substances including morphine, codeine and oxycodone, and to import other controlled substances. *See* 71 FR at 9836. In contrast to Respondent, who has no relevant experience, Chattem had extensive experience in the regulatory scheme and the effective implementation of controls against diversion.

Respondent also notes Dr. ElSohly's testimony to the effect that when the University of Mississippi first applied in 1968 for the contract to grow marijuana for NIDA's predecessor, ''he lacked experience and expertise in security measures relating to controlled substances.'' Respondent Resp. at 27. Respondent ignores, however, that the registration belongs to the University of Mississippi and was issued to it 12 years before Dr. ElSohly took over the project and under a different statutory scheme and further that Dr. ElSohly had been working on the marijuana project for four years at the time he succeeded his predecessor. *See* Tr. at 1131–32, 1152.

[89] *Cf. Stephen J. Heldman*, 72 FR 4032, 4034 (2007) (noting that even ''[w]ere there no evidence of Respondent having engaged in illicit activity * * * his lack of experience bars his registration'').

[90] As explained in part C of the discussion section, this aspect of paragraph 823(a)(5) requires DEA to consider, among other things, whether Respondent has demonstrated that he will have in place appropriate physical security and employee screening as required by the DEA regulations and as confirmed through a DEA on-site inspection of the premises. Also as explained in part C, this aspect of paragraph 823(a)(5)—which involves an evaluation of the applicant's particular facility, proposed security measures, and other controls against diversion to be implemented by the applicant—is best viewed as being distinguished from the requirement under paragraph 823(a)(1) that *DEA* maintain effective controls against diversion ''by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions.''

agreed to meet all DEA security requirements. Tr. 79. The Government did not dispute these assertions. I therefore find that Respondent has met his burden of demonstrating that, if the registration were granted, he would have in place effective controls against diversion.[91] In sum, the evidence bearing on factor five weighs both in favor of and against Respondent's application: it indicates that he has no past experience in the manufacture of controlled substances but that he will have in the establishment effective controls against diversion.

6. Public Interest Factor Six

The sixth and final public interest factor is ''such other factors as may be relevant to and consistent with the public health and safety.'' 21 U.S.C. 823(a)(6). At the outset, it should be noted that, because the text of this provision calls on me to consider ''such *other* factors,'' I will *not* restate in the discussion of factor six the evidence that I have already taken into account for purposes of the first five public interest factors—even though such evidence might be relevant to the determination of whether Respondent's proposed registration would be consistent with the public health and safety.

The most notable evidence relevant to factor six is that relating to Mr. Doblin.[92] Before addressing this evidence, it needs to be made clear that I consider irrelevant for purposes of this application whether Mr. Doblin, in the expression of his political viewpoints, supports the legalization of marijuana and other controlled substances. I also consider irrelevant the political activities of the organization he heads, MAPS. The expression of political viewpoints enjoys the protection of the first amendment. However, it is certainly relevant for purposes of factor six whether a person who might be in a position to directly influence the activities of a registrant has engaged in actual conduct involving controlled substances that fails to comply with the federal or state law.

The evidence indicates that Mr. Doblin has been significantly involved in Respondent's application process and plans to retain a key role in Respondent's activities if the registration is granted. Mr. Doblin came up with the idea of sponsoring an applicant for a DEA registration who would be a supplier of marijuana other than NIDA, and he selected Respondent to be that applicant. Tr. 210–12, 219. Mr. Doblin assisted Respondent in filling out the application, supplied answers to DEA's supplemental written questions, and agreed, on behalf of MAPS, to ''cover all the costs'' associated with the registered activities, including the costs of equipment, manufacturing, and security installations. Tr. 221–22, 351–52; 383, 583; GX 3, at 1. Respondent has agreed that Mr. Doblin, in his role as head of MAPS, will take an active role in deciding to whom Respondent will supply the marijuana. Tr. 224–26, 358–360. Respondent described the process of applying for the DEA registration and the ''project of developing marijuana'' as a ''joint effort'' by Mr. Doblin and himself. Tr. 390–91. Indeed, Respondent testified that his ''understanding'' of his ''role,'' as well as that of Mr. Doblin, was that dictated to him by Mr. Doblin.[93] *Id.* at 358. Another part of Mr. Doblin's role would be to ''route'' the ''investigators'' (those seeking marijuana for research) to Respondent. *Id.* Mr. Doblin would also decide for Respondent the ''strains'' of marijuana to produce and ''allocate'' the marijuana produced in accordance with MAPS's priorities. Tr. 589.

In short, Mr. Doblin has mapped out and assisted in most acts, if not every act, that Respondent has taken toward applying for a registration to manufacture marijuana and, if the registration were granted, Mr. Doblin would continue to maintain responsibility for managing and monitoring the activities of the registrant. Given this level of involvement by Mr. Doblin—and the passive, if not subservient, nature of Respondent's involvement—it is appropriate under factor six to consider the following conduct by Mr. Doblin relating to controlled substances. First, Mr. Doblin admits that he smokes marijuana for ''recreational use'' on a weekly basis. Tr. 716, 718–19. Thus, Mr. Doblin violates federal and state laws relating to controlled substances on a weekly basis.[94] This demonstrates that Mr. Doblin has disregard for the controlled substances laws. It is simply inconceivable that DEA would—consistent with its obligations under the CSA—grant a registration to engage in certain activities involving controlled substances where it is clear that a person who will have *any* role in the oversight and management of such activities routinely engages in the illegal use of controlled substances. It is still more untenable where that person has the level of oversight and management that Mr. Doblin would have—and where the controlled substance he illegally uses is the very controlled substance the applicant seeks to produce. Indeed, it is remarkable that Mr. Doblin would—given his admitted illegal involvement in controlled substances—ask DEA to effectively grant him permission to take on such a prominent role in the manufacture of the most widely abused illegal controlled substance in the United States.

Respondent points to Mr. Doblin's testimony that MAPS has previously sponsored research by DEA registrants involving schedule I controlled substances other than marijuana. Respondent's Resp. at 23 (citing Tr. 482–491). Respondent characterizes such research as having taken place ''all without a hint of * * * diversion.'' *Id.* at 23–24. However, there is nothing in the record that confirms or refutes this

[91] Because the DEA regulations require all registered manufacturers of controlled substances to have certain control measures in place at all times (21 CFR 1301.71–.74, .76), DEA may not issue a certificate of registration to a new applicant until the required security measures are actually in place.

Moreover, while I acknowledge that Respondent testified that he would secure the growing area and meet ''appropriate security conditions'' (Tr. 79), and I find it is highly unlikely that Respondent would personally divert, this does not establish that the risk of diversion is minimal. Respondent testified that he usually does not go down to the greenhouse to water the plants but leaves this task to a technician. Tr. at 254. Moreover, the graduate students and technicians ''would probably do the transplanting'' and the ''daily check on any environmental controls.'' *Id.* at 254–55. Respondent's testimony begs the question of who would be supervising these workers. Furthermore, while Respondent has promised to meet appropriate security conditions, it is undisputed that he has no experience in the manufacture of controlled substances and the regulatory scheme. As he testified: ''I have no experience in the control against diversion.'' Tr. 79.

Thus, my finding under factor five that Respondent would have in place effective controls against diversion might be viewed as being generous toward Respondent.

[92] By its terms, paragraph 823(a)(6) is not limited to conduct on the part of the applicant. Rather, its broad wording indicates that it is a catchall provision that calls on the agency to consider ''such other factors [not covered by factors (a)(1) through (a)(5)] as may be relevant to and consistent with the public health and safety.''

[93] Further indication that MAPS is the driving force behind this application is that, when asked to explain the meaning of one of his written answers to the questions submitted by DEA as a follow up to the application, Respondent admitted that he had ''no idea'' whether he was referring to Chemic when he answered that one of the proposed recipients of the marijuana that he seeks to produce would be an entity that would use ''marijuana delivered through a vaporizer device.'' Tr. at 225–26. Nor did Respondent know if this entity was authorized under the law to conduct such research or the amount of marijuana that would be needed for this research. *Id.* at 229. Respondent said that such questions would have to be referred to Mr. Doblin. *Id.* at 226. Respondent acknowledged that the only entity he had in mind as a recipient of the marijuana he seeks to grow was the researcher that would test the vaporizer. Tr. at 235.

[94] 21 U.S.C. 844; Mass. Gen. Laws Ann. ch. 94C, § 34 (West 2008). Mr. Doblin lives in Massachusetts. Tr. 472.

characterization; nor does the record indicate exactly what role Mr. Doblin played in the prior MAPS-sponsored research.[95] In any event, even assuming that MAPS has previously sponsored DEA-registered researchers without incident, this does not undo the legitimate concerns that came to light in this proceeding about Mr. Doblin's fitness for directing, at least in part, the activities of a DEA-registered bulk manufacturer of marijuana, given Mr. Doblin's routine illegal use of marijuana.

Thus, Mr. Doblin's ongoing illegal marijuana use, by itself (i.e., even putting aside the treaty considerations and Respondent's failure to demonstrate inadequate supply or competition within the meaning of paragraph 823(a)(1)), provides a sufficient independent basis upon which DEA may deny the application.

Accordingly, based on a consideration of all six pubic interest factors set forth in 21 U.S.C. 823(a), I conclude the Respondent has failed to meet his burden of demonstrating that his proposed registration is consistent with the public interest. To the contrary, the evidence is compelling that the registration is inconsistent with the public interest.

C. The Meaning of 21 U.S.C. 823(a)(1)

This section of the discussion contains a far more extensive analysis of 21 U.S.C. 823(a)(1) (hereafter, ''paragraph 823(a)(1)'') than DEA has previously published. As indicated above, for ease of exposition, due to the length of this analysis, it is being presented here as a separate section of the discussion rather than inserting it directly into the above discussion of the public interest factors.

1. The Text of the Statute

The appropriate starting point for the analysis of any statute is the text of the statute itself. The text of § 823(a) remains the same today as it was when the CSA was enacted by Congress in 1970. It states:

> (a) Manufacturers of controlled substances in schedule I or II
>
> The 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 in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:
>
> (1) Maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances 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;
>
> (2) Compliance with applicable State and local law;
>
> (3) Promotion of technical advances in the art of manufacturing these substances and the development of new substances;
>
> (4) Prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;
>
> (5) Past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and
>
> (6) Such other factors as may be relevant to and consistent with the public health and safety.

Thus, the statute allows DEA to register an applicant to bulk manufacture a schedule I or II controlled substance only if the Deputy Administrator[96] determines that the proposed registration would be consistent with both (i) the Single Convention and (ii) the public interest. In determining whether the proposed registration is consistent with the public interest, the statute requires DEA to evaluate the above six factors. The first factor, set forth in 21 U.S.C. 823(a)(1) (referred to in this discussion as ''paragraph 823(a)(1)''), requires the Deputy Administrator to consider ''maintenance of effective controls against diversion * * * *by limiting the * * * bulk manufacture of such controlled substances 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.'' (Emphasis added.) Thus, Congress stated in paragraph 823(a)(1) that—in order to maintain effective controls against diversion of a given schedule I or II controlled substance—DEA must consider limiting the number of registered bulk manufactures of the substance to that ''which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions.''

While the above-quoted text of paragraph 823(a)(1) is relatively straightforward, consulting the dictionary helps to confirm the meaning. The word ''limiting'' (or ''limit''), when used as a verb, is defined as ''to assign certain limits to; prescribe,'' ''to restrict the bounds or limits of,'' or ''to curtail or reduce in quantity or extent.'' [97] The word ''limit,'' when used as a noun, is defined as ''something that bounds, restrains or confines'' or ''the utmost extent.'' [98] Thus, the command under paragraph 823(a)(1) that DEA consider ''limiting'' the number of registered bulk manufacturers of a given schedule I or II controlled substance can be construed to mean that the *upper boundary* on the number of such manufacturers is that ''which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes.''

It is notable that, by requiring DEA to consider *limiting* the number of bulk manufactures of a given schedule I controlled substance to that ''which can produce an adequate and uninterrupted supply * * * under adequately competitive conditions,'' paragraph 823(a)(1) does *not* allow DEA simply to register as many bulk manufacturers of a given schedule I or II controlled substance as the market will bear. Rather, DEA is obligated under paragraph 823(a)(1) to consider disallowing additional entrants into the schedule I and II bulk manufacturing market *unless* DEA concludes that addition of a particular applicant is necessary to produce ''an adequate and uninterrupted supply of [a given substance] under adequately competitive conditions.''

This reading of paragraph 823(a)(1) is also consistent with the overall structure of the CSA. The Act places each controlled substance into one of five schedules based on: whether the substance has a currently accepted medical use in the United States; the substance's relative potential for abuse; and the extent to which abuse of the substance may lead to psychological or physical dependence.[99] As the United States Supreme Court has stated, ''[t]he Act then imposes restrictions on the

[95] Respondent does not appear to contend that DEA granted the prior registrations to MAPS-sponsored researchers knowing that MAPS was the sponsor with Mr. Doblin having the same level of involvement that he seeks here, and he cites no part of the record for such a proposition.

[96] Pursuant to 21 U.S.C. 871(a), functions vested in the Attorney General by the CSA have been delegated to the Administrator of DEA. 28 CFR 0.100(b). The function of issuing final orders regarding applications for registration has been further delegated to the Deputy Administrator. 28 CFR 0.104, appendix to subpart R, sec. 7(a).

[97] Merriam-Webster OnLine, *http://www.merriam-webster.com/dictionary* (2008).

[98] *Id.*

[99] 21 U.S.C. 812(b).

manufacturing and distribution of the substance according to the schedule in which it has been placed.'' [100] ''Schedule I,'' as the Court observed, ''is the most restrictive schedule.'' This is commensurate with the fact that schedule I controlled substances are the only controlled substances with no currently accepted medical use in treatment in the United States. Schedule II restrictions are the next most restrictive (less restrictive than those for schedule I controls but more restrictive than those for schedules III, IV, and V)—commensurate with schedule II substances having the highest potential for abuse of those controlled substances that have a currently accepted medical use (those in schedules II through V).

Consistent with this basic CSA principle of applying greater controls to the substances that are most subject to abuse and most harmful when abused, the CSA is structured to apply certain critical control provisions to schedule I and II substances but not to those in schedules III, IV, and V. For example, the CSA imposes quota restrictions and order form requirements for schedule I and II controlled substances but not for those in schedules III, IV, and V.[101] Paragraph 823(a)(1) is another example of this principle. The required consideration in paragraph 823(a)(1) of limiting the number of bulk manufacturers of schedule I and II controlled substances (to that which can produce an adequate and uninterrupted supply of a given substance under adequately competitive conditions) is noticeably absent from paragraph 823(d)(1), which governs the registration of manufacturers of schedule III, IV, and V controlled substances. This contrast between the presence of the ''limiting'' language in paragraph 823(a)(1) and its absence from paragraph 823(d)(1) underscores the importance of this requirement—particularly in view of Congress's overall scheme of placing the greatest restrictions on substances in schedules I and II.

