No. 09-1220

IN THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

LYLE E. CRAKER,
PETITIONER

V.

DRUG ENFORCEMENT ADMINISTRATION,
RESPONDENT

ON PETITION FOR REVIEW OF A NON-FINAL DECISION OF THE DRUG ENFORCEMENT ADMINISTRATION

BRIEF FOR THE DRUG ENFORCEMENT ADMINISTRATION

CARMEN M. ORTIZ
UNITED STATES ATTORNEY

MARK T. QUINLIVAN
ASSISTANT U.S. ATTORNEY
JOHN JOSEPH MOAKLEY U.S. COURTHOUSE
1 COURTHOUSE WAY
SUITE 9200
BOSTON, MASSACHUSETTS 02210
(617) 748-3606

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

TREATIES

LEGISLATIVE MATERIALS

REGULATIONS AND ADMINISTRATIVE MATERIALS

STATEMENT OF JURISDICTION

This Court lacks statutory jurisdiction under 21 U.S.C. §877 – which permits any person aggrieved by a "final decision" under the Controlled Substances Act ("CSA") to petition the Court within 30 days after notice of the decision – because the petitioner, Lyle E. Craker, Ph.D., has not petitioned for review of a "final decision" of the Drug Enforcement Administration ("DEA").

On January 7, 2009, the Deputy Administrator of DEA issued a final order denying Dr. Craker's application for registration as a bulk manufacturer of marijuana, which was published in the *Federal Register* on January 14, 2009. *Lyle E. Craker; Denial of Application*, 74 FR 2101 (Jan. 14, 2009) (hereafter the "2009 final order"). On January 30, 2009, Dr. Craker moved for reconsideration of that order. [DEA.App.3-20].[1] He then petitioned for review of the 2009 final order on February 13, 2009, and simultaneously moved this Court to hold the petition for review in abeyance pending DEA's consideration of his motion for reconsideration. [DEA.App.23-36]. On March 12, 2009, this Court granted his motion to hold the petition for review in abeyance. [DEA.App.37].

[1] Citations are as follows: Dr. Craker's brief is cited as "(Brief at __)," his addendum is cited as "[Add.__]," and his appendix is cited as [App.__]." The DEA's supplemental appendix is cited as "[DEA.App.__]."

On August 8, 2011, the Administrator of DEA[2] issued a final order denying the motion for reconsideration, which was published in the *Federal Register* on August 18, 2011. *Lyle E. Craker, PhD; Order Regarding Officially Noticed Evidence and Motion for Reconsideration*, 76 FR 51403 (Aug. 18, 2011) (hereafter the "2011 final order"). Dr. Craker did not petition for review of that order.

As set forth in greater detail below, this Court lacks statutory jurisdiction to review the 2009 final order because that order was not a "final decision" under §877, and lacks statutory jurisdiction to review the 2011 final order because Dr. Craker did not petition for review of that order.

STATEMENT OF ISSUES

1. This Court lacks statutory jurisdiction over Dr. Craker's petition for review.

2. The Administrator's denial of Dr. Craker's application to bulk manufacture marijuana on the ground that it was inconsistent with the public interest was not arbitrary and capricious.

3. The Administrator's denial of Dr. Craker's application on the alternate ground that it was inconsistent with the federal government's obligations under the Single Convention was not arbitrary and capricious.

---

[2] On December 22, 2010, the Senate unanimously confirmed Michelle M. Leonhart, who was then serving as the Acting Administrator and the Deputy Administrator of DEA, as the tenth Administrator of DEA.

STATEMENT OF THE CASE

On June 28, 2001, Dr. Craker applied for registration and, on August 22, 2002, filed a supplemental application for registration as a bulk manufacturer of marijuana. [App.1-10].

On December 10, 2004, DEA issued an Order to Show Cause proposing the denial of Dr. Craker's application. [App.11-18]. Dr. Craker timely requested a hearing. On February 12, 2007, the Administrative Law Judge ("ALJ") issued a recommended decision that Dr. Craker's application be granted. [Add.13-100].

On January 7, 2009, the Deputy Administrator denied Dr. Craker's application. 74 FR at 2101-33. Dr. Craker moved for reconsideration of that order. [DEA.App.3-20]. On August 8, 2011, the Administrator denied the motion for reconsideration. 76 FR at 51403-12.

LEGAL BACKGROUND

A. Controlled Substances Act

The CSA establishes a comprehensive federal scheme for the regulation of drugs and other dangerous substances. *Gonzales v. Raich*, 545 U.S. 1, 12 (2005). When it enacted the CSA, Congress acknowledged that many controlled substances "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people," but also found that "[t]he illegal

importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people." 21 U.S.C. §§801(1)-(2). Congress therefore "devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA." *Raich*, 545 U.S. at 14.

