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Maureen M. Katz,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

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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.

[FR Doc. E9–605 Filed 1–13–09; 8:45 am]

BILLING CODE 4410–CW–P

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

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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

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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

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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.

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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