Another consideration when interpreting the language of paragraph 823(a)(1) is a comparison of its terms with those of paragraph 823(a)(5). As indicated above, paragraph 823(a)(5) is one of the six factors DEA must consider when evaluating an application for registration to bulk manufacture a schedule I or II controlled substance. Paragraph 823(a)(5) requires consideration of, among other things, ''the existence *in the establishment* of effective control against diversion.'' (Emphasis added.) The plain meaning of this language is that the Deputy Administrator must evaluate whether the particular facility in which the applicant proposes to manufacture the schedule I or II controlled substance will have in place effective safeguards to prevent diversion. This would include, among other considerations, appropriate physical security and employee screening as required by the DEA regulations [102] as confirmed through a DEA on-site inspection of the premises. That paragraph 823(a)(5) expressly requires the Deputy Administrator to consider ''the existence *in the establishment* of effective control against diversion'' is a further indication that paragraph 823(a)(1) is not intended to cover precisely the same consideration. To restate this interpretation somewhat, whereas paragraph 823(a)(1) can be viewed as preventing diversion on a registrant-wide scale (by directing the agency to consider limiting the total number of registered bulk manufacturers and importers of schedule I and II controlled based on the principle—discussed below—that fewer registrants decreases the likelihood of diversion), paragraph 823(a)(5) can be viewed as preventing diversion on an individual-registrant basis (by directing the agency to consider whether the applicant will have in place, in its particular establishment, effective controls against diversion).[103]

In sum, for the preceding reasons, examining the text of paragraph 823(a)(1) can lead squarely to the conclusion that it requires DEA to maintain effective controls against diversion by considering ''limiting the * * * bulk manufacture of [schedule I and II] controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions.''

2. Legislative History of the Statute

Congress derived paragraph 823(a)(1) from the Narcotics Manufacturing Act of 1960 [104] (which was superseded by the CSA in 1970). Under the 1960 Act, a person seeking to manufacture a basic class of narcotic drugs was required to obtain a license from the Secretary of the Treasury Department. Within the Treasury Department, this function was delegated to the Commissioner of the Bureau of Narcotics (a predecessor of DEA). Section 8 of the 1960 Act set forth the criteria that the Commissioner was required to consider in determining whether to issue a narcotics manufacturing license. Paragraph (a)(1) of section 8 of the 1960 Act was the analog to paragraph 823(a)(1) of the CSA. Paragraph (a)(1) provided that, in determining whether to issue a license to an applicant seeking to manufacture a basic class of narcotic drug, the Commissioner was required to consider:

> Maintenance of effective controls against the diversion of the particular basic class of narcotic drug and of narcotic drugs compounded therefrom into other than legitimate medical and scientific channels *through limitation of manufacture of the particular basic class of narcotic drug to the smallest number of establishments which will produce an adequate and uninterrupted supply* of narcotic drugs of or derived from such basis class of narcotic drugs for medical and scientific purposes, consistent with the public interest.

(Emphasis added.)

As the italicized language above indicates, the 1960 Act reflected the then-policy of the United States to limit the number of licensed manufacturers ''to the smallest number of establishments which will produce an adequate and uninterrupted supply''—without regard to whether there was adequate competition. Plainly, there are both similarities to and distinctions between this provision of the 1960 Act and its counterpart in the CSA. The CSA carried forward the concept of ''limiting'' the number of registered manufacturers (with respect to schedule I and II controlled substances). However, the CSA modified this requirement by providing that this limitation on the number of manufacturers be based not only on that which can produce ''an adequate and uninterrupted supply,'' but also on that which provides for ''adequately competitive conditions.'' Put slightly differently, when Congress enacted the CSA, it raised the ceiling on the number of manufacturers from that which can produce ''an adequate and uninterrupted supply'' to a consideration of that which can produce ''an adequate and uninterrupted supply * * * under adequately competitive conditions.'' [105] The policies underlying

[100] OCBC, 532 U.S. at 492 (2001).

[101] 21 U.S.C. 826 & 828.

[102] *See* 21 CFR 1301.71–1301.93.

[103] As discussed below, some prior DEA final orders have construed paragraph 823(a)(1) to require consideration of the existence in the establishment of effective control against diversion. While this factor must be considered in evaluating any application for registration under § 823(a), it is best considered only for purposes of paragraph 823(a)(5) and not mingled with the analysis under paragraph 823(a)(1).

[104] 74 Stat. 55 (1960).

[105] To be precise, the text of the CSA (in contrast to that of the 1960 Act) does not unambiguously impose an absolute ceiling on the number of registered manufacturers (that which can produce an adequate and uninterrupted supply under adequately competitive conditions). Rather, as indicated above, the text of the CSA requires DEA

this change in the law are summarized in the following exchange during the Congressional hearings on the enactment of the CSA. The exchange was between Senator Hruska (one of the co-sponsors of the various bills that led up to the CSA) and then-Attorney General Mitchell:

Senator Hruska: We have two national policies involved here. One is the anticompetitive situation policy. The antitrust law is a very well-established concept * * * . We also have another national policy have we not, Mr. Attorney General? We have entered into a global series of agreements in which we undertake in joint action with other nations the business of controlling the manufacture and distribution of the opiates and final derivatives of opium. Among those agreements is this principle: That we urge upon nations to keep the number of producers down to as low a point as possible to facilitate and to make more certain their ability to control and supervise the output and to keep it in normal and proper legal channels. We have these two national policies involved here, have we not?

Mr. Mitchell: Yes sir, you have both of them, and there is no intention on the part of the Justice Department nor the Bureau of Narcotics and Dangerous Drugs by this provision to expand beyond necessity, and of course those are the key words, any manufacturers in this particular area. We felt it was necessary to maintain the protection of the consumer from the price structure point of view and that is why the additional provisions have been added.[106]

During that same hearing, the Department of Justice submitted in writing its position regarding a proposed version of what would become paragraph 823(a)(1). In that document, the Department of Justice stated the following with respect to the then-pending proposal to deviate in the CSA from the 1960 Act by adding the consideration of adequacy of competition, and how the Department would carry out such proposal, if enacted:

There is no reason to assume that the Attorney General will prejudice his primary objectives of effective control by excessive licensing. Nor will he undertake direct price control. He will be empowered to take cognizance of evidence showing that prices are clearly and persistently excessive. The criteria for determining whether prices far exceed that which is reasonable relate to reasonable costs and reasonable profits. No explicit statement of criteria is needed. If evidence indicates that additional licensing will result in more reasonable prices with no significant diminution in the effectiveness of drug control, the Attorney General should be able to license the additional manufacturers.[107]

Consistent with the foregoing statements made during the Senate hearings, a subsequent Senate report contained the following statement, which echoes the language of what is now in paragraph 823(a)(1): ''[T]he Attorney General must limit the importation and manufacture of schedules I and II substances to a number of establishments which can produce an adequate and uninterrupted supply under adequately competitive conditions for legitimate purposes.'' [108]

Thus, the legislative history reaffirms several principles already evident from the text of paragraph 823(a)(1) and expands upon those principles. The legislative history confirms that paragraph 823(a)(1) indeed was designed to require the Attorney General to take into account limiting the number of bulk manufacturers (and importers) of schedule I and II controlled substances. However, this limit was not as restrictive as under the law that preceded the CSA. Whereas under the 1960 Act, additional manufacturers could only be added if supply was inadequate, the CSA added the consideration of adequacy of competition. Nonetheless, as the legislative history reflects, Congress under the CSA placed the burden on the applicant seeking to become registered to bulk manufacture a schedule I or II controlled substance to put forth evidence demonstrating either inadequate supply or inadequate competition.

The legislative history also reflects the recognition by Congress of a crucial principle underlying paragraph 823(a)(1): That the risk of diversion tends to increase with each new registered bulk manufacturer of a schedule I or II controlled substance. At the same time, the language of paragraph 823(a)(1) reflects the determination by Congress that—despite the increased risk of diversion resulting from the addition of each new registered manufacturer—it is beneficial to the public interest to allow the registration of additional manufacturers where the Attorney General finds that doing so is necessary to produce an adequate and uninterrupted supply of a given substance under adequately competitive conditions.[109]

3. Treaty Considerations

The principle that limiting the number of producers of narcotics and other schedule I and II controlled substances tends to promote more effective control has long been a part of United States policy and incorporated into the international drug control treaties to which the United States has been a party and which predate the CSA. Under the Single Convention, article 29 addresses the manufacture of narcotic drugs. Paragraph 2(b) of article 29 requires parties to the treaty to ''[c]ontrol under license the establishment and premises in which such manufacture may take place.'' With respect to this provision, the Commentary to the Single Convention states: ''It is suggested that, in order to facilitate control, the licensing system under subparagraph (b) should be employed to ensure that the manufacture of drugs, their salts and preparations is restricted to as small a number of establishments and premises as is practicable.'' Commentary at 322 (emphasis added); *see also id.* at 319 (discussing how the concept of limiting the number of manufacturers of narcotic drugs was inherent in the international drug control treaties that preceded the Single Convention).[110] This is the same

to ''consider * * * limiting'' the number of manufacturers to such a number (along with considering the other public interest factors). It should also be noted that, whereas the 1960 Act referred to allowing only ''the *smallest* number of establishments which will produce an adequate and uninterrupted supply'' (emphasis added), the CSA does not contain the term ''smallest'' in paragraph 823(a)(1). Nonetheless, as explained above, the use of the term ''limiting'' in paragraph 823(a)(1) can be construed to mean that DEA, when evaluating an application under § 823(a), must consider keeping as the upper boundary on the number of manufacturers that which can produce an adequate and uninterrupted supply under adequately competitive conditions. In other words, even though Congress when it enacted the CSA did not carry forward from the 1960 Act the term ''smallest,'' because it did carry forward the term ''limiting,'' it retained the concept of an upper limit on the number of manufacturers as a factor to be considered when evaluating an application for registration under § 823(a).

[106] *Hearings Before the Subcomm. to Investigate Juvenile Delinquency of the Comm. on the Judiciary, United States Senate*, 91st Cong. 261–262 (1969).

[107] *Id.* at 372. Although this statement by the Department of Justice was commenting on an earlier version of the bill, the modified version of the bill that ultimately was enacted retained the same principles as the earlier version under which the adequacy of competition would become a consideration in determining whether to grant applications to become registered to manufacture schedule I or II controlled substances.

[108] *Controlled Dangerous Substances Act of 1969: Report of the Comm. on the Judiciary, United States Senate*, 91st Cong. 7 (1969).

[109] As the statute states, an application for registration under § 823(a) may only be granted if DEA determines that such registration is consistent with *both* the public interest and United States obligations under the Single Convention. Thus, even if a proposed registration were found by DEA to be consistent with the public interest based on a consideration of the six public interest factors of § 823(a), the registration must be denied if DEA finds it would be inconsistent with United States obligations under the Single Convention.

[110] Also illustrative of this point are the following statements contained in a 1979 resolution issued by the United Nations Commission on Narcotic Drugs, which DEA has cited in a prior **Federal Register** publication: ''Recalling the relevant provisions of

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principle as that referred to in the legislative history of the CSA (in the above-quoted exchange between Senator Hruska and the then-Attorney General).

4. Pertinent Provision of the DEA Regulations

The only applications for registration for which the DEA regulations require the agency to publish notice in the **Federal Register** are those by persons seeking to bulk manufacture and import schedule I and II controlled substances. 21 CFR 1301.33(a) & 1301.34(a). These are the applications governed by 21 U.S.C. 823(a). In the cases of such applications, the regulations further require DEA to mail (simultaneously with the publication in the **Federal Register**) a copy of the **Federal Register** notice to each person registered as a bulk manufacturer of the particular schedule I or II controlled substance and to each person who has submitted a pending application therefor. *Id.* Any such person may also file written comments or objections to the proposed registration. *Id.*

That the regulations provide the foregoing procedures in the case of applications filed pursuant to 21 U.S.C. 823(a)—and for no other categories of applications—is indicative of the distinction between the statutory factors for registration contained in subsection 823(a) and those contained in all other subsections of § 823. As explained above in the discussion of the text of the statute, whereas paragraph 823(a)(1) requires DEA to consider limiting the number of registered bulk manufacturers and importers of a given schedule I or II controlled substance to that which can produce an adequate and uninterrupted supply under adequately competitive conditions, this consideration appears nowhere else in § 823 (i.e., it is inapplicable to all other applications for registration). Moreover, the consideration of adequacy of supply and competition is the *only* factor that is unique to subsection 823(a). It is therefore implicit that the notice-and-comment provisions of the regulations listed above (those contained in 21 CFR 1301.33(a) and 1301.34(a)) are designed to effectuate the consideration by DEA of adequacy of supply and competition. This implication is also consistent with the view that, in addition to DEA and the applicant itself, those registrants that constitute the existing suppliers (bulk manufacturers) of a given schedule I or II controlled substance have the requisite knowledge to comment on whether the existing market is capable of producing an adequate and interrupted supply under adequately competitive conditions.

Thus, the notice-and-comment provisions of 21 CFR 1301.33(a) and 1301.34(a) provide further support for interpreting paragraph 823(a)(1) as requiring DEA to consider, for purposes of determining the public interest, limiting the number of registered bulk manufacturers and importers of schedule I and II controlled substances to that which can produce an adequate and uninterrupted supply under adequately competitive conditions.

Another provision of the regulations that warrants discussion is 21 CFR 1301.33(b), which states:

> In order to provide adequate competition, the Administrator shall not be required to limit the number of manufacturers in any basic class to a number less than that consistent with maintenance of effective controls against diversion solely because a smaller number is capable of producing an adequate and uninterrupted supply.

Although this provision is somewhat awkwardly phrased, a careful examination reveals that it is merely a corollary to paragraph 823(a)(1). In construing subsection 1301.33(b), it is important to bear in mind that an agency regulation cannot deviate from any mandate imposed by Congress under the statute that the regulation implements. Thus, any reading of subsection 1301.33(b) must be consistent with Congress's direction in paragraph 823(a)(1) that DEA consider limiting the number of bulk manufacturers of schedule I and II controlled substances to that which can produce an adequate and uninterrupted supply under adequately competitive conditions.

With the foregoing principles in mind, subsection 1301.33(b) can be broken down into its constituent elements for purposes of analysis as follows:

■ ''In order to provide adequate competition''; i.e., if it has been determined under paragraph 823(a)(1) that granting a particular applicant a registration to bulk manufacture a given schedule I or II controlled substance is necessary to provide an adequate and uninterrupted supply of that substance under adequately competitive conditions,

■ ''The Administrator shall not be required to limit the number of manufacturers in any basic class to a number less than that consistent with maintenance of effective controls against diversion''; i.e., if granting the applicant's registration (based on a finding of inadequate competition) will bring the total number of registered bulk manufacturers of a given schedule I or II controlled substance to a number which remains consistent with maintenance of effective controls against diversion, DEA is not obligated to keep the total *less than* that number,

■ ''Solely because a smaller number is capable of producing an adequate and uninterrupted supply''; i.e., based solely on the fact that the existing number of manufacturers already produces an adequate and uninterrupted supply (but under *in*adequately competitive conditions).

Viewing these elements together, it is apparent that subsection 1301.33(b) merely states what are direct outgrowths of 21 U.S.C. 823(a)(1):

(1) That the existence of an adequate and uninterrupted supply of a given schedule I or II controlled substance is *not* a sufficient basis to deny an application by a person seeking to become an additional manufacturer of that substance (since inadequate competition may provide an independent basis for registration under paragraph 823(a)(1)) and

(2) That DEA need not keep the number of registered bulk manufacturers to a number *below* that which is consistent with maintenance of effective controls against diversion where adding an additional manufacturer is necessary to provide for adequate competition.