Congress also established a comprehensive regulatory scheme in which controlled substances are placed in one of five "schedules" depending on their potential for abuse, the extent to which they may lead to psychological or physical dependence, and whether they have a currently accepted medical use in treatment in the United States. 21 U.S.C. §812(b). A drug is included in schedule I, the most restrictive schedule, if it has "a high potential for abuse," "no currently accepted medical use in treatment in the United States," and "a lack of accepted safety for use * * * under medical supervision." *Id.* §§812(b)(1)(A)-(C). Because schedule I drugs have no accepted medical use and a high potential for abuse, they may only be dispensed in research projects that have been determined by the Secretary of Health and Human Services ("HHS") to be meritorious. *Id.* §823(f). When it enacted the CSA in 1970, Congress classified marijuana as a schedule I controlled substance, where it remains today. *Id.* §812(c) (schedule I(c)(10)); *see Raich*, 545 U.S. at 14-15.

The CSA provides that the Attorney General[3] 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," with the public interest determination based on the following six factors:

> (1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;
>
> (2) compliance with applicable State and local law;
>
> (3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;
>
> (4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;
>
> (5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

[3] The Attorney General has delegated his authority under the CSA to the Administrator of DEA. 28 C.F.R. §0.100(b).

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

21 U.S.C. §823(a)(1)-(6). At any hearing before the agency on such application, the applicant bears the burden of proving that the foregoing requirements for registration are satisfied. 21 C.F.R. §1301.44(a).

B. The Single Convention on Narcotic Drugs

The CSA implements the Single Convention on Narcotic Drugs ("Single Convention"), 18 U.S.T. 1407, which imposes a comprehensive series of measures to control narcotic drugs and other substances including marijuana (referred to in the Single Convention as "cannabis"). 21 U.S.C. §801(7). Under article 28 of the Single Convention, "[i]f a Party permits the cultivation of the cannabis plant for the production of cannabis or cannabis resin, it shall apply thereto the system of controls as provided in article 23 respecting the control of the opium poppy." Single Convention, art. 28, ¶1. Article 23 of the Single Convention, in turn, provides that a signatory party shall establish one or more agencies for carrying out the purposes of the treaty, and 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." *Id.* art. 23, ¶2(e).

C. 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 has held the requisite registrations under the CSA authorizing the University to conduct such activity. 74 FR at 2104. The contract, which is open for competitive bidding at periodic intervals (currently five years), is administered by the National Institute on Drug Abuse ("NIDA"), a component of the National Institutes of Health ("NIH"), which in turn is a component of HHS. *Id*.

STATEMENT OF FACTS

A. Dr. Craker's Application

On June 28, 2001, Dr. Craker, a Professor in the Department of Plant, Soil and Insect Sciences at the University of Massachusetts, Amherst, applied for registration to manufacture marijuana in "dosage form." [App.1-2]. The application was sponsored by the Multidisciplinary Association for Psychedelic Studies ("MAPS"). 74 FR at 2106.

Because the activity for which he sought registration was actually the "bulk" (rather than dosage form) manufacture of marijuana, DEA advised Dr. Craker that his application needed to be revised accordingly, and also asked him, in accordance with

standard agency practice, to complete a questionnaire. *Id.* at 2106 & n.17. On August 22, 2002, Dr. Craker filed a supplemental application for registration to bulk manufacture marijuana in which he stated, *inter alia,* that: "The plant material will be grown for federally-approved uses only, including analytical, pre-clinical, and clinical research." [App.3-10]. In a follow-up letter, Dr. Craker 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." 74 FR at 2107.

B. The Order to Show Cause

On December 10, 2004, the Deputy Assistant Administrator of DEA's Office of Diversion Control issued an order to show cause proposing the denial of Dr. Craker's application on two grounds: (1) that Dr. Craker's application would not be consistent with the public interest under 21 U.S.C. §823(a); and (2) that Dr. Craker's application would be inconsistent with the federal government's obligations under the Single Convention. [App.11-18].

C. The ALJ's Decision

Dr. Craker timely requested a hearing, and the ALJ conducted an evidentiary hearing on August 22-26 and December 12-14 and 16, 2005. 74 FR at 2102. On February 12, 2007, the ALJ issued her recommended decision that Dr. Craker's

application be granted. [Add.13-100]. The ALJ first determined that the Single Convention did not preclude Dr. Craker's application, stating that, although "not entirely clear," it appeared that the marijuana grown by the National Center or by any other registrant for utilization in research would qualify as either "medicinal" or as "special stocks" under the Single Convention. [Add.95].

The ALJ next determined, after considering the factors set forth in §823(a), that Dr. Craker's registration would be consistent with the public interest. [Add.95-99]. With respect to the first factor, the ALJ noted that in *Noramco of Delaware v. DEA*, 375 F.3d 1148 (D.C. Cir. 2004), the D.C. Circuit had indicated that DEA could interpret this provision in two distinct ways regarding the issue of "adequately competitive conditions" – either by considering or not considering the issue – and therefore stated that she would address both issues. [Add.95-96]. Under the first approach – in which DEA must disregard the issue of "adequately competitive conditions" if it finds that the applicant would provide effective controls against diversion – the ALJ concluded that "there is no evidence or contention that either [Dr. Craker] or anyone working with him would be likely to divert" the marijuana. [Add.96-97].