Thus, 21 CFR 1301.33(b) can be reconciled with the statutory text (paragraph 823(a)(1))—as must be the case for the regulation to be valid.[111]

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the Single Convention * * * to limit cultivation, production, manufacture and use of narcotic drugs to an amount required for medical and scientific purposes * * *'' and ''Bearing in mind that the treaties which establish this system are based on the concept that the number of producers of narcotic materials for export should be limited in order to facilitate effective control. * * *'' Cited in 44 FR 33695 (1979) and available at *http://daccessdds.un.org/doc/RESOLUTION/GEN/NR0/638/29/IMG/NR063829.pdf?OpenElement.*

[111] It is unclear why subsection 1301.33(b) was written in the manner that it was. Given that the regulation was promulgated shortly after the enactment of the CSA in 1970, it is possible that it was written to emphasize how paragraph 823(a)(1) represented a departure from the provision it superseded in the 1960 Narcotic Manufacturing Act. As explained above, the 1960 Act limited the number of licensed manufacturers ''to the smallest number of establishments which will produce an adequate and uninterrupted supply''—without regard to whether there was adequate competition. In contrast, when Congress enacted the CSA, it raised the ceiling on the number manufacturers to that which can produce an adequate and uninterrupted supply *under adequately competitive conditions.* Subsection 1301.33(b) seems to emphasize this distinction between the 1960 Act and the CSA by pointing out that, under the latter, DEA may not deny an application based solely on the existence of an adequate and uninterrupted supply.

In 2004, the Department of Justice provided Congress with an explanation of subsection 1301.33(b) that is consistent with the explanation

5. Prior DEA Statements Regarding the Meaning of Paragraph 823(a)(1)

As discussed above, I now conclude that the text of paragraph 823(a)(1) indicates a directive, which is confirmed by the legislative history, that the agency consider limiting the number of registered bulk manufacturers and importers of controlled substances in schedules I and II to that which can produce an adequate and uninterrupted supply under adequately competitive conditions. Yet, in various final orders and other statements issued by DEA over the years, the agency has at times followed this approach and at other times failed to do so.

For example, in *Roxane Laboratories, Inc.,* 63 FR 55891 (1998), the agency applied paragraph 823(a)(1) consistent with the interpretation that requires the applicant to demonstrate that the existing manufacturer of the controlled substance in question is unable to provide an adequate and uninterrupted supply of the substance under adequately competitive conditions. Roxane Laboratories, Inc. (Roxane) was a company that applied to become registered to import cocaine hydrochloride, a schedule II controlled substance, for use in pharmaceutical products. As § 823(a) states, both an application to import a schedule I or II controlled substance and an application to bulk manufacture such a substance must be evaluated under the same criteria set forth in § 823(a).[112] Thus, in *Roxane,* the Acting Deputy Administrator had to evaluate whether the proposed registration was consistent with the public interest in view of the six public interest factors of § 823(a), including paragraph 823(a)(1).

Consistent with the interpretation of paragraph 823(a)(1) under which the adequacy of supply and competition must be considered, the parties in *Roxane* presented extensive evidence as to whether there was adequate competition within the meaning of the statute.[113] Toward that end, much of the testimony and other evidence introduced in the proceedings focused on the historical and prevailing prices for bulk cocaine hydrochloride charged by what was then the only registered importer of that substance. In addition to presenting factual evidence regarding such prices, each side presented its own economic expert to testify whether, in view of the prices, competition in the market was adequate within the meaning of paragraph 823(a)(1).[114] Ultimately, the Acting Deputy Administrator found that the applicant had met its burden under paragraph 823(a)(1) of demonstrating that competition was inadequate and, in view of all the applicable statutory factors, granted Roxane's application to become registered as an importer of cocaine hydrochloride.

Four years later, in *Johnson Matthey, Inc.*, 67 FR 39041 (2002), DEA again addressed the paragraph 823(a)(1) issue. As in *Roxane,* Johnson Matthey had applied to become registered as, among other things, an importer of schedule II controlled substances. Thus, as in *Roxane,* one of the central issues in *Johnson Matthey* was whether granting the application was necessary to provide adequate competition within the meaning of paragraph 823(a)(1).[115] The application was opposed by two firms that were already registered as importers of the same substances that Johnson Matthey sought to import. These competing firms contended at the administrative hearing that they maintained an adequate and uninterrupted supply of the substances under adequately competitive conditions. The two firms therefore objected to the proposed registration under paragraph 823(a)(1), among other grounds.

The final order in *Johnson Matthey* contains no description of the evidence presented by the parties during the administrative hearing on the competition issue as the final order expressly declared such evidence to be irrelevant. Nor does the *Johnson Matthey* final order contain a recitation of the text of paragraph 823(a)(1) or an independent analysis of the statutory text. Instead, the *Johnson Matthey* final order simply adopted a proposed rule that was published 18 years earlier by DEA and subsequently withdrawn by the agency. In that subsequently withdrawn 1974 proposed rule (39 FR 12138 (1974)), DEA proposed to revise its regulations to state that, during an administrative hearing on an application to manufacture a controlled substance in schedule I or II, if the ALJ determines that the registration would be consistent with maintenance of effective controls against diversion, he shall exclude as irrelevant evidence bearing on whether existing manufacturers are capable of producing an adequate and uninterrupted supply under adequately competitive conditions.

The *Johnson Matthey* final order failed to state that, two months after DEA published the aforementioned proposed rule in 1974, the agency published a notice in the **Federal Register** that three firms (which were then registered bulk manufacturers under § 823(a)) filed objections to, and requested a hearing on, the proposed rule, asserting that ''the Controlled Substances Act requires a finding respecting the adequacy of competition prior to registering any person to engage in the bulk manufacture of a schedule I or II substance.'' 39 FR 20382 (1974). These objections that were submitted in response to the 1974 proposed rule reflect precisely the same conclusion regarding the meaning of paragraph 823(a)(1) that I find—for the reasons discussed above—to be most

provided in the text above. *See Marijuana and Medicine: The Need for a Science-Based Approach: Hearing Before the Subcomm. on Criminal Justice, Drug Policy and Human Resources*, 108th Cong. 208 (2004) (letter from Assistant Attorney General William Moschella to Subcomm. Chairman Rep. Souder) (''The meaning of [21 CFR 1301.33(b)] can be restated as follows: *If DEA determines there is inadequate economic competition among the existing manufacturers of the particular controlled substance that the applicant seeks to produce* (e.g., substantial overcharging by the existing manufacturers due to an insufficient number of competing manufacturers of that controlled substance), and provided further that granting the applicant's registration (and thereby increasing the total number of manufacturers) is consistent with maintenance of effective controls against diversion, DEA is not required to deny the application solely because the number of manufacturers currently registered can adequately supply the market for that controlled substance in terms of quantity and quality of product.'') (emphasis in original).

[112] *See also* 21 U.S.C. 958(a) (a registration to import a schedule I or II controlled substance must be consistent with the public interest, based on consideration of the six criteria of § 823(a)). Further, 21 U.S.C. 952(a)(2)(B) requires a person seeking to become registered to import a schedule I or II controlled substance to demonstrate not only that competition among domestic manufacturers of the particular substance is inadequate but also that competition ''will not be rendered adequate by the registration of additional [domestic] manufacturers under section 823.'' Thus, an applicant to import a schedule I or II substance must make an additional showing beyond that required for an applicant to bulk manufacture such a substance. However, as § 823(a) indicates, both the applicant seeking to import and the applicant seeking to bulk manufacture are subject to the same 823(a) criteria, including the same determination under paragraph 823(a)(1) regarding the adequacy of competition.

[113] That the existing supply of cocaine hydrochloride was adequate within the meaning of paragraph 823(a)(1) was not in dispute in *Roxane.*

[114] As indicated above, because *Roxane* involved an application to import a schedule II controlled substance, the applicant was required demonstrate that competition was inadequate not only within the meaning of paragraph 823(a)(1), but also within the meaning of 21 U.S.C. 952(a)(2)(B). As to the latter, the DEA regulations require consideration of the factors set forth in 21 CFR 1301.34(d). These factors are specifically designed to assess competition in the context of an import application. However, as § 823(a) indicates, an application to import a schedule I or II controlled substance must also be evaluated under paragraph 823(a)(1) regarding the adequacy of competition.

[115] As Johnson Matthey had applied to import narcotic raw materials, the application also had to be evaluated under 21 U.S.C. 952(a)(1).

reconcilable with the text of the statute. That DEA withdrew the 1974 proposed rule a month after publishing these objections (39 FR 26031 (1974)) is consistent with the conclusion that the proposed rule could not be firmly reconciled with the statute.[116]

Thus, the *Johnson Matthey* final order appears to have been flawed both procedurally (by relying entirely upon a proposed rule that was withdrawn) and substantively (by relying on an interpretation of paragraph 823(a)(1) that is, in my view, difficult to reconcile with the statutory text). Nonetheless, it must be recognized that the *Johnson Matthey* final order was upheld on appeal in *Noramco* v. *DEA*, 375 F.3d 1148 (D.C. Cir. 2004). Examining the *Noramco* decision is therefore warranted. Before doing so, however, it is necessary to review another DEA final order that was issued shortly after *Johnson Matthey*.

In *Penick Corporation Inc.*, 68 FR 6947 (2003), DEA evaluated the paragraph 823(a)(1) issue in a different manner than it had done eight months earlier in the *Johnson Matthey* final order. As in *Roxane* and *Johnson Matthey*, Penick had applied with DEA to become registered as, among other things, an importer of schedule II controlled substances. Also as in *Roxane* and *Johnson Matthey*, the applicant's competitors (who were already in the market as registered importers of the same substances) objected to the proposed registration contending, among other things, that the applicant had failed to demonstrate the existence of inadequate competition within the meaning of paragraph 823(a)(1). However, in contrast to the *Johnson Matthey* final order, the *Penick* final order did not disregard the competition issue as irrelevant. Nor did the *Penick* final order mention the 1974 proposed rule (that was subsequently withdrawn), which was relied upon in *Johnson Matthey*. Rather, the *Penick* final order did examine the evidence presented on the competition issue and ultimately concluded: ''Having found that the market is not adequately competitive, the Deputy Administrator concludes that this factor weighs in favor of granting Penick's application, even though *Noramco* and Mallinckrodt are capable of maintaining an adequate and uninterrupted supply.'' [117] The *Penick* final order did not address the *Johnson Matthey* final order or why the two final orders took a differing approach as to the competition issue.

Both the *Johnson Matthey* final order and the *Penick* final order were challenged by a competitor (Noramco) in *Noramco* v. *DEA*. The United States Court of Appeals for the D.C. Circuit consolidated Noramco's two petitions for review into one appellate proceeding. With respect to the *Johnson Matthey* final order, Noramco contended that DEA erred by failing to consider the adequacy of competition and limit the number of importers to that which can produce an adequate and uninterrupted supply under adequately competitive conditions as paragraph 823(a)(1) requires. The D.C. Circuit panel reviewed DEA's decision ''under the familiar two-step *Chevron* framework.'' [118] Under this framework, if the reviewing court finds that the statute does not directly address ''the precise question at issue'' (step one), the court must sustain the agency's interpretation if it is ''based on a permissible construction of the statute'' (step two).[119] The court of appeals in *Noramco* upheld the *Johnson Matthey* final order, under *Chevron* step two, finding that DEA's decision to disregard competition to be a ''permissible interpretation'' of paragraph 823(a)(1).[120] Simultaneously, the court of appeals in *Noramco* upheld the *Penick* final order after reciting how DEA did consider the competition issue as paragraph 823(a)(1) directs. That the final orders in *Johnson Matthey* and *Penick* were inconsistent with one another as to the interpretation of paragraph 823(a)(1) was rejected by the court of appeals as a basis for reversal.[121]

It is especially important to note here that, under *Chevron* step two, ''[t]he court need not conclude that the agency construction was the only one it permissibly could have adopted to uphold the construction, or even the reading the court would have reached if the question initially had arisen in a judicial proceeding.'' [122] Accordingly, when the court in *Noramco* upheld the final order in *Johnson Matthey,* it was not offering an opinion whether that final order had interpreted paragraph 823(a)(1) in the best manner; rather, the court was merely stating that DEA (being owed the measure of *Chevron* deference accorded to an agency that administers a statute) had put forth a ''permissible interpretation'' of the statute. This point is underscored by the fact that the court in *Noramco* also upheld the *Penick* final order, which interpreted paragraph 823(a)(1) in a notably different manner than did the *Johnson Matthey* final order.

Thus, nothing in the *Noramco* decision constrains DEA from concluding, as I now do, that the most sound reading of the text of paragraph 823(a)(1) is that which requires the agency to consider limiting the number of bulk manufacturers and importers of schedule I and II controlled substances to that which can produce an adequate and uninterrupted supply of a given substance under adequately competitive conditions.

In 2006, another final order was issued involving the competition issue. In *Chattem Chemicals, Inc.*, 71 FR 9834 (2006), *petition for review denied, Penick Corp., Inc.* v. *DEA*, 491 F3d 483 (D.C. Cir. 2007), the applicant sought to become registered to import a schedule II controlled substance, just as Roxane, Johnson Matthey, and Penick had previously done. In the final order, which I issued, I followed the *Johnson Matthey* approach of declining to consider the adequacy of competition or supply. In doing so, I expressly noted that this approach had been ''approved by the appellate court in *Noramco.*'' [123] Upon review of the *Chattem* final order, the court of appeals likewise reaffirmed that, under *Noramco*, this approach of not considering adequacy of competition was a permissible reading of the statute. *Penick*, 491 F.3d at 491 n.11. However, for the reasons discussed at length above, I now believe that this approach—though deemed permissible upon *Chevron* review—must be rejected in favor of that which more accurately follows the text of the statute; i.e., the approach that was taken in *Roxane* and *Penick* of considering limiting the number of bulk manufacturers and importers of a given schedule I or II controlled substance to that which can produce an adequate and uninterrupted supply under adequately competitive conditions.[124] In addition

[116] The notice of withdrawal of the proposed rule stated that DEA was in the midst of reviewing and revising all the agency regulations in their entirety and that the proposed amendments regarding the competition issue ''are withdrawn so that all proposed changes to the regulations may be published together.'' However, DEA never again proposed to amend its regulations to eliminate the consideration—that paragraph 823(a)(1) mandates—of adequacy of supply and competition.

[117] 68 FR at 6950.

[118] 375 F.3d at 1152 (citing *Chevron U.S.A, Inc.* v. *Natural Res. Def. Council*, 467 U.S. 837, 842–43 (1983)).

[119] *Id.*

[120] 375 F.3d at 1153.

[121] 375 F.3d at 1157 n.8.

[122] 467 U.S. at 843 n.11.

[123] 71 FR at 9838.

[124] While it is certainly preferable that an agency interpret a statutory provision that it administers in a consistent manner throughout the agency's existence, the head of an agency ''is not estopped from changing a view she believes to have been grounded upon a mistaken legal interpretation.'' *See Thomas Jefferson University* v. *Shalala*, 512 U.S. 504, 517 (1994); *cf. Chevron*, 467 U.S. at 863 (''The fact that the agency has from time to time

to finding this interpretation to be that which most closely mirrors the text of the statute, I believe that, upon consideration of the legislative history and treaty considerations discussed above, this interpretation most effectively achieves the principles underlying the statutory text: Balancing the overarching goal of preventing the United States from being a source of domestic and international diversion by limiting the number of bulk manufacturers of schedule I and II controlled substances with the desire to ensure a level of competition adequate to prevent legitimate purchasers of these substances from being charged unreasonable prices.[125] The alternative interpretation, though found to be permissible, does not give full effect to these principles and provides no mechanism to prevent the proliferation of bulk suppliers of schedule I and II controlled substances beyond that necessary to adequately supply the legitimate United States demand for these materials under adequately competitive conditions. It is axiomatic that the proliferation of suppliers of bulk schedule I and II controlled substances heightens the risk of oversupply, which in turn increases the risk of diversion. The alternative interpretation, therefore, does not effectuate the statute and its underlying purposes as well as the interpretation followed in this final order.

D. Summary of the Discussion

For the reasons indicated above, I have determined that Respondent's proposed registration is inconsistent with United States obligations under the Single Convention and with the public interest based on a consideration of the factors set forth in 21 U.S.C. 823(a). With respect to the Single Convention, Respondent's desire to become registered in order to achieve MAPS's goal of ending the Federal Government's monopoly on the wholesale distribution of marijuana cannot be squared with the requirement under the Convention that there be precisely such a monopoly. With respect to the public interest, Respondent's failure to demonstrate that the longstanding existing system in the United States of producing and distributing research-grade marijuana under the oversight of HHS and NIDA is inadequate within the meaning of 21 U.S.C. 823(a)(1) weighs heavily against granting his application. Also with respect to the public interest, the admitted conduct relating to controlled substances of Respondent's sponsor, Mr. Doblin (in particular, Mr. Doblin's past and ongoing conduct relating to marijuana) is unacceptable for anyone seeking to have a prominent role in overseeing the controlled substance activities of a DEA registrant—especially where the registrant's proposed activities are the manufacture and distribution of the very drug marijuana. In sum, there are three independent grounds, any of which, standing alone, provide a sufficient (indeed, compelling) legal basis for denying Respondent's application.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(a), as well as 28 CFR 0.100(b) & 0.104, appendix to subpart R, sec. 7(a), I order that the application of Lyle E. Craker, Ph.D., for a DEA certificate of registration as a manufacturer of marijuana be, and hereby is, denied. This order is effective February 13, 2009.

Dated: January 7, 2009.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E9–521 Filed 1–13–09; 8:45 am]

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changed its interpretation of [a statutory provision] does not * * * lead us to conclude that no deference should be accorded the agency's interpretation of the statute.'').

[125] DEA has never invoked the ''limiting'' language of paragraph 823(a)(1) as a basis to revoke the registration of an existing bulk manufacturer that is currently utilizing its registration to supply the market for a given schedule I or II controlled substance, and this final order should not be construed as suggesting a departure from such practice.

DEPARTMENT OF JUSTICE

Foreign Claims Settlement Commission of the United States

Privacy Act of 1974; System of Records

AGENCY: Foreign Claims Settlement Commission of the United States.

ACTION: Notice of a New System of Records.

SUMMARY: Pursuant to the Privacy Act of 1974 (5 U.S.C. 552a), the Foreign Claims Settlement Commission (Commission), Department of Justice, proposes to establish a new system of records to enable the Commission to carry out its statutory responsibility to determine the validity and amount of the claims submitted to the Commission against Libya. The Claims Against Libya System will include documentation provided by the claimant as well as background material that will assist the Commission in the processing of their claims. The system will also include the final decision of the Commission regarding the claim.

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), the public is given a 30-day period in which to comment; and the Office of Management and Budget (OMB), which has oversight responsibility under the Act, requires a 40-day period in which to conclude its review of the system. Accordingly, please submit any comments by February 17, 2009.

ADDRESSES: The public, OMB, and Congress are invited to submit any comments to the Foreign Claims Settlement Commission of the United States, 600 E Street, NW., Suite 6002, Washington, DC 20579.

FOR FURTHER INFORMATION CONTACT: The Administrative Office, Foreign Claims Settlement Commission, U.S. Department of Justice, 600 E Street, NW., Suite 6002, Washington, DC 20579, or by telephone at 202–616–6975. In accordance with 5 U.S.C. 552a(r), the Department has provided a report to OMB and the Congress on the new system of records.

Dated: January 9, 2009.

Mauricio Tamargo,

Chairman.

JUSTICE/FCSC–29

SYSTEM NAME:

Libya, Claims Against.

SYSTEM LOCATION:

Offices of the Foreign Claims Settlement Commission, 600 E Street, NW., Suite 6002, Washington, DC 20579.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Persons with claims against Libya covered by the August 14, 2008 Claims Settlement Agreement Between the United States of America and the Great Socialist People's Libyan Arab Jamahiriya and referred by the Department of State to the Foreign Claims Settlement Commission.

CATEGORIES OF RECORDS IN THE SYSTEM:

Claim information, including name and address of claimant and representative, if any; date and place of birth or naturalization; nature of claim; description of loss or injury including medical records; and other evidence establishing entitlement to compensation.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority to establish and maintain this system is contained in 5 U.S.C. 301 and 44 U.S.C. 3101, which authorize the Chairman of the Commission to create

Drug	Schedule
Tetrahydrocannabinols (7370)	I
Methamphetamine (1105)	II
Pentobarbital (2270)	II
Nabilone (7379)	II

With regard to Gamma Hydroxybutyric Acid (2010), Tetrahydrocannabinols (7370), and Methamphetamine (1105) only, the company manufactures these controlled substances in bulk solely for domestic distribution within the United States to customers engaged in dosage-form manufacturing.

With regard to Nabilone (7379) only, the company presently manufactures a small amount of this controlled substance in bulk solely to conduct manufacturing process development within the company. It is the company's intention that, when the manufacturing process is refined to the point that its Nabilone bulk product is available for commercial use, the company will export the controlled substance in bulk solely to customers engaged in dosage-form manufacturing outside the United States. The company is aware of the requirement to obtain a DEA registration as an exporter to conduct this activity.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Norac, Inc. to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Norac, Inc. to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: August 9, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–21073 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated April 13, 2011, and published in the **Federal Register** on April 20, 2011, 76 FR 22146, Stepan Company, Natural Products Dept., 100 W. Hunter Avenue, Maywood, New Jersey 07607, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Cocaine (9041)	II
Ecgonine (9180)	II

The company plans to manufacture the listed controlled substances in bulk for distribution to its customers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a), and determined that the registration of Stepan Company to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Stepan Company to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: August 10, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–21081 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated April 25, 2011, and published in the **Federal Register** on May 4, 2011, 76 FR 25375, Rhodes Technologies, 498 Washington Street, Coventry, Rhode Island 02816, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Tetrahydrocannabinols (7370)	I
Methylphenidate (1724)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Oripavine (9330)	II
Thebaine (9333)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Fentanyl (9801)	II

The company plans to manufacture the listed controlled substances in bulk for conversion and sale to dosage form manufacturers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Rhodes Technologies to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Rhodes Technologies to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: August 10, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–21080 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 05–16]

Lyle E. Craker, PhD; Order Regarding Officially Noticed Evidence and Motion for Reconsideration

Lyle E. Craker, PhD (Respondent) has requested that I reconsider the Final Order I issued on January 7, 2009 (74 FR 2101), which denied his application to

become registered as a bulk manufacturer of marijuana. For the reasons provided below, Respondent has failed to demonstrate that the Final Order contains any erroneous material findings of fact or conclusions of law. Accordingly, Respondent's motion for reconsideration does not provide a basis for altering the decision in the Final Order to deny his application.

I. Post-Final-Order Proceedings

Following the issuance of the January 7, 2009, Final Order, Respondent submitted a letter to me dated January 21, 2009, noting that, in several places in the Final Order, I indicated I was taking official notice of certain documents that were not submitted during the administrative hearing. With respect to such documents, the Final Order states: ''To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within fifteen days of service of this order which shall commence with the mailing of the order.'' Thus, Respondent had until January 23, 2009, to file a motion for reconsideration of the facts of which I took official notice. In his January 21, 2009, letter, Respondent requested an extension of this filing deadline until January 30, 2009. I granted this request for an extension by letter dated January 22, 2009.

On January 30, 2009, Respondent submitted to me a document entitled ''Request for Opportunity Under 5 U.S.C. 556(e) To Respond to New Officially Noticed Evidence and Motion for Reconsideration.'' In this document, Respondent provided a preliminary response to those documents of which I took official notice. However, Respondent asked for additional time to supplement his preliminary response, given the length of the Final Order as well as that of the documents of which I took official notice. I granted this request, allowing Respondent until March 11, 2009, to supplement his response and motion. I further instructed that counsel for the Government would have to submit its response no later than 15 days after being served with Respondent's submission.

On March 11, 2009, Respondent submitted ''Respondent's Supplemental Brief in Support of Request Under 5 U.S.C. 556(e) To Respond to New Officially Noticed Evidence and Motion for Reconsideration.'' In this document, Respondent provided the legal and factual bases for his motion for reconsideration of the Final Order. Also in the document, Respondent requested that the administrative hearing be reopened so that he may call additional witnesses in view of certain documents of which I took official notice in the final order. The Government submitted its response on April 13, 2009. In view of these submissions, and to clarify Respondent's request, I issued an interim order on May 18, 2009, directing Respondent to submit a list of all witnesses he would call if his request to reopen the administrative hearing were granted and to provide a summary of the proposed testimony for each witness. This interim order further instructed Respondent to indicate precisely which documents he sought to introduce for purposes of his motion for reconsideration and, for each document, whether he wanted me to take official notice of it, or whether he wished to introduce it through witnesses if his request to reopen the hearing were granted.

On June 5, 2009, Respondent submitted his ''Witness List and Document List in Support of Motion for Reconsideration.'' On December 2, 2010, I issued an order granting in part, and denying in part, Respondent's request that I take official notice of certain documents. The order denied Respondent's request that I reopen the hearing to allow him to call additional witnesses. Having ruled on which new documents would be considered part of the record (through my taking official notice thereof), the order then gave Respondent an additional opportunity to file a final brief in support his motion for reconsideration. The order stated that Respondent was required to submit such brief on or before March 7, 2011, and that the Government's responsive brief was due no later than 30 days after receipt of Respondent's brief. Respondent submitted his brief on March 7, 2011 (hereafter, ''Respondent's latest submission''), and the Government submitted its responsive brief on April 1, 2011.

II. Respondent's Additional Proposed Documentary Exhibits

Respondent's request to introduce additional documents for purposes of his motion for reconsideration was addressed at length in my December 2, 2010, Order. For each such document Respondent sought to introduce, the December 2, 2010, Order stated (pages 23–27) whether I would take official notice of the document, and the reasons therefor. Only *one* category of documents that Respondent sought to introduce was left unresolved by the December 2, 2010, Order. As to this category, the order stated (page 26):

> If Respondent submits all of the correspondence between Chemic and HHS (or any of its components) relating to this application [Chemic's application to HHS to receive marijuana for research] that he has in his possession or can reasonably access (including, but not limited to, any such correspondence on the MAPS website, such as the January 23, 2009, letter from HHS to Chemic), I will take official notice of all such correspondence.

Thus, the only additional documents that might be considered at this juncture for inclusion in the record (by my taking official notice thereof) are the ''correspondence between Chemic and HHS'' described in the above-quoted sentence. Respondent's latest brief seeks to introduce 11 new documents (which Respondent labels Exhibits A–K). However, only four of these documents (Exhibits C, I, J, and K) appear to be correspondence between Chemic and HHS. The remaining seven documents (A, B, D, E, F, G, and H) do not appear to be correspondence between Chemic and HHS, and Respondent makes no assertion in his brief that they are such. The Government asserts in its responsive brief that these Exhibits A, B, E, F, G, and H are not ''correspondence'' and further that ''Respondent has not laid any foundation to demonstrate that these exhibits were provided to HHS by Chemic.'' For this reason, among others, the Government objects to including these documents in the record.

Accordingly, I rule as follows with respect to these latest proposed exhibits:

(1) I will take official notice of Exhibits C, I, J, and K; and

(2) As Exhibits A, B, D, E, F, G, and H do not comport with the instructions contained in the December 2, 2010, Order, I will not take official notice of these documents, and they will not be considered part of the administrative record considered by the agency in this adjudication.

III. Respondent's Motion for Reconsideration

Given the number of written submissions made by Respondent following the issuance of the January 7, 2009, Final Order, along with the Government's responses thereto and the interim orders I issued regarding these submissions, it is important to reiterate here the purpose for which Respondent was given an opportunity to file a motion for reconsideration. That purpose was stated in the January 7, 2009, Final Order: ''To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within fifteen days of service of this order which shall

commence with the mailing of the order.'' 74 FR at 2108 n.24. This was restated in the interim orders I issued following the Final Order. As explained in the Final Order and the December 2, 2010, Order, this opportunity to seek reconsideration of facts of which the agency takes official notice is derived from the Administrative Procedure Act (5 U.S.C. 556(e)) and the DEA regulations (21 CFR 1316.59(e)).

Respondent's post-Final-Order submissions have, in many respects, gone beyond seeking reconsideration of facts of which I took official notice. Respondent has essentially sought broad reconsideration of the factual and legal bases for the Final Order—generally without predicating such arguments on the taking of official notice of any fact. Neither the Controlled Substances Act (CSA) nor the DEA regulations provide for such a broad-based motion for reconsideration of a Final Order.[1] Nonetheless, in the exercise of my discretion, taking into account the complex and sometimes novel issues involved in this matter, I have considered all of the arguments Respondent has submitted in his post-Final-Order submissions—including those that go beyond the scope of what is permitted by 5 U.S.C. 556(e) and 21 CFR 1316.59(e).

The arguments contained in Respondent's post-Final-Order submissions are, for the most part, reiterations of the same arguments that were addressed at length and rejected in the Final Order. In a few instances, as noted below, Respondent does present some slightly different assertions than he previously offered. However, even in these instances, Respondent's core contentions remain those that I previously rejected. Furthermore, Respondent fails in these latest submissions to rebut the fundamental reasons that were provided in the Final Order for denying his application.

[1] The CSA appeal provision, 21 U.S.C. 877, states: ''All final determinations, findings, and conclusions of the [Administrator of DEA] under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the [Administrator] may obtain review of the decision in the United States Court of Appeals * * *.'' This provision suggests that—outside of the scenario provided by the DEA regulations and APA in which a party, on timely request, seeks the opportunity to controvert facts of which the agency took official notice—DEA is not obligated to allow parties to seek reconsideration of final orders regarding applications for registration. DEA also adheres to the Supreme Court's decision in *Interstate Commerce Comm'n* v. *Bhd. of Locomotive Eng'rs,* 482 U.S. 270 (1987), regarding the reopening of proceedings where it is alleged that new evidence or changed circumstances render the agency's original order inappropriate. *See also Fry* v. *DEA,* 353 F.3d 1041, 1044 (9th Cir. 2003).