Under the second approach – in which DEA must consider whether "adequately competitive conditions" exist – the ALJ first 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," and that "there is no evidence that researchers whom NIDA approves to obtain marijuana have experienced difficulties in obtaining marijuana from the National Center when they need it." [Add.97]. The ALJ found, however, that NIDA's system for evaluating requests for marijuana for research has resulted in some researchers being unable to conduct their research because NIDA has refused to provide them with marijuana, and therefore concluded that "the existing supply of marijuana is not adequate." [Add.97]. The ALJ also rejected the contention that adequately competitive conditions exist because the NIDA contract is open to competitive bidding, and therefore found that the first statutory factor weighed in favor of granting Dr. Craker's application. [Add.98].

The ALJ also found that all but one of the remaining statutory factors weighed in favor of granting Dr. Craker's application, and therefore concluded that granting Dr. Craker's application would be in the public interest, and recommended that the application be granted. [Add.98-100].

D. The 2009 Final Order

On January 7, 2009, the Deputy Administrator denied Dr. Craker's application for registration on two separate and independent grounds: (1) that his registration was inconsistent with the Single Convention, and (2) that his registration was not in the public interest under §823(a). 74 FR at 2101-33.

1. Single Convention

The Deputy Administrator first determined that Dr. Craker's registration was inconsistent with the Single Convention. *Id.* at 2114-18. The Deputy Administrator emphasized that Dr. Craker's purpose for seeking a registration was not simply to grow marijuana, but to distribute it outside of the HHS system, which "would defy one of the central control provisions of the Single Convention with respect to cannabis cultivation" – the requirement of a government monopoly on the wholesale and international trade of the product. *Id.* at 2114-15. Indeed, the Deputy Administrator noted, "the central theme of [Dr. Craker's] argument * * * is that the very Government monopoly over the wholesale distribution of marijuana that the Single Convention demands is the primary evil that [Dr. Craker] seeks to defeat through obtaining a DEA registration." *Id.* at 2115.

The Deputy Administrator also rejected the ALJ's conclusion that the marijuana Dr. Craker sought to grow would qualify as "medicinal" under the Single Convention,

explaining that there were no recognized standards with respect to herbal marijuana (as opposed to "medicinal opium"), that marijuana has no currently accepted medical use in the United States, and that there are no FDA-approved medical products consisting of marijuana. *Id.* at 2116-17. Furthermore, even if the marijuana that Dr. Craker sought to produce were treated as akin to "medicinal opium," the Deputy Administrator reasoned, his proposed activity would still be inconsistent with the Single Convention because the marijuana plant material used to manufacture the "medicinal cannabis" must be obtained by the national cannabis agency, which Dr. Craker was unwilling to accept. *Id.* at 2117.

Finally, the Deputy Administrator rejected Dr. Craker's contention that the marijuana he sought to grow would qualify as retail "stocks" under the Single Convention, noting that Dr. Craker was not a licensed pharmacist or physician and his proposed activity thus did 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. *Id.*[4]

[4] The Deputy Administrator rejected the ALJ's conclusion that the marijuana Dr. Craker sought to grow would qualify as "special stocks" under the Single Convention, noting that Dr. Craker agreed that the ALJ had erred in this regard. *Id.*

2. The Public Interest Under §823(a)

The Deputy Administrator also concluded that Dr. Craker's registration was inconsistent with the public interest. *Id.* at 2118-33. The Deputy Administrator first noted, as had the ALJ, that DEA had construed the first public interest factor under §823(a)(1) inconsistently in prior final orders, and therefore undertook an extensive analysis of this provision anew, taking into account the text of the provision, legislative history, treaty considerations, DEA regulations, and prior DEA statements. *Id*. at 2118, 2127-32. After exhaustively examining each of these factors, the Deputy Administrator concluded that the best construction of §823(a)(1) was that under which the Administrator must 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. *Id.* at 2132-33.

In then applying §823(a)(1), the Deputy Administrator found that both the quantity and quality of the supply of marijuana was adequate, noting with respect to the former that as of the date of the hearing, there were approximately 1055 kilograms of marijuana of various potencies in the NIDA vault; that NIDA has supplied marijuana for every one of the 17 pre-clinical or clinical studies sponsored by the Center for Medicinal Cannabis Research ("CMCR") since 1999, when HHS changed

its guidelines; and the three examples identified by Dr. Craker – involving Dr. Donald Abrams, Dr. Ethan Russo, and Chemic Laboratories – were either denied prior to when HHS changed its guidelines or on the basis that they lacked scientific merit. *Id.* at 2118-20. With respect to the quality of marijuana supplied by NIDA, the Deputy Administrator accepted the ALJ's recommended finding that Dr. Craker had not met his burden of demonstrating that NIDA is incapable of producing marijuana of sufficient quality to meet legitimate research needs, noting that his complaints were largely anecdotal and were belied by the record. *Id.* at 2120-21.

Turning to the question of whether "adequately competitive conditions" exist, the Deputy Administrator noted that NIDA has always provided marijuana to researchers at cost or for free, and there consequently was no basis to suggest that the cost to any research under the existing supply arrangements was unreasonable. *Id.* at 2121. Moreover, the Deputy Administrator found, the fact that the NIDA contract is open to competitive bidding further suggests that "adequately competitive conditions" exist. *Id.* at 2022-23.

The Deputy Administrator adopted the ALJ's findings with respect to the second through fourth public interest factors, found the evidence regarding the fifth public interest factor in equipoise, and found that the sixth public interest factor weighed against granting Dr. Craker's application due to the active involvement of

Rick Doblin, the Director of MAPS, who admitted to routine illegal use of marijuana. *Id.* at 2123-27. After weighing these factors, the Deputy Administrator concluded that Dr. Craker's registration was not consistent with the public interest. *Id.* The Deputy Administrator therefore ordered that Dr. Craker's application be denied. *Id.* at 2133. The Deputy Administrator nonetheless afforded Dr. Craker the opportunity to file a motion for reconsideration within fifteen days in order to refute any of the facts of which she had taken official notice. *Id.* at 2108 n.24.

E. Dr. Craker's Motion for Reconsideration

On January 21, 2009, Dr. Craker sought additional time to file a motion for reconsideration, which the Deputy Administrator granted. [DEA.App.1-2]. On January 30, 2009, Dr. Craker filed a request to respond to officially noticed evidence and a motion for reconsideration, which was accompanied by a 15-page supporting brief. [DEA.App.3-20]. On March 11, 2009, Dr. Craker filed a 28-page supplemental brief with exhibits providing the legal and factual bases for his motion for reconsideration, and also requested that the administrative hearing be reopened so that he might call additional witnesses. [DEA.App.39-103].

On December 2, 2010, the Deputy Administrator denied Dr. Craker's request that the administrative hearing be reopened, but took official notice of certain documents that he submitted and allowed him an additional opportunity to file a final

brief in support of his motion for reconsideration. [App.21-28]. In so doing, the Deputy Administrator stated that "[a]llowing Respondent this additional briefing opportunity is especially warranted given the complexities of this adjudication," and that the brief "may include arguments previously submitted as well as any additional arguments he wishes to present." [App.27]. On March 7, 2011, Dr. Craker submitted a 24-page second supplemental brief. [DEA.App.105-128].

F. The 2011 Final Order

On August 8, 2011, the Administrator denied Dr. Craker's motion for reconsideration. 76 FR at 51403-12. The Administrator noted at the outset that neither the CSA nor DEA's implementing regulations expressly provide for a broad-based motion for reconsideration of a final order, but stated that, "in the exercise of my discretion, taking into account the complex and sometimes novel issues involved in this matter," she had considered all of the arguments that Dr. Craker had raised in his submissions seeking reconsideration of the 2009 final order. *Id.* at 51405 & n.1.

In then turning to the merits, the Administrator first rejected Dr. Craker's contention that the involvement of the U.S. Public Health Service and NIDA in reviewing proposed marijuana research protocols has the effect of blocking legitimate research into marijuana, emphasizing that under §823(f), it is the Secretary of HHS, not DEA, who is responsible for reviewing all proposed research into schedule I

controlled substances and, moreover, that Dr. Craker's "latest submission contains no citations to actual *evidence* that supports his claims of 'institutional biases' or 'political' motivations on the part of the Public Health Service and NIDA." *Id.* at 51405-06 (emphasis in original). The Administrator additionally noted that Dr. Craker's "institutional bias" theory was belied by the fact that, since HHS changed its policies in 1999 to make marijuana more readily available to researchers, every one of the 17 preclinical or clinical studies sponsored by CMCR had been approved. *Id.* The Administrator also reviewed additional correspondence relating to the proposed research protocols of Dr. Russo and Chemic and concluded that the letters confirmed that the protocols were denied based on scientific merit, not political or institutional bias. *Id.* at 51406-07.