A. Respondent's Arguments Relating to the Review of Research Protocols by the Department of Health and Human Services

In his post-Final-Order submissions, Respondent continues to focus on what was his primary theme throughout the adjudication proceedings leading up to the Final Order: his desire to have the Public Health Service and the National Institute on Drug Abuse (NIDA) removed from the process by which the Department of Health and Human Services (HHS) carries out its statutory duty to review proposed research involving marijuana. For purposes of context, it is repeated here, as explained in the Final Order, that under the CSA (21 U.S.C. 823(f)), the Secretary of HHS is responsible for reviewing all proposed research involving schedule I controlled substances. Specifically, section 823(f) provides that, with respect to applications for registration by practitioners wishing to conduct research with schedule I controlled substances, ''the Secretary * * * shall determine the qualifications and competency of each practitioner requesting registration, *as well as the merits of the research protocol.''* (Emphasis added.) Thus, under section 823(f), a research proposal involving marijuana may only go forward where the Secretary both (1) Deems the practitioner qualified and competent and (2) determines the research protocol to be meritorious. Or, as stated by HHS in its 1999 announcement of its policies for providing marijuana to researchers: ''To receive such a registration [under § 823(f)], a researcher must first be determined *by HHS* to be qualified and competent, and the proposed research must be determined *by HHS* to have merit.'' 74 FR at 2120 n.70 (emphasis added in Final Order).

Respondent does not dispute that the statute assigns the foregoing functions to the Secretary of HHS. However, Respondent objects to the manner in which these functions are carried out within HHS. In particular, Respondent seeks to have the Public Health Service and NIDA stripped of any role in this process.[2]

For purposes of addressing this issue, it is useful to repeat the following parts of the Final Order, which discussed the scientific review process that has been utilized by HHS since 1999 to evaluate marijuana research proposals:

> [I]n 1999, due in part to an increased interest in marijuana research and taking into account the IOM report, HHS decided to change the procedures by which it would supply marijuana to researchers. The new procedures were announced in a document released by NIH on May 21, 1999. In the announcement, ''HHS recognize[d] the need for objective evaluations of the potential merits of cannabinoids for medical uses[,]'' and that ''[i]f a positive benefit is found, * * * the need to stimulate development of alternative, safer dosage forms.'' Toward this end, NIH explained that the new procedures were designed to increase the availability of marijuana for research purposes by, among other things, making such marijuana ''available on a cost-reimbursable basis.'' This new procedure allowed researchers who were privately funded to obtain marijuana from HHS by reimbursing the NIDA contractor for the cost of the marijuana. This was a departure from the prior practice (pre-1999), whereby HHS only made marijuana available to persons who received NIH funding. The new procedures implemented by HHS in 1999 remain in effect today.
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> * * * * *
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> At the administrative hearing in this case, Steven Gust, PhD, Special Assistant to the Director of NIDA, explained that, in addition to seeking to facilitate research into the possible medical utility of marijuana, the new procedures implemented by HHS in 1999 were intended ''to make the process more standardized, and to * * * provide some expertise that did not really exist at NIDA in terms of reviewing applications that involved * * * the use of marijuana * * * for treatment of diseases.'' Accordingly, HHS ''established a separate peer review process that * * * moved the review into the Public Health Service [a component of HHS] * * * where additional expertise from other NIH Institutes and other Federal agencies'' could be utilized in reviewing the scientific merit of the applications. Dr. Gust further explained that the members of the review committee are drawn from the various specialty institutes of NIH, and the Substance Abuse and Mental Health Services Administration (SAMHSA). Dr. Gust also testified that the ''scientific bar has been set very low, [so] that any project that has scientific merit is approved,'' and that ''anything that gets approved gets NIDA marijuana.'' As of April 2004, HHS had approved at least seventeen pre-clinical or clinical studies of marijuana, which were sponsored by the California Center for Medical Cannabis Research (CMCR). According to one witness who testified on behalf of Respondent, all of the CMCR-sponsored researchers who applied to NIDA for marijuana did in fact receive marijuana from NIDA.
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> In his testimony, Dr. Gust explained the term ''peer review'' as follows: ''Peer review is a process that has been used, certainly by NIH, and I think in other agencies in the Department of Health and Human Services, and probably the Federal Government, where outside expertise is acquired and outside opinions on the scientific merit of specific research proposals.'' Dr. Gust added that the NIH peer review committees ''review

[2] *See, e.g.,* 74 FR at 2106 (noting testimony of Rick Doblin, the Director of MAPS, that ''what we're trying to do is get the Public Health Service and NIDA out of the picture'').

proposals three times a year for the NIH, and there are—occasionally a Federal employee participates in one of those reviews, but probably 90 percent or more of the participants are researchers who are in the private sector, for the most part in academic institutions.''

74 FR at 2015, 2119 n.67 (footnotes and citations omitted).

Again, it is Respondent's contention that the involvement of the Public Health Service and NIDA in reviewing proposed marijuana research protocols has the effect of blocking legitimate research into marijuana. Indeed, the primary argument Respondent puts forth in support of his proposed registration is that the current system by which the United States Government makes marijuana available to researchers fails to provide an adequate supply of marijuana within the meaning of 21 U.S.C. 823(a)(1)—precisely because, in Respondent's opinion, the Public Health Service and NIDA have ''institutional biases'' against certain types of marijuana research.

This argument was carefully examined in the Final Order. *See* 74 FR at 2107–08, 2119–20. Respondent's post-Final-Order submissions as to this issue are not materially different from the claims that were rejected in the Final Order. In fact, the new documents that Respondent has submitted following the Final Order, and of which I have taken official notice, provide further confirmation of certain determinations made in the Final Order. Respondent's latest submission contains no citations to actual *evidence* in the record that supports his claims of ''institutional biases'' or ''political'' motivation on the part of the Public Health Service and NIDA.

As to this issue, the Final Order stated, among other things:

> Respondent also introduced into evidence a letter from the President of Chemic to HHS responding to several points raised by the PHS Committee in denying Chemic's application. Respondent's letter does not, however, establish that HHS impermissibly denied Chemic's application for marijuana. To the contrary, *the evidence supports the conclusion that HHS (acting through the PHS Committee) made its determination not to supply marijuana on this occasion based on scientific considerations, finding that Chemic's then-latest proposed study was duplicative of prior and ongoing research and not likely to provide useful data.*

74 FR at 2109 (emphasis added; footnote and citation omitted). As noted, I granted Respondent's post-Final-Order request to introduce additional correspondence between Chemic and HHS relating to Chemic's proposed research protocol involving marijuana. Respondent produced six additional pieces of correspondence between Chemic and HHS relating to this matter that were not produced in the administrative hearing. As indicated above and in the December 2, 2010, Order, I have taken official notice of all six of these documents. Each of these documents further confirms that HHS's rejection of the Chemic protocol was—as the Final Order found—based purely on scientific merit.

It is difficult to understand why Respondent would seek to introduce at this juncture six letters between Chemic and HHS that reaffirm what was found in the Final Order—and how Respondent construes these letters as ''rebuttal'' evidence. The statements by HHS in these letters are, without question, focused entirely on the scientific inadequacies of various iterations of Chemic's research proposal. The letters demonstrate that the HHS scientists have actively engaged in a dialogue with Chemic for many years, and have gone to great lengths to explain to Chemic each of the areas in which Chemic needs to revise its protocol so that it can be deemed scientifically meritorious. The letters thereby reaffirm that HHS (including, but not limited to, the Public Health Service and NIDA) has never indicated any opposition (political, philosophical, or otherwise) to any *category* of marijuana research. To the contrary, the letters—particularly the most recent one submitted by Respondent, dated January 23, 2009—actually show that HHS is interested in Chemic's proposal and willing to supply Chemic with marijuana, provided that Chemic provides validation data that is necessary to support Chemic's scientific measurements. In short, the evidence continues to point squarely to the conclusion that HHS is doing precisely what it is required to do under 21 U.S.C. 823(f): Allow only those schedule I research proposals that it determines to be scientifically meritorious to go forward. As the Final Order stated: ''That Respondent finds this process to be scientifically rigorous—and thereby not automatically accepting of any proposed study sponsored by MAPS—provides no basis for any valid objection or any contention that the HHS supply of marijuana is inadequate.'' 74 FR at 2120 (footnotes omitted).[3]

Moreover, Respondent's ''institutional bias'' theory is belied by the following crucial fact. As stated in the Final Order: ''The record reflects that since HHS changed its policies in 1999 to make marijuana more readily available to researchers (by, among other things, allowing privately funded researchers to obtain marijuana), every one of the 17 CMCR [California Center for Medical Cannabis Research]-sponsored pre-clinical or clinical studies that requested marijuana from NIDA was provided with marijuana.'' 74 FR at 2119. Despite the enormity of this fact in relation to Respondent's ''institutional bias'' claim, Respondent makes only the following vague reference to it in his latest submission (page 9): ''Though the DEA points to other marijuana research that NIDA has allowed, none of these studies aimed to develop marijuana into a legal prescription medicine.'' What Respondent downplays as ''other marijuana research that NIDA has allowed'' is, in fact, *seventeen* different clinical trials involving marijuana proposed by CMCR—*all* of which were approved by the Public Health Service and NIDA. As stated in the Final Order:

> Any suggestion that the HHS scientific review process is unduly rigorous is belied by the testimony of Dr. Gust that the ''scientific bar has been set very low, [so] that any project that has scientific merit is approved,'' and that ''anything that gets approved gets NIDA marijuana'' (Tr. at 1700–01) as well as the uncontroverted evidence that every one of the 17 CMCR-sponsored research protocols submitted to HHS was deemed scientifically meritorious by HHS and was supplied with marijuana (GX 31, at 3; Tr. 694–95).

74 FR at 2120 n.71.

As for Respondent's contention that ''none of these studies aimed to develop marijuana into a legal prescription medicine,'' this too is contradicted by the record. As stated in the Final Order:

> The California research studies were conducted pursuant to a law enacted by California in 1999 known as the Marijuana Research Act of 1999. Cal. Health & Safety Code § 11362.9. This state law established the ''California Marijuana Research Program'' to develop and conduct studies on the potential medical utility of marijuana. *Id.* (The program is also referred to as the ''Center for Medicinal Cannabis Research'' (CMCR). Tr. 396.) The state legislature

[3] It is unclear whether Respondent is suggesting that I should refuse to accept at face value what HHS stated in its correspondence with Chemic and instead conclude—without any evidentiary basis for doing so—that the HHS scientists who are responsible for reviewing proposed marijuana research have conspired for years to carry out an elaborate ruse aimed at thwarting marijuana research. If this is Respondent's mind-set, adopting it would be the antithesis of the principle inherent to the Administrative Procedure Act (APA) that agency action must be presumed to be valid where a reasonable basis exists for its decision. *See, e.g., Kern County Farm Bureau* v. *Allen,* 450 F.3d 1072, 1076 (9th Cir. 2006). It is also at odds with the APA concept that bars a reviewing court—much less a member of the public—from substituting its judgment for that of the agency. *Id.*

appropriated a total of $9 million for the marijuana research studies. Tr. 397.

74 FR at 2105–06 n.16. It is thus beyond question that the CMCR studies were aimed at what Respondent characterizes as ''develop[ing] marijuana into a legal prescription medicine.'' [4]

For the same reasons, the record contradicts Respondent's related claim that the involvement of the Public Health Service and NIDA in determining the scientific merit of proposed marijuana research ''renders the supply [of marijuana] inadequate because entire categories of legitimate medical research are effectively foreclosed.'' Respondent fails to explain what ''categories of legitimate medical research'' are supposedly being foreclosed. Again, it seems (but is unclear) that Respondent is suggesting that the Chemic research proposal, and/or Dr. Russo's proposal (see below), were more geared toward ''develop[ing] marijuana into a legal prescription medicine'' than were the 17 CMCR studies. In other words, Respondent appears to be suggesting that the Public Health Service and NIDA went into their alleged ''institutional bias'' mode when reviewing the Chemic and Russo proposals, but turned off that mode when reviewing the 17 CMCR proposals because the latter were less geared toward developing marijuana into an FDA-approved medicine. If this is what Respondent is suggesting, there is no evidentiary foundation for such a claim as neither Chemic's proposal nor Dr. Russo's could be characterized as closer than the CMCR studies to the goal of obtaining FDA approval of marijuana as a drug.[5]

To address further the portion of Respondent's latest submission pertaining to Dr. Russo, the following part of the Final Order is recited:

> [Dr. Ethan Russo] sought funding from NIDA to study the use of marijuana to treat migraine headaches beginning around 1996. The precise dates of the events related to Dr. Russo are somewhat unclear as Respondent presented these events through the testimony of Mr. Doblin. (Dr. Russo did not testify.) Based on Mr. Doblin's testimony, it appears that during 1996–97, NIDA twice rejected Dr. Russo's protocol for reasons which are not clearly established by the record. However, according to Mr. Doblin, Dr. Russo conceded that, on both of these two occasions when NIDA rejected his protocol, NIDA's bases for doing so did include ''some valid critiques.'' Mr. Doblin testified that Dr. Russo subsequently attempted for a third time to obtain marijuana from NIDA, but on this third occasion he decided not to seek government funding but to seek private funding to purchase the marijuana from NIDA. According to Mr. Doblin, this third protocol submitted by Dr. Russo was approved by both the FDA and Dr. Russo's institutional review board, but NIDA again refused to supply marijuana. When asked when this last denial by NIDA occurred, Mr. Doblin testified: ''I think it was 1999.''
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> As noted above, NIH announced on May 21, 1999, HHS's new procedures for making marijuana available to researchers. Bearing in mind that Respondent had the burden of proving any proposition of fact that he asserted in the hearing, 21 CFR 1301.44(a), nothing in Mr. Doblin's testimony, or any other evidence presented by Respondent, established that HHS denied Dr. Russo's request for marijuana under the new procedures implemented by the agency in 1999. Indeed, Respondent produced no evidence showing that HHS has denied marijuana to any clinical researcher with an FDA-approved protocol subsequent to the adoption of the 1999 guidelines.

74 FR at 2108 (citations omitted).

In his post-Final-Order submissions, Respondent submitted a letter dated February 1, 2000, from the Public Health Service and NIDA to Dr. Russo (Exhibit C to Respondent's March 11, 2009, Supplemental Brief). In the December 2, 2010, Order, I granted Respondent's request to take official notice of this document. As Respondent indicates, this letter was issued after HHS announced in 1999 its new procedures for providing marijuana to researchers. Even assuming, arguendo, that this letter demonstrates that the third protocol submitted by Dr. Russo was evaluated by HHS under the new procedures established in 1999,[6] this does not materially alter the conclusions in the Final Order. This is because the Final Order stated, in essence, that even if Dr. Russo's proposal had been evaluated by HHS under the post-1999 procedures, ''the evidence indicates that the denials involving * * * Dr. Russo were based on HHS finding [his] protocols to be lacking in scientific merit.'' *See* 74 FR at 2119 n.68.

The most recent document submitted by Respondent regarding Dr. Russo (the February 1, 2000, letter from Public Health Service to Dr. Russo) confirms yet again that the Public Health Service and NIDA focus on *scientific merit* in reviewing proposed marijuana research. The February 1, 2000, letter advised Dr. Russo that a scientific review of his protocol had been conducted by the Center for Scientific Review (CSR) of the National Institutes of Health on behalf of the Public Health Service, and that the CSR recommended certain changes to the protocol. If, the letter continued, such changes were incorporated into a new protocol and submitted by Dr. Russo, the Public Health Service would reconsider his request. Among the specific changes that Dr. Russo was advised to make were the following: Including a placebo arm; taking steps to account for possible attrition of research subjects; and ensuring that research subjects received equivalent doses of THC. These are quintessentially scientific refinements that the researcher was being asked to make—not, as Respondent alleges, a refusal to allow a category of research to take place.

Thus, even when viewing Respondent's newly submitted evidence regarding Dr. Russo as an example of a denial by HHS of marijuana under the post-1999 HHS procedures, it is in the same category as the Chemic protocols: A denial based on scientific merit under the post-1999 procedures. This would bring the total figures under the post-1999 procedures to the following: 17 studies approved and supplied with marijuana; two studies denied until the researcher makes certain changes in the protocol to render the proposal scientifically meritorious. Stated alternatively, under the post-1999 procedures, HHS's approval rate for marijuana studies is at least 89.5 percent, with the possibility of that figure rising to 100 percent if two of the researchers were willing to make adjustments to their protocols to make them scientifically meritorious.

Respondent's latest submission also refers to certain documentary and testimonial statements by NIDA officials, which Respondent contends support his claim of ''institutional bias.'' As these statements were part of the record that the parties addressed in their pre-Final-Order submissions, and since the Final Order already addressed this type of argument by Respondent, it is not necessary to reexamine this issue at length here. Moreover, the *actions* by HHS in response to actual research proposals are by far the best evidence of the agency's true willingness to supply marijuana to researchers, and these actions render inconsequential any attempt by Respondent to surmise ''institutional bias'' from abstract statements isolated from the documents

[4] The process by which FDA approves new drugs for marketing is summarized in the Final Order. 74 FR at 2106 n.21.

[5] As stated in the Final Order, no clinical trials involving marijuana—not even the 17 CMCR studies—have advanced beyond Phase 1 of the three phases required for FDA approval of a new drug. 74 FR at 2107 n.23. The proposed Chemic study does not even appear to be a clinical trial, let alone a study more advanced in the phases of FDA approval than the CMCR studies.

[6] While the letter itself is dated February 1, 2000, Respondent failed to present evidence indicating when Dr. Russo submitted his third protocol, or when HHS began its review of that protocol. Thus, it remains uncertain whether this third protocol was evaluated under the pre-1999 or post-1999 HHS procedures.

and testimony. The same considerations apply with respect to Respondent's argument that NIDA's mission stands as an obstacle to allowing legitimate marijuana research to take place. This argument was addressed in the Final Order and is overwhelmingly refuted by the evidence of HHS's actual track record in supplying marijuana to researchers.[7]

Respondent also asserts that two provisions of the Federal Food, Drug, and Cosmetic Act (FDCA) and an FDA regulation mandate that the FDA—and not NIDA—must carry out the Secretary of HHS's responsibility under 21 U.S.C. 823(f) to determine the scientific merit of proposed marijuana research. Specifically, Respondent cites 21 U.S.C. 393(b) (FDA's mission statement), 21 U.S.C. 355 (new drug approval process), and 21 CFR 312.22(a) (general principles of submission of an investigational new drug application (IND)), in support of this assertion.

This assertion is mistaken in a number of respects, including, but not limited to, the following. First, the fact that the FDA's statutory mission statement lists certain functions by no means precludes other agencies within HHS from having overlapping functions.[8] Second, while FDA is indeed the agency within HHS that is chiefly responsible for administering the new drug approval process under 21 U.S.C. 355, this is a distinctly different function than the determination under 21 U.S.C. 823(f) of the scientific merit of proposed research involving schedule I controlled substances. There is certainly no basis for Respondent (or any other member of the public) to dictate to the Secretary that the same agency within HHS that carries out the former function must also carry out the latter.[9] Third, although the review by FDA of an IND may (depending on the phase of the investigation) be similar in certain respects to the review under § 823(f) of a schedule I research proposal, the two types of reviews are distinct administrative functions carried out within HHS. This is evident from the first sentence of the very regulation that Respondent cites, 21 CFR 312.22(a), which states: ''FDA's primary objectives in reviewing an IND are, in all phases of the investigation, to assure the safety and rights of subjects, and in Phase 2 and 3, to help assure that the quality of the scientific evaluation of drugs is adequate to permit an evaluation of the drug's effectiveness and safety.'' Thus, in reviewing an IND for a Phase 1 investigation, FDA's primary objective is to assure the *safety and rights of subjects*—not to assess the scientific quality of the clinical investigation. This is especially notable since, as stated above, none of the clinical trials involving marijuana that have been proposed to HHS has advanced beyond Phase 1.

The foregoing discussion also sheds light on another assertion made by Respondent in his latest submission: That ''several research projects have been blocked by NIDA in spite of FDA-approved protocols.'' [10] Preliminarily, it should be noted that Respondent fails to specify exactly what he means here by ''several research projects.'' The record reveals only *two* clinical research proposals submitted to HHS involving marijuana that did not receive marijuana: Dr. Abrams's proposal (in the pre-1999 era) and Dr. Russo's proposal.[11] In addition, it is important at this juncture to correct an error in terminology. *FDA does not ''approve'' INDs.* Rather, the IND process works as follows. An investigator seeking to use an investigational new drug in a clinical trial must submit an IND for the drug to the FDA. 21 CFR 312.40. The IND automatically goes into effect 30 days after the FDA receives the IND,[12] unless the FDA notifies the sponsor that the investigation is subject to a clinical hold. *Id.*

Thus, it is incorrect for Respondent to state that the FDA ''approved'' any ''protocols'' for proposed marijuana research.[13] More accurately stated, the most that can be inferred from the evidence is that the FDA *reviewed INDs* submitted by Dr. Abrams and Dr. Russo, and that the FDA did not place a clinical hold on either proposed investigation.[14] However, as just explained, the FDA regulations indicate that, for Phase 1 investigations, FDA's review of an IND focuses primarily on the safety and rights of subjects—not the scientific quality of the clinical investigation. Thus, while the FDA appears to have concluded that allowing Dr. Russo's and Dr. Abrams's Phase 1 studies to proceed would not have presented an unacceptable risk of harm to the human research subjects,[15] there is no evidentiary basis to conclude that FDA evaluated the scientific quality of either proposal—and particularly no basis to conclude that FDA determined that the studies were scientifically meritorious within the meaning of 21 U.S.C. 823(f).

As stated in the Final Order, under the procedures implemented by HHS in 1999 for reviewing proposed marijuana research, the review by FDA on an IND is *one part* of that process.[16] Yet, Respondent seems to want FDA's

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[7] Although HHS's actual record in supplying marijuana to researchers is the best evidence of its willingness to do so, the following testimony of Dr. Gust at the hearing explains how HHS took steps in 1999 to ensure the availability of marijuana to researchers—including those interested in pursuing medical uses of marijuana—irrespective of NIDA's mission:

It was about this time [1999] when there was some increased interest in research, in pursuing the medical use of marijuana, and in an effort to make the process more standardized, and to basically provide some expertise that did not really exist at NIDA in terms of reviewing applications that involved primarily the use of marijuana or any other substance for that matter for treatment of diseases, which did not really fall within NIDA's mission, the department [HHS] established a separate peer review process that made the review—that moved the review into the Public Health Service at the time where additional expertise from other NIH Institutes and other Federal agencies could be brought to bear to help—and help provide reviews, appropriate reviews, of the scientific merit of these applications.

Tr. 1632–33. Thus, Respondent's attempt to focus on NIDA's particular mission, without regard to the mission of other components of HHS involved in review of marijuana research proposals, and without regard to the overall aims of the procedures established by HHS in 1999 for providing marijuana to researchers, is misplaced.

[8] Moreover, not even those functions expressly listed in FDA's statutory mission statement are carried out solely by the FDA. As stated in the very next subsection after the one cited by Respondent, 21 U.S.C. 393(c), which is entitled ''Interagency collaboration'': ''The Secretary [of HHS] shall implement programs and policies that will foster collaboration between the [FDA], the National Institutes of Health, and other science-based Federal agencies, to enhance the scientific and technical expertise available to the Secretary in the conduct of the duties of the Secretary with respect to the development, clinical investigation, evaluation, and postmarket monitoring of emerging medical therapies, including complementary therapies. * * *''

[9] Under 21 U.S.C. 823(f), Congress assigned to the Secretary of HHS sole discretion to determine how HHS carries out its responsibility to review the scientific merit of schedule I research proposals.

[10] Respondent uses this particular wording on page 9 of his latest submission, and he reiterates the assertion numerous times in the document.

[11] As Respondent seems to concede, Chemic's proposed research involving marijuana is *not* a clinical trial. Accordingly, Respondent does not appear to be suggesting that Chemic submitted an IND to the FDA for its research proposal. Thus, it does not appear that Respondent is including the Chemic situation in his category of ''research projects [that] have been blocked by NIDA in spite of FDA-approved protocols.''

[12] The FDA may also notify the investigator that the clinical investigation may begin earlier than 30 days after the FDA receives the IND. 21 CFR 312.40(b)(2).

[13] The word ''approve'' (or ''approval'') is a term of art in the FDCA. The FDA ''approves'' new drug applications upon an adequate showing of safety and efficacy for the uses in the proposed labeling, which allows a drug to be legally marketed. 21 U.S.C. 355; 21 CFR 314. An effective IND is considered ''accepted,'' not ''approved,'' by FDA.

[14] I am assuming, for the sake of discussion, that Dr. Russo and Dr. Abrams submitted INDs and that the FDA did not issue clinical holds, even though Respondent did not introduce such INDs or call Dr. Russo or Dr. Abrams to testify.

[15] *See* 21 CFR 312.42(b) (grounds for imposition of a clinical hold of a Phase 1 study under an IND).

[16] *See* 74 FR at 2105.

review of an IND for Phase 1 investigations—which focuses on the safety and rights of subjects, rather than the scientific quality of the clinical investigation—to serve as the entire review process, *i.e.,* to supplant the full-fledged evaluation of the scientific merit required by 21 U.S.C. 823(f). Had Congress intended such a result, it could have easily stated in 21 U.S.C. 823(f) that the only scientific prerequisite to conducting research with a schedule I controlled substance is that an IND be in effect with respect to such research.[17] But it is evident from the language of § 823(f) that Congress intended HHS to conduct a different type of evaluation of the scientific merit of research proposals than that which will suffice for purposes of an IND. It is unclear whether Respondent fails to understand this distinction between the review by FDA of a Phase 1 IND and the review of the scientific merit of a research proposal under § 823(f), or if Respondent does understand this distinction and simply wishes that the less rigorous review (the Phase 1 IND review) would suffice so that even those marijuana research proposals that lack scientific merit could be carried out.[18] For the reasons noted above, neither of the foregoing is a legally valid position.

In sum, Respondent's motion for reconsideration provides no basis for deviating from the conclusions in the Final Order relating to the process by which HHS determines the scientific merit of proposed marijuana research pursuant to 21 U.S.C. 823(f). Congress assigned to the Secretary of HHS responsibility for deciding how to carry out that function within HHS, and the evidence demonstrates that the procedures established by HHS in 1999, including the Public Health Service interdisciplinary review process, properly focus on the scientific merit of research proposals. As the Final Order indicated, that process makes marijuana available to all researchers who meet the criteria of § 823(f), and Respondent's post-Final-Order submissions provide no evidence suggesting otherwise. Respondent's desire to substitute his opinion for that of the Secretary as to what type of scientific review should be carried out under § 823(f), and who within HHS should carry it out, is legally untenable.

Respondent's claim that the supply of marijuana is inadequate is dependent on his supposition that the current HHS process for supplying marijuana to researchers improperly denies marijuana to researchers. That supposition was found in the Final Order to be without merit, and his latest submission warrants no departure from that finding, as explained above. Accordingly, Respondent has provided no basis to change the conclusion in the Final Order that he failed to meet his burden of proving that the supply of marijuana is inadequate within the meaning of 21 U.S.C. 823(a)(1).

B. Respondent's Arguments Relating to the Single Convention on Narcotic Drugs, 1961

Respondent seeks reconsideration of the determinations in the Final Order relating to the Single Convention on Narcotic Drugs, 1961 (Single Convention). Respondent's post-Final-Order arguments relating to the Single Convention are not predicated on the taking of official notice of any fact. Nonetheless, as indicated, I have considered these arguments. Respondent's core contentions regarding the Single Convention were addressed in the Final Order and, therefore, it is unnecessary to repeat all of that discussion here. However, in view of his latest submissions, a few points warrant reiteration and/or clarification.

Under 21 U.S.C. 823(a), DEA must deny an application by a person seeking to become registered as a bulk manufacturer of a schedule I controlled substance if the agency determines that such registration would be inconsistent with United States obligations under applicable international drug control treaties—*i.e.,* the Single Convention. When it comes to marijuana (referred to under the treaty as ''cannabis''), one of the key principles of the Single Convention is that the federal government maintain a monopoly over the wholesale distribution of the drug. As to this point, the Final Order recited the following statement from the Official Commentary to the Single Convention:

> Countries * * * which produce * * * cannabis * * *, [i]n so far as they permit private farmers to cultivate the plants * * *, cannot establish with sufficient exactitude the quantities harvested by individual producers. If they allowed the sale of the 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 régime would thus be considerably weakened. In fact, experience has shown that permitting licensed private traders to purchase the crops results in diversion of large quantities of drugs into illicit channels. * * * [T]he acquisition of the crops and the wholesale and international trade in these agricultural products cannot be entrusted to private traders, but must be undertaken by governmental authorities in the producing countries. Article 23 * * * and article 28 * * * therefore require a government monopoly of the wholesale and international trade in the agricultural product in question in the country which authorizes its production.

74 FR at 2115 (citing Commentary at 278).

As indicated in the Final Order, the United States has, since 1968, implemented this aspect of the treaty through the following system carried out within HHS. NIDA enters into a contract with a private grower, with the grower being obligated under the contract to produce the amount and quantity of marijuana specified by NIDA and to produce marijuana cigarettes to supply researchers as directed by NIDA.[19] Throughout the 44 years since the United States ratified the Single Convention in 1967, the entire United States supply of marijuana for researchers has been distributed through this system. In this manner, the United States Government has always monopolized the wholesale trade in marijuana, consistent with its obligations under the treaty.

It is true, as Respondent points out in his post-Final-Order submissions, that the Single Convention (article 23, paragraph 3) calls upon parties to carry out the functions of article 23 by a single government agency. It is also true, as Respondent indicates, that the United States fails to adhere strictly to this provision of the treaty as both DEA and HHS carry out certain functions set forth in article 23, paragraph 2.[20] Specifically, DEA carries out those functions of article 23 paragraph 2 that are encompassed by the DEA registration system, and HHS (through NIDA) carries out those functions relating to purchasing the marijuana and maintaining a monopoly over the wholesale distribution. That these

[17] Several provisions of the CSA reference the IND provision of the FDCA. For example, 21 U.S.C. 827(c)(2)(A) expressly excludes ''research conducted in conformity with an exemption granted under [21 U.S.C. 355(i)]'' from the CSA's recordkeeping requirements.

[18] Illustrative of this point is Respondent's statement in his latest submission (page 14) that ''if a research protocol is good enough for the FDA, it should be good enough to be carried out.''