The Administrator also rejected Dr. Craker's assertion that provisions of the Federal Food, Drug and Cosmetic Act and a regulation of the Food and Drug Administration ("FDA") mandate that the FDA – and not NIDA – carry out the Secretary of HHS's responsibility under §823(f) to determine the scientific merit of marijuana research. *Id.* at 51408. The fact that the FDA's statutory mission lists certain functions did not preclude other agencies within HHS from having overlapping functions; the responsibilities for administering the new drug approval process under 21 U.S.C. §355 and reviewing Investigatory New Drug ("IND") applications are

distinct functions from the determination under §823(f) of the scientific merit of proposed research into schedule I controlled substances; and there was no basis to dictate to the Secretary of HHS which agencies within her domain should carry out which functions. *Id.*

The Administrator next rejected Dr. Craker's arguments relating to the Single Convention. *Id.* at 51409-11. The Administrator explained that Dr. Craker's stated goal of becoming registered for the purpose of ending the federal government's monopoly on the wholesale distribution of marijuana to researchers was directly at odds with the Single Convention. *Id.* at 51410. The Administrator also rejected Dr. Craker's contention that the marijuana he seeks to grow is exempt from the Single Convention's requirement of a government monopoly on the wholesale distribution of marijuana because it was "medicinal," reiterating that marijuana produced for such research is not "medicinal cannabis" within the meaning of the treaty. *Id.* at 51410-11.

Finally, as to the role of Mr. Doblin, the Administrator explained that while it was conceivable that arrangements could have been made to mitigate the concerns raised regarding Mr. Doblin's marijuana activity if those other grounds did not exist, "consideration of such an approach was not feasible here given the other grounds for denying the application." *Id.* at 51412.

SUMMARY OF ARGUMENT

1. This Court lacks statutory jurisdiction to review the 2009 final order denying Dr. Craker's application for registration because it was not a "final decision" under 21 U.S.C. §877. Dr. Craker moved for reconsideration of the 2009 final order, and the Administrator not only considered and denied his motion for reconsideration on the merits, but also stated that she was supplementing the reasoning of the 2009 final order in doing so. The 2009 final order therefore was not DEA's "last word on the matter," and this Court lacks statutory jurisdiction over Dr. Craker's petition for review because it was "incurably premature." This Court also lacks statutory jurisdiction to review the 2011 final order because Dr. Craker did not petition for review of that decision.

2. The Administrator's denial of Dr. Craker's application to become registered as a bulk manufacturer of marijuana on the ground that it was inconsistent with the public interest was supported by substantial evidence and was not arbitrary and capricious. The Administrator exhaustively examined the meaning of 21 U.S.C. §823(a)(1) in considering Dr. Craker's application, and concluded that that paragraph requires DEA to effectuate the maintenance of controls against diversion "by limiting" the number of bulk manufacturers of schedule I or II controlled substances to that number of establishments "which can produce an adequate and uninterrupted supply

of these substances under adequately competitive conditions." That construction follows from the plain language of §823(a)(1) and, even if the statutory text is ambiguous, it is a quintessential example of reasoned agency analysis that is entitled to deference. Applying this factor, the Administrator evaluated whether the existing supply of research-grade marijuana in the United States is adequate in terms of quantity, quality, and competitive conditions, and reasonably concluded that Dr. Craker had failed to meet his burden of proving that the supply of marijuana was inadequate or that "adequately competitive conditions" did not exist.

3. The Administrator's denial of Dr. Craker's application on the alternative ground that it was inconsistent with the federal government's obligations under the Single Convention also was not arbitrary and capricious. As the Administrator found, the very purpose of Dr. Craker's application – to set up a marijuana distribution scheme outside the HHS system – fails to adhere to the Single Convention's requirement of a government monopoly. Dr. Craker's proposed manufacture of marijuana also does not fall within the Single Convention's exemption for "medicinal opium."

ARGUMENT

I. THIS COURT LACKS STATUTORY JURISDICTION OVER DR. CRAKER'S PETITION FOR REVIEW.

Dr. Craker petitions for review of the 2009 final order denying his application for registration as a bulk manufacturer of marijuana. This Court lacks statutory jurisdiction over that petition for review.

1. Dr. Craker invokes the jurisdiction of this Court pursuant to 21 U.S.C. §877 of the CSA, which provides:

> All final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

Although this Court has not previously had occasion to determine whether §877's "final decision" requirement is jurisdictional, there can be little doubt that the answer to that question is "yes." Where judicial review is sought pursuant to a statute that expressly prescribes finality as a prerequisite of judicial review, courts have deemed the statutory finality requirement to be jurisdictional in nature. *See*, *e.g.*,

Weinberger v. Salfi, 422 U.S. 749, 766 (1975) (holding that the "final decision" requirement of 28 U.S.C. §405(h) that confers subject-matter jurisdiction on district courts is a "statutorily specified jurisdictional prerequisite"); *Trudeau v. FTC*, 456 F.3d 178, 184 n.8 (D.C. Cir. 2006) ("Final agency action requirements can be jurisdictional in other statutes that, unlike the APA, confer jurisdiction on federal courts.") (citing cases).