[19] Prior to 1999, NIDA entered into two contracts: one with the grower and one with the entity that produced the cigarettes. In 1999, NIDA decided that a single contract should be awarded for both activities, which resulted in the contractor (a division of the University of Mississippi) continuing to grow the marijuana, but subcontracting to Research Triangle Institute the responsibility of producing the cigarettes. 74 FR at 2122 n.79.

[20] Respondent is incorrect, however, in asserting that the Final Order stated that NIDA carries out all the functions under article 23, paragraph 2. No such statement appears in the Final Order.

functions are divided among the two agencies—rather than being carried out by a single agency—is a result of the existing statutes, regulations, and Congressional appropriations.[21] Nonetheless, when evaluating an application for registration under 21 U.S.C. 823(a), DEA must attempt to conform with the provisions of the Single Convention to the fullest extent possible under the existing statutory and regulatory framework. Accordingly, even in the absence of a single government agency carrying out all the functions referred to in article 23, paragraph 2, DEA must seek to adhere to the other provisions of this article that are attainable within the existing statutory and regulatory framework, including that which calls upon the United States Government to monopolize the wholesale distribution of marijuana.[22]

Therefore, for the reasons detailed in the Final Order, Respondent's stated goal of becoming registered for the purpose of ending the Government monopoly on the wholesale distribution of marijuana to researchers is directly at odds with the Single Convention, which independently warrants denial of his application. Respondent seems to continue to either ignore and/or misunderstand this fundamental aspect of the treaty. In his latest submission, Respondent states (pages 20–21): ''It is certainly true Dr. Craker seeks to cultivate marijuana outside *NIDA's* monopoly, but it does not follow that Dr. Craker seeks to cultivate marijuana outside the structures of *any government regulation.* * * * Dr. Craker and [Mr. Doblin] are in no way opposed to the regulation of marijuana by [DEA].'' (Emphasis in original.) This statement suggests that Respondent believes incongruously that as long as he agrees to comply with the DEA regulations relating to registration and security, his proposed registration should be deemed consistent with the Single Convention. Based on this flawed assumption, Respondent is effectively arguing that the provision of the Single Convention requiring a Government monopoly over the wholesale distribution of marijuana may be jettisoned whenever an applicant for registration promises to comply with the DEA regulations governing registration and security.

Respondent also continues to argue that the marijuana he seeks to grow is ''exempt'' from the Single Convention requirement of a government monopoly over the wholesale distribution of marijuana. According to Respondent, because he is seeking to supply marijuana to researchers for the purpose of conducting research that he hopes will someday lead to the FDA approval of marijuana as medicine, the marijuana he is seeking to grow should be deemed ''medicinal cannabis'' within the meaning of the Single Convention and thus the government monopoly set forth in article 23, paragraph 2(e) should be considered inapplicable to his proposed activity. The Government correctly suggests in its responsive brief (pages 8–9) that Respondent's interpretation would vitiate the language of article 23, paragraph 2(e). As I stated in the December 2, 2010, Order, it is theoretically possible that a marijuana-derived drug might be approved by the FDA in the future that would constitute ''medicinal cannabis'' within the meaning of the Single Convention. However, no drug product derived from marijuana has been approved by the FDA and, therefore, there is currently no such thing as ''medicinal cannabis'' in the United States. For this reason, the exception in article 23, paragraph 2(e) for ''medicinal cannabis'' has no bearing on this adjudication.

For purposes of the Single Convention, the marijuana that Respondent seeks to produce is clearly ''cannabis'' subject to the government monopoly under article 23, paragraph 2(e). As to this point, the Final Order observed:

> In its 2005 Annual Report, the [International Narcotics Control Board] reiterated: ''Articles 23 and 28 of the [Single] Convention provide for a national cannabis agency to be established in countries where the cannabis plant is cultivated licitly for the production of cannabis, even if the cannabis produced is used for research purposes only.''

74 FR at 2115 (footnote omitted).

Respondent also makes the following statement in his latest submission (pages 15–16): ''Additionally, the conduct of the one currently DEA-licensed manufacturer, who has been permitted by DEA to grow large amounts of marijuana *outside* of the NIDA contract, disproves the theory that marijuana grown for any purpose other than to supply NIDA-approved research would violate the Convention.'' (Emphasis in original.) Respondent is referring here to the cultivation of marijuana by the National Center for Natural Products Research (National Center), a division of the University of Mississippi.[23] As explained in the Final Order, in 1999, DEA and the National Center entered into a Memorandum of Agreement (MOA) under which the National Center was granted an additional registration to manufacture marijuana and THC independent of its contract with NIDA. 74 FR at 2104 n.13. The Final Order further explained:

> As set forth in the MOA, the purpose of the registration was ''to allow the Center to develop a new product formulation for effecting delivery of THC in a pharmaceutically acceptable dosage form suppository * * * and to provide crude THC extract to a DEA-registered manufacturer of THC for further purification.'' The MOA further stated that, under the terms thereof, the Center would ''manufacture marijuana for the purpose of extracting THC therefrom.'' Subsequently, the Center submitted a new application for a registration to bulk manufacture marijuana and THC ''to prepare marihuana extract for further purification into bulk active [THC] for use in launching FDA-approved pharmaceutical products.'' DEA has not yet issued a final order as to this application. (DEA publishes in the Federal Register all final orders on applications for registration to bulk manufacture schedule I and II controlled substances.)
>
> *The MOA further provided that ''[i]n accordance with articles 23 and 28 of the Single Convention on Narcotic Drugs * * * private trade in 'cannabis' is strictly prohibited. Therefore, the Center shall not distribute any quantity of marijuana to any person other than an authorized DEA employee.''* Continuing, the MOA explained that ''[t]he Single Convention does not prohibit private trade in 'cannabis preparations,''' and noted that this term, ''within the meaning of the Single Convention, is a mixture, solid or liquid containing cannabis, cannabis resin, or extracts or tinctures of cannabis.'' Because ''[t]he THC that the Center will extract from marijuana [is] considered such a 'cannabis preparation[,]' * * * the Center may, in accordance with the Single Convention, distribute the crude THC extract to private entities'' provided the Center otherwise complies with the CSA and DEA regulations. The MOA also set forth a detailed series of controls to maintain accountability of the marijuana from acquisition of the seeds through the extraction of THC from the harvested material.

Id. (emphasis added; citations omitted). The Final Order further stated:

[21] Whether, in the absence of Congressional action, DEA could promulgate regulations that would result in DEA alone carrying out all the functions of article 23 is beyond the scope of this adjudication.

[22] Although Respondent argues that the Government does not take actual physical possession of the marijuana grown by the NIDA contractor (as contemplated by article 23, paragraph 2(d)), one could conclude that the NIDA contract process does fulfill this obligation. For the reasons indicated above, this does not compel DEA to abandon the provision of article 23 requiring a government monopoly on the wholesale distribution of marijuana. *See* 74 FR at 2114 (''taking possession and engaging in wholesale distribution are two separate activities under the Convention'').

[23] For ease of understanding, the National Center is sometimes referred to here and in the Final Order as ''the University of Mississippi.''

In 2005, the University of Mississippi applied for a new registration to manufacture marijuana ''to prepare marihuana extract for further purification into bulk active [THC] for use in launching FDA-approved pharmaceutical products.'' DEA has not yet issued a final order as to this application and the University therefore does not currently have DEA authorization to undertake such activity. As with Respondent's application, DEA may only grant the pending University of Mississippi application if the agency determines that the University has demonstrated that the registration would be consistent with United States treaty obligations and the public interest. In making such determinations, DEA will not simply rely on the prior issuance of registration under the 1999 MOA but will consider the application anew, in view of the current circumstances and consistent with this final order. Among other things that must be considered with respect to the pending University of Mississippi application, I note that the Commentary to the Single Convention states the following with respect to the exemption for ''opium preparations'' under Article 23, paragraph (e): ''Opium-producing countries may thus authorize private manufacture of, and private international and domestic wholesale trade in, medicinal opium and opium preparations. *The opium other than medicinal opium needed for such manufacture must however be procured from the national opium agency.''* Commentary at 284 (emphasis added). Whether the University of Mississippi's proposed registration would be consistent with this aspect of the treaty has not yet been determined by DEA and is not the subject of this adjudication.

74 FR at 2118 n.61 (emphasis in original; citations omitted).

When viewing the foregoing statements from the Final Order in juxtaposition with Respondent's latest assertions regarding the National Center, two points should be considered. First, the above statements reflect that as part of the 1999 MOA with the National Center, DEA insisted—as it has in Respondent's case—on adherence to the principle under the Single Convention of prohibiting private trading in cannabis. The National Center has never been permitted to distribute marijuana to any persons except upon the specific instructions of NIDA through the system described above. Second, contrary to Respondent's assertion, DEA has never taken the position that ''marijuana grown for any purpose other than to supply NIDA-approved research would violate the Convention.'' Rather, as just noted, DEA has consistently taken the position that, in accordance with the Single Convention, the Government must maintain a monopoly on the wholesale distribution of cannabis.

One other argument made by Respondent in his latest submission warrants a brief response. Respondent repeatedly makes erroneous assertions about the legal and factual circumstances surrounding his application, then denounces the situation as a ''catch-22.'' For example, on page 17 of his latest submission, Respondent describes the following as a ''catch-22'': ''Medical marijuana does not exist, according to DEA, unless it is an FDA-approved medicine, but Dr. Craker's license to supply marijuana for the research necessary to test such a medicine and secure FDA approval cannot be granted because medical marijuana does not exist.'' In fact, not only DEA, but also the United States Supreme Court, interpreting the text of the CSA, has stated—*unanimously*—that marijuana is not medicine. In *United States* v. *Oakland Cannabis Buyers' Cooperative,* 532 U.S. 483, 491 (2001), the Court stated: ''[F]or purposes of the [CSA], marijuana has 'no currently accepted medical use' at all.'' Moreover, Respondent, in denouncing the notion that marijuana must gain FDA-approval to be considered medicine, is objecting to what has been a cornerstone of the FDCA for 50 years—that a drug may not be marketed as medicine in this country unless the FDA has determined, based on submissions of scientific evidence established in clinical trials, that the drug is safe and effective for the treatment of a disease or condition. As for Respondent's contention that marijuana research cannot go forward unless he becomes registered to grow marijuana, as explained above in section A., this is flatly refuted by the fact that HHS and DEA authorized 17 of the last 17 marijuana research proposals submitted by CMCR—all of which were aimed at establishing a scientific foundation for the FDA approval of marijuana. Thus, Respondent's use of the term ''catch-22'' is empty rhetoric.

C. Respondent's Arguments Relating to the Involvement of Rick Doblin in Respondent's Proposed Activities

Respondent also seeks reconsideration of my determinations in the Final Order relating the involvement of Rick Doblin in Respondent's application and proposed activities. Again, in the exercise of my discretion, I have considered Respondent's post-hearing submissions as to this issue, even though they do not arise out of the taking of official notice of any fact.

To briefly recap, the Final Order listed the various ways in which Mr. Doblin was involved in Respondent's application process and how Mr. Doblin would have a role in Respondent's activities if the application were granted. 74 FR at 2126. The Final Order then stated:

In short, Mr. Doblin has mapped out and assisted in most acts, if not every act, that Respondent has taken toward applying for a registration to manufacture marijuana and, if the registration were granted, Mr. Doblin would continue to maintain responsibility for managing and monitoring the activities of the registrant. Given this level of involvement by Mr. Doblin—and the passive, if not subservient, nature of Respondent's involvement—it is appropriate under factor six to consider the following conduct by Mr. Doblin relating to controlled substances. First, Mr. Doblin admits that he smokes marijuana for ''recreational use'' on a weekly basis. Thus, Mr. Doblin violates federal and state laws relating to controlled substances on a weekly basis. This demonstrates that Mr. Doblin has disregard for the controlled substances laws. It is simply inconceivable that DEA would—consistent with its obligations under the CSA—grant a registration to engage in certain activities involving controlled substances where it is clear that a person who will have *any* role in the oversight and management of such activities routinely engages in the illegal use of controlled substances. It is still more untenable where that person has the level of oversight and management that Mr. Doblin would have—and where the controlled substance he illegally uses is the very controlled substance the applicant seeks to produce. Indeed, it is remarkable that Mr. Doblin would—given his admitted illegal involvement in controlled substances—ask DEA to effectively grant him permission to take on such a prominent role in the manufacture of the most widely abused illegal controlled substance in the United States.

Id. (emphasis in original; citations and footnotes omitted).

In his latest submission, Respondent points out that in the Final Order, under the fifth public interest factor (21 U.S.C. 823(a)(5)), I concluded that if the registration were granted, Respondent would have in the establishment (*i.e.,* in his growing facility) effective controls against diversion. 74 FR 2125–26. Respondent contends that this conclusion precludes me from concluding under the sixth public interest factor (21 U.S.C. 823(a)(6)) that Mr. Doblin's involvement in Respondent's activity weighs against granting his application.

It is plain when comparing the text of factor five with that of factor six that a favorable finding with respect to factor five does not preclude an unfavorable finding under factor six. As explained in the Final Order, under public interest factor five, ''the existence in the establishment of effective control against diversion'' includes, among other considerations, appropriate physical security and employee screening as required by the DEA

regulations as confirmed through a DEA on-site inspection of the premises. 74 FR at 2128 (citing 21 CFR 1310.71–1301.93). Factor six, in contrast, is a catchall category that is designed to give DEA wide latitude to consider all evidence that might reasonably bear on the suitability of an applicant for registration. In other words, even if a registrant has promised to undertake security procedures sufficient to obtain a favorable finding under factor five, if other evidence (not covered by factors one through five) casts doubt on whether the applicant can be entrusted with the responsibility of a DEA manufacturing registration, such evidence may be considered under factor six.

Consider, for example, if a person were seeking to become registered as a manufacturer of oxycodone, and the applicant promised to install and maintain in the facility all the physical security measures and employee screening procedures required by the regulations. Assume further that evidence came to light that the main investor in the facility, who planned to make the decisions as to how the facility would distribute oxycodone, admitted that he obtains oxycodone illegally and uses it for ''recreational'' purposes on a weekly basis. In such circumstances, it would certainly be appropriate for DEA to draw an adverse inference under factor six based on such person's illicit activity involving oxycodone—regardless of whether the applicant made assurances that it would comply with the security regulations. Thus, I cannot adopt Respondent's suggestion that Mr. Doblin's regular marijuana use should be ignored as a factor relevant to his application.

Nonetheless, it bears repeating that the ultimate decision in this matter did not turn on consideration of Mr. Doblin's marijuana activity. As stated in the Final Order, two other independent grounds existed for denying the application and, therefore, the same result would have been reached had I determined that Mr. Doblin's marijuana activity were irrelevant.

To be clear, if I determined that the proposed registration were consistent with United States obligations under the Single Convention and further that the supply of marijuana available to researchers in the United States were inadequate within the meaning of 21 U.S.C. 823(a)(1), it is conceivable that arrangements could have been made to mitigate the concerns regarding Mr. Doblin's marijuana activity. For example, under a conditional grant of registration or memorandum of agreement, sufficient terms perhaps could have been imposed to ensure that Mr. Doblin would not be allowed to have access to the growing facility and would have no role in any decision making relating to management of the facility or the distribution of marijuana. However, consideration of such an approach was not feasible here given the other grounds for denying the application.

IV. Conclusion

For the foregoing reasons, Respondent's motion for reconsideration is hereby denied. The administrative record is modified as indicated herein and in my December 2, 2010, order. The January 14, 2009, Final Order, as supplemented by this order, is effective on September 7, 2011.

Dated: August 8, 2011.

Michele M. Leonhart,

Administrator.

[FR Doc. 2011–21064 Filed 8–17–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Joe C. Fermo, M.D.; Revocation of Registration

On September 30, 2009, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Joe C. Fermo, M.D. (Registrant), of Tulsa, Oklahoma. The Show Cause Order proposed the revocation of Registrant's DEA Certificate of Registration, BF7430781, as well as the denial of any pending applications to renew or modify his registration, on the ground that his ''continued registration would be inconsistent with the public interest.'' Show Cause Order at 1 (citing 21 U.S.C. 823(f) and 824(a)(4)).

The Show Cause Order specifically alleged that on February 23, 1990, Registrant was convicted in the District Court for Oklahoma County, State of Oklahoma, of ten counts of submitting false claims to the Oklahoma Department of Human Services in violation of Oklahoma law, and that on June 20, 1990, the United States Department of Health and Human Services excluded him from participating in federal health care programs under 42 U.S.C. 1320a–7(a). *Id.* at 1–2. The Order further alleged that based on his convictions, on June 21, 1990, the Oklahoma State Board of Medical Licensure placed his medical license on probation and that Registrant materially falsified three separate applications (in 1991, 1994, and 1997) to renew his DEA registration by failing to disclose the state board's action. *Id.* at 2 (citing 21 U.S.C. 824(a)(1)).[1]

Finally, the Show Cause Order alleged that on August 27, September 24, and September 26, 2007, an undercover officer had obtained prescriptions from Registrant for alprazolam (at all three visits) and propoxyphene (at the first two visits), both of which are schedule IV controlled substances. *Id.* The Order further alleged that these prescriptions lacked a legitimate medical purpose and were issued outside of the usual course of professional practice in violation of Federal and State laws. *Id.* (citing 21 CFR 1306.04 and Okla. Admin. Code 475.30–1–3(a)).

On or about October 5, 2009, the Show Cause Order, which also notified Registrant of his right to either request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedures for doing so, and the consequence if he failed to do so, was served on Registrant by certified mail addressed to him at the address of his registered location. *Id.* at 2–3 (citing 21 CFR 1301.43). Since service of the Show Cause Order, more than thirty days have now passed and neither Registrant, nor anyone purporting to represent him, has either requested a hearing or submitted a written statement in lieu of a hearing. *See* 21 CFR 1301.43(b)–(d). Accordingly, I find that Registrant has waived his rights to a hearing or to submit a written statement. *Id.* 1301.43(d). I therefore issue this Decision and Final Order without a hearing based on relevant evidence contained in the investigative record submitted by the Government.

Findings

Registrant is the holder of DEA Certificate of Registration, BF7430781, which authorizes him to dispense controlled substances in schedules II through V as a practitioner at the registered location of 5970 E. 31 St., Suite O, Tulsa, Oklahoma. While his registration was to expire on September 30, 2010, on August 13, 2010, Registrant filed a renewal application. In accordance with the Administrative Procedure Act and DEA regulations, I find that Registrant's registration remains in effect pending the issuance

[1] The Show Cause Order alleged that in March 2001, Registrant and DEA entered into a Memorandum of Agreement (MOA) which settled a Show Cause Proceeding filed in April 2000 based on the allegations described above. Show Cause Order at 2. The Show Cause Order also alleged that under the MOA, Registrant surrendered his registration and was allowed to reapply no earlier than March 2004, and that in October 2004, DEA issued him a new registration. *Id.*

Proposed Rules

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[21 CFR Part 1301]

BULK MANUFACTURE OF SCHEDULE I AND II SUBSTANCES

Proposed Application Procedures

Section 303(a) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 823(a)) provides that the Attorney General "shall register an applicant to manufacture controlled substances in Schedules I or II if he determines that such registration is consistent with the public interest" and with certain international obligations of the United States. This authority has been delegated to the Administrator of the Drug Enforcement Administration pursuant to § 0.100 of Title 28 of the Code of Federal Regulations.

Section 303(a) sets forth six factors to be considered in determining the public interest, among them the "maintenance of effective controls against diversion * * * by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions."

Section 1301 43 of Title 21 of the Code of Federal Regulations sets forth the procedures relating to the application for registration or reregistration as a bulk manufacturer of a particular Schedule I or Schedule II substance. At the time such an application is submitted, a notice of the application is sent to each registrant and applicant who has applied for registration to manufacture the basic class of the controlled substance. Recipients of the notice are afforded an opportunity to object to the proposed application and request a hearing pursuant to §§ 1301.44 and 1301.45.

Various interpretations by bulk manufacturing registrants of the phrase "limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions" have precipated requests for hearings on proposed applications.

The Drug Enforcement Administration of the United States Department of Justice, presently interprets the statute as requiring the registration of otherwise qualified applicants to manufacture any controlled substance, as long as the total number of registrants remains within the effective control by the Administration.

We believe that section 303(a)(1) permits the Drug Enforcement Administration to restrict entry to a number of registrants constituting adequate competition only when actually necessary to maintain effective controls against diversion. Stated conversely, section 303(a)(1) requires the Drug Enforcement Administration to register an applicant who meets all the other statutory requirements, without regard to the adequacy of competition, if the Administration determines that registering another manufacturer will not increase the difficulty of maintaining effective controls against diversion.

The legislative history of the Act clearly supports this construction of the Act. The sole purpose of section 303(a) was the prevention of diversion. Nowhere in the legislative history of the Act is there any indication that Congress based section 303(a)(1) on a determination that fully effective competition of controlled substances or entry into these markets is in itself undesirable. Nor is the Administrator aware of any reason to limit competition to an "adequate" level in the absence of a danger to the maintenance of effective controls against diversion.

This construction of section 303(a)(1) is consistent with, if not required by, numerous Supreme Court decisions holding that our national competitive policies are to be subverted only when necessary to make a particular regulatory scheme effective.

In order to simplify the administrative process by avoiding an unnecessary, expensive, and time consuming hearing on the adequacy of competition each time a new manufacturer seeks registration or an existing manufacturer seeks reregistration and to minimize unnecessary obstacles to the registration of qualified manufacturers, the Administration proposes two amendments to Part 1301, Title 21 of the Code of Federal Regulations.

Proposed § 1301.43(b) makes it clear that the Administration will limit the number of competitors to an "adequate" level only if necessary to maintain effective controls against diversion.

Proposed § 1301.58 would require the presiding officer to defer all evidence relating to the adequacy of competition until he determines whether the granting of the application would present a diversion problem. If the presiding officer finds the granting of the application would not raise a diversion control problem, then a complex and costly inquiry into whether competition is "adequate" need never be undertaken.

Therefore, under the authority vested in the Attorney General by sections 301 and 505 of the Comprehensive Drug Abuse and Prevention Act of 1970 (21 U.S.C. 821, 875) and delegated to the Administrator of the Drug Enforcement Administration by § 0.100 of Title 28 of the Code of Federal Regulations, the Administrator proposes that:

1. Section 1301.43(b) of Title 21 of the Code of Federal Regulations be amended to read as follows:

§ 1301.43 Application for Bulk manufacture of Schedule I and II Substances.

* * * * *

(b) The Administrator shall not limit the number of manufacturers in any basic class to a number less than that consistent with the maintenance of effective controls against diversion solely because a smaller number is capable of producing an adequate and uninterrupted supply under adequately competitive conditions.

* * * * *

2. Part 1301 of Title 21 of the Code of Federal Regulations be amended by adding a new § 1301.58 to read as follows:

§ 1301.58 Order of receiving and relevance of certain evidence.

(a) At any hearing on an application to manufacture any controlled substance listed in Schedule I or II, the presiding officer shall defer receiving evidence bearing on whether existing manufacturers are capable of producing an adequate and uninterrupted supply under adequately competitive conditions until such time as he determines whether the registration of the applicant would be consistent with the maintenance of effective controls against diversion.

(b) If the presiding officer determines that the registration of the applicant would be consistent with the maintenance of effective controls against diversion, he shall (pursuant to § 1301.43(b)) exclude as irrelevant all evidence bearing on whether existing manufacturers are capable of producing an adequate and uninterrupted supply under adequately competitive conditions.

All interested persons are invited to submit their comments and objections in writing regarding this proposal or the legal consideration upon which it rests. These comments or objections should state with particularity the issues concerning which the person desires to be heard. Comments and objections should be submitted in quintuplicate to the Hearing Clerk, Office of the Chief Coun-

sel, Drug Enforcement Administration, Department of Justice, Room 611, 1405 I Street, NW., Washington, D.C., 20537, and must be received no later than May 17, 1974.

In the event that an interested party submits objections to this proposal which present reasonable grounds for this rule not to be finalized and requests a hearing in accordance with 21 CFR 1308.45, the party will be notified by registered mail that the hearing will be held at the time and place set forth in the letter. A notice of hearing will simultaneously be published in the FEDERAL REGISTER. If objections submitted do not present such reasonable grounds, the parties will be so advised by registered mail.

If no objections which present reasonable grounds for a hearing on the proposal are received within the time limitation and all interested parties waive or are deemed to waive their opportunity for a hearing or to participate in a hearing, the Administrator shall issue his final order pursuant to 21 CFR 1308.48 without a hearing.

Dated: March 27, 1974.

JOHN R. BARTELS, Jr.,
Administrator,
Drug Enforcement Administration.

[FR Doc.74-7710 Filed 4-2-74;8:45 am]

Immigration and Naturalization Service

[8 CFR Part 103]

APPEARANCE AND DELIVERY BOND; CONDITION AGAINST UNAUTHORIZED EMPLOYMENT

Notice of Proposed Rule Making

Pursuant to section 553 of Title 5 of the United States Code (80 Stat. 383), notice is hereby given of the proposed amendment of § 103.6(a)(2) of Title 8 of the Code of Federal Regulations, pertaining to the inclusion in an appearance and delivery bond of a condition barring unauthorized employment.

The Attorney General, in a recent decision (Matter of Toscano-Rivas, A-19923806, January 9, 1974), approved the imposition of a condition against unauthorized employment as part of an appearance and delivery bond in connection with a deportation proceeding. In order to incorporate this condition into the regulations, the amendment to § 103.6(a)(2) is being proposed.

In accordance with section 553 of Title 5 of the United States Code (80 Stat. 383), interested persons may submit to the Commissioner of Immigration and Naturalization, Room 7100-C, 425 Eye Street, NW., Washington, D.C. 20536, written data, views, or arguments, in duplicate, with respect to the proposed rule. Such representations may not be presented orally in any manner. All relevant material received by May 3, 1974, will be considered.

In § 103.6, paragraph (a)(2) is amended in the following respects: the existing material is redesignated subdivision (i) and the caption "General" is added immediately following the subparagraph (i) designation; and new subdivisions (ii) and (iii) are added. As amended, § 103.6 (a)(2) reads as follows:

§ 103.6 Surety bonds.

(a) *Posting of surety bonds.* * * *

(2) *Bond riders*—(i) *General.* Bond riders shall be prepared on Form I-351 and attached to Form I-352. If a condition to be included in a bond is not on Form I-351, a rider containing the condition shall be executed and forwarded with Form I-352 to the regional commissioner for approval.

(ii) *Condition against unauthorized employment.* In the discretion of the district director and with the prior approval of the regional commissioner, a condition barring unauthorized employment may be included in an appearance and delivery bond in connection with a deportation proceeding.

(iii) *Factors to be considered.* Among the factors to be considered in connection with the imposition of the bond condition barring unauthorized employment are: Safeguarding employment opportunities for United States citizens and legal resident aliens; impact on and dislocation of American workers by aliens' employment; the number of aliens involved in performing the unauthorized employment; prior immigration violations by the alien or aliens and the likelihood of continued violations with the same employer; availability for hearings or deportation; whether the nature of the employment requires possible changes of addresses by the alien so as to make him difficult to locate for future hearings or deportation; the nature of the charges against the alien and his activities in the United States, e.g., subversive, criminal, narcotic; whether the employment might enable the alien to carry on illicit activities in such a manner as to pose a threat to the national security or public safety; whether the alien is presenting a substantial issue as to his deportability or a reasonable basis for consideration of discretionary relief; whether a spouse or children are dependent on the alien for support, or other equities exist. These factors are intended as examples only and are not exclusive.

* * * * *

(Sec. 103, 66 Stat. 173 (8 U.S.C. 1103))

Dated: March 28, 1974.

L. F. CHAPMAN, Jr.,
Commissioner of
Immigration and Naturalization.

[FR Doc.74-7662 Filed 4-2-74;8:45 am]

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

[7 CFR Part 244]

DETERMINING ELIGIBILITY FOR FREE AND REDUCED PRICE MEALS AND FREE MILK IN CHILD-CARE INSTITUTIONS

Notice of Proposed Rulemaking

Notice is hereby given that the Food and Nutrition Service, Department of Agriculture, intends to issue regulations governing the service of free and reduced price meals and free milk in child-care institutions. The regulations are intended to replace and update the notice of October 18, 1968, and to implement the free milk provisions in child-care institutions mandated by Pub. L. 93-150. Under this proposed part, child-care institutions which serve meals or milk at no separate charge to the children would file a simple affidavit type policy statement. Institutions which have a pricing situation would need a full free and reduced price policy. The regulations are proposed to be effective upon final publication in the FEDERAL REGISTER in regard to the Special Food Service Program for Children, and in regard to the Special Milk Program, upon final publication in the FEDERAL REGISTER of the amendment to Part 215 implementing the free milk provision of Pub. L. 93-150.

Comments, suggestions, or objections are invited and in order to be sure of being considered should be delivered to Herbert D. Rorex, Director, Child Nutrition Division, Food and Nutrition Service, U.S. Department of Agriculture, Washington, D.C. 20250, or submitted by mail postmarked not later than April 23, 1974. While the comment period is shorter than the 30 days normally provided, it is necessary in order to implement the provisions for the summer operations of the Special Food Service Program for Children. Communications should identify the regulations section and paragraph on which comments, etc., are offered. All comments, suggestions, or objections will be considered before the final amendments are published. All written submissions received pursuant to this notice will be made available for public inspection at the Office of the Director, Child Nutrition Division, during the regular business hours (8:30 a.m. to 5:00 p.m.) (7 CFR 1.27(b)).

Sec.
244.1 General purpose and scope.
244.2 Definitions.
244.3 Action by State agencies and FNSROs.
244.4 Action by child-care institutions.
244.5 Policy statements for determining eligibility for free and reduced price meals and free milk.
244.6 Public announcement of eligibility criteria.

AUTHORITY: Secs. 3 and 10, Pub. L. 89-642, 80 Stat. 885, 889, as amended (42 U.S.C. 1772, 1779); sec. 13, Pub. L. 79-396, 60 stat. 230, as added sec. 3, Pub. L. 90-302, 82 Stat. 117, as amended (42 U.S.C. 1761).

§ 244.1 General purpose and scope.

(a) Section 13 of the National School Lunch Act, as amended (42 U.S.C. 1761), authorizes a food service program in child-care institutions for children from areas in which poor economic conditions exist and from areas in which there are high concentrations of working mothers. The Act further provides that meals shall be served without cost or at a reduced price to children determined by the child-care institutions to be unable to