Here, §877 expressly provides that one may petition for review only from a "final decision" of the Attorney General, and that "final decision" requirement consequently "is jurisdictional" in nature. *John Doe, Inc. v. DEA*, 484 F.3d 561, 565 (D.C. Cir. 2007); *accord Fry v. DEA*, 353 F.3d 1041, 1044 (9th Cir. 2003) (timely-filed petition for review under §877 is a jurisdictional requirement for appellate review); *Nutt v. DEA*, 916 F.2d 202, 203 (5th Cir. 1990) (same).

2. Dr. Craker only petitioned for review of the 2009 final order, so this Court must determine whether that order constitutes a "final decision" under §877. It does not. "The well-settled rule in administrative law is that a final agency action is one that mark[s] the consummation of the agency's decisionmaking process." *Omnipoint Holdings, Inc. v. City of Cranston*, 586 F.3d 38, 46 (1st Cir. 2009) (internal emphasis and quotations omitted). In assessing the finality of an agency action, "[t]he core question is whether the agency has completed its decision-making process, and

whether the result of that process is one that will directly affect the parties." *Franklin v. Massachusetts*, 505 U.S. 788, 797 (1992). In other words, "[i]t means a 'final determination' in a case by an administrative agency; that is, whether the agency rendered its last word on the matter. *Only* after an agency's final action may courts review the agency's decision." *Omnipoint Holdings*, 586 F.3d at 146 (emphasis in original, internal quotation omitted).

Courts thus have held that the timely filing of a motion for reconsideration not only tolls the running of a statutory limitation period for filing a petition for review until the motion is resolved, *see, e.g.*, *ICC v. Bhd. of Locomotive Eng'rs*, 482 U.S. 270, 284 (1987); *Clifton Power Corp. v. F.E.R.C.*, 294 F.3d 108, 110 (D.C. Cir. 2002), but also renders a petition for review filed during the pendency of the motion for reconsideration "incurably premature and in effect a nullity." *Gorman v. NTSB*, 558 F.3d 580, 586 (D.C. Cir. 2009) (internal quotation omitted). As the Supreme Court stated in *Locomotive Engineers*:

> When the [agency] reopens a proceeding for any reason and, after reconsideration, issues a new and final order setting forth the rights and obligations of the parties, that order – even if it merely reaffirms the rights and obligations set forth in the original order – is reviewable on the merits. Where, however, the agency *refuses* to reopen a proceeding, what is reviewable is merely the lawfulness of the refusal.

482 U.S. at 278 (emphasis in original) (internal citation omitted); *see Fry*, 353 F.3d at 1043-44 (applying *Locomotive Engineers* under §877 in case where physician sought to reopen the proceedings regarding the denial of her registration).

3. In this case, the 2009 final order no doubt was a "final decision" for purposes of §877 when it was issued, as it marked the consummation of DEA's decisionmaking process at the time. But that changed once Dr. Craker availed himself of the opportunity afforded him by the Deputy Administrator and sought "broad reconsideration of the factual and legal bases" of the 2009 final order. In response to that motion, the Administrator reopened the proceedings, allowed Dr. Craker the opportunity to file a supplemental brief and to supplement the record with additional documents attached to his motion for reconsideration, considered each of the arguments Dr. Craker raised in his motion and denied them on the merits, and stated in doing so that the 2009 final order was "supplemented by this order." 76 FR at 51404-12. In these circumstances, the 2009 final order no longer constituted DEA's "last word on the matter," and it therefore is not a "final decision" under §877. This Court therefore lacks statutory jurisdiction over the petition for review because it was "incurably premature." *See Council Tree Communications, Inc. v. FCC*, 503 F.3d 284, 287 (3d Cir. 2007) ("We have no jurisdiction to consider an incurably premature petition for review. * * * An agency order is non-final as to an aggrieved party whose

petition for reconsideration remains pending before the agency.") (internal citations omitted).

This conclusion is not altered by the fact that neither the CSA nor DEA's implementing regulations provide for a motion for reconsideration.[5] The Deputy Administrator expressly afforded Dr. Craker the opportunity to refute the facts of which she had taken official notice by filing a motion for reconsideration within fifteen days of service of the final order, 74 Fed. Reg. at 2108 n.24, and, after Dr. Craker availed himself of that opportunity and also sought broader reconsideration of the order, the Deputy Administrator gave him the opportunity to file supplemental briefs, including specifically allowing him the opportunity to "include arguments previously submitted as well as any additional arguments he wishes to present." [App.27]. Dr. Craker was not obligated to move for reconsideration, of course, but once he made that choice and the Administrator reopened the proceedings, the 2009 final order no longer was a "final decision" under §877. *See Clifton Power Corp.*, 294 F.3d at 111 ("Having chosen in February to return to the Commission, Clifton could

[5] *Compare City of Colorado Springs v. Solis*, 589 F.3d 1121, 1131 (10th Cir. 2009) (tolling rule of *Locomotive Engineers* "is not applicable in this case because the DOL has not established a rehearing or reconsideration procedure for §13(c) certifications).

not seek judicial review until its request for administrative reconsideration was resolved by the Commission on March 28.").

This case is therefore different from *Sackett v. EPA*, — S. Ct. —, 2012 WL 932018 (U.S. May 21, 2012), in which the Supreme Court held that a compliance order of the Environmental Protection Agency that invited a party to "engage in informal discussions of the terms and requirements of the order" and inform the agency of any allegations that were inaccurate "confers no entitlement to further agency review" because "[t]he mere possibility that an agency might reconsider in light of 'informal discussion' and invited contentions of inaccuracy does not suffice to make an otherwise final agency action nonfinal." *Id.* at *4. Here, by contrast, the Administrator not only reopened the proceedings following Dr. Craker's motion for reconsideration, but considered and rejected each of the arguments he raised on the merits and further stated that the 2009 final order was "supplemented by this order." Those actions make pellucid that the "final decision" under §877 was not the 2009 final order, but rather the 2011 final order. Indeed, the Supreme Court has held that where a court considers even an *untimely* request for reconsideration on the merits, the underlying action is rendered non-final for purposes of appellate review. *Bowman v. Lopereno*, 311 U.S. 262, 303-04 (1940) ("[W]here the court allows the filing [of an untimely petition for reconsideration] and, after considering the merits, denies the

petition, the judgment of the court as originally entered does not become final until such denial, and the time for appeal runs from the date thereof."); *see Gorman*, 558 F.3d at 587 (citing *Bowman* in context of petition for review of agency action); *Director, OWCP v. Hileman*, 897 F.2d 1277, 1279 (4th Cir. 1990) (same).

This Court therefore lacks statutory jurisdiction over the petition for review because the 2009 final order was not a "final decision" under §877. And while the Administrator's final order denying Dr. Craker's motion for reconsideration was a "final decision" within the meaning of §877, this Court lacks jurisdiction to review that decision because Dr. Craker never petitioned for review from that final order.

4. This also is not a case in which finality rules serve to "create traps for the unwary," *Collins v. NTSB*, 351 F.3d 1246, 1250 (D.C. Cir. 2003), as Dr. Craker has long been aware that the pendency of his motion for reconsideration raised the possibility that the 2009 final order was not a "final decision" under §877. In a letter to the Administrator dated February 10, 2009, Dr. Craker stated that because DEA had accepted his motion for reconsideration and allowed additional briefing, "it appears to us that DEA intends that its January 14 Order no longer be considered a 'final determination' for purposes of judicial review" under §877. [DEA.App.21-22]. Likewise, in moving this Court for a stay to hold appellate proceedings in abeyance pending the adjudication of his motion for reconsideration, Dr. Craker emphasized

that: "To be clear, Petitioner does not concede that the January 14 order is *in fact* a final order; he has merely filed a petition for review to preserve his appellate rights in the event this Court holds the January 14 order to be final." [DEA.App.26].

Moreover, the Administrator expressly stated in denying reconsideration that DEA "adheres to the Supreme Court's decision in [*Locomotive Engineers*] regarding the reopening of proceedings where it is alleged that new evidence or changed circumstances renders the agency's original order inappropriate." 76 FR at 51405 n.1 (citing *Locomotive Engineers*, 482 U.S. 270, and *Fry*, 353 F.3d at 1044). Dr. Craker thus was well aware his motion for reconsideration impacted the question whether the 2009 final order was a "final decision" under §877. Nor, in granting Dr. Craker's motion to hold appellate proceedings in abeyance and thereafter lifting the stay following the issuance of the 2011 final order, did this Court say anything that suggested that the 2009 final order was a "final decision" under §877, or that Dr. Craker did not need to take additional steps to ensure appellate review. Whatever reason he might have for not petitioning for review of the 2011 final order, Dr. Craker was not caught in a trap for the unwary.

II. THE ADMINISTRATOR'S DENIAL OF DR. CRAKER'S APPLICATION TO BULK MANUFACTURE MARIJUANA ON THE GROUND THAT IT WAS INCONSISTENT WITH THE PUBLIC INTEREST WAS NOT ARBITRARY AND CAPRICIOUS.

Dr. Craker contends (Brief at 33-48) that the Administrator's[6] conclusion that his proposed registration as a bulk manufacturer of marijuana was arbitrary and capricious because (1) the plain language of §823(a)(1) requires that supply and competition may be considered only as a means to control against diversion; (2) the Administrator's new interpretation of §823(a)(1) is not a permissible reading of the statute; and (3) DEA's shifting interpretations of §823(a)(1) evince arbitrary and capricious decisionmaking. In the alternative, he contends (Brief at 48-58) that the Administrator arbitrarily and capriciously applied the "adequate and uninterrupted supply" and "adequately competitive conditions" factors. Those contentions lack merit.

A. Standard of Review

A court may set aside a final agency decision only where the decision is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. §706(2)(A). "Review under the arbitrary and capricious standard is

[6] Inasmuch as the 2011 final order was the "final decision" of DEA under §877, we refer herein to the Administrator's denial of Dr. Craker's application for registration, as the 2011 final order both incorporated and supplemented the 2009 final order. 76 FR at 51412.

narrow and this Court may not substitute its judgment for that of the agency, even if it disagrees with the agency's conclusions." *River Street Donuts, LLC v. Napolitano*, 558 F.3d 111, 114 (1st Cir. 2009). Under this standard, an agency's explanation of the basis for its decision must include "a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Assn. v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation omitted). If this Court determines that the agency's action is supported by a rational basis, it must affirm. *River Street Donuts*, 558 F.3d at 114.

This Court reviews the Administrator's decision insofar as it interprets the CSA under the standard articulated by the Supreme Court in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Under *Chevron*, when a court reviews an agency's construction of the statute it administers, it must first ask whether "Congress has directly spoken to the precise question at issue" and, if the intent of Congress is unambiguous, the court must follow that intent. *Id.* at 842-43. If, on the other hand, the intent of Congress is ambiguous, the agency's interpretation is entitled to deference "when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001). Under *Chevron*, such agency

interpretations must be upheld if they are "based on a permissible construction of the statute." 467 U.S. at 843.

B. The Administrator's Construction of §823(a)(1) is the Best Reading and is Entitled to Deference

1. *Chevron* Step One

Dr. Craker first contends (Brief at 35-38) that the plain language of §823(a)(1) requires that the questions of whether adequate supply and adequately competitive conditions exist may be considered only where doing so is necessary to control against diversion. He is wrong, as the plain language of that paragraph indicates.

1. The "starting point for interpretation of a statute is the language of the statute itself." *Kaiser Aluminum & Chem. Corp. v. Bonjorno*, 494 U.S. 827, 835 (1990) (internal quotation omitted). Here, the CSA provides that, in determining whether the registration of an applicant to manufacture controlled substances in schedules I or II is in the public interest, the Attorney General must consider, *inter alia*:

> (1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes.

21 U.S.C. §823(a)(1).

This language is most naturally read to mean that, in order to "maintain[] effective controls" against the diversion of schedule I or II controlled substances, DEA must "limit[] 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." In other words, the first or "purpose clause" of §823(a)(1) sets out the Congressional objective – to "maintain[] effective controls" against the diversion of schedule I or II controlled substances – while the second or "limiting clause" sets out how Congress intended that objective to be achieved – "by limiting" the number of bulk manufacturers of schedule I or II controlled substances to that number of establishments "which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions."

This conclusion is underscored by a comparison of §823(a)(1) with §823(d), which governs the registration of manufacturers of controlled substances in schedules III, IV, and V. *See Saysana v. Gillen*, 590 F.3d 7, 13 (1st Cir. 2009) (noting that the "plain meaning" of a statutory provision "is often made clear not only by the words of the statute but by its structure as well."). The parallel paragraph of that subsection

provides that, in considering the public interest, the Attorney General shall consider "(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substances in schedule III, IV, or V compounded therefrom into other legitimate medical, scientific, or industrial channels." 21 U.S.C. §823(d)(1). In contrast to §823(a)(1), §823(d)(1) merely sets out the Congressional objective to "maintain[] effective controls" against the diversion of controlled substances, but does not contain a parallel limiting clause specifying precisely how that Congressional objective is to be achieved. The inclusion of the limiting clause in §823(a)(1) – and its absence in §823(d)(1) – suggests that Congress wanted to stipulate in §823(a)(1) precisely how controls against the diversion of controlled substances in schedules I and II, the most restrictive schedules, are to be maintained. *See Russello v. United States*, 464 U.S. 16, 23 (1983) ("[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (internal quotation omitted).

By contrast, Dr. Craker's construction of §823(a)(1) misses the obvious meaning of the statutory text – that limiting the number of registered bulk manufacturers of a given schedule I or II controlled substance is itself the primary means Congress chose for maintaining effective controls against diversion of such

drugs. Instead of following that natural reading of the text, Dr. Craker insists (Brief at 35) that it be read so that DEA may only limit the number of registered manufacturers where doing so is "necessary to 'maintain[] * * * effective controls against diversion" (Brief at 35). To arrive at that interpretation, Dr. Craker not only reads the words "only where that is necessary" into §823(a)(1) where they nowhere appear, he also is forced to *invert* the order of the two clauses in the paragraph, making the purpose clause a mere restriction or limitation on the limiting clause. Dr. Craker's construction of §823(a) thus is at war with the language which Congress has chosen.

Dr. Craker's interpretation also is untenable because it would reduce the scope of §823(a)(1) to territory already covered by §823(a)(5), which directs the Attorney General to consider, *inter alia*, "the existence in the establishment of effective controls against diversion." As the Administrator explained, §823(a)(1) addresses diversion control by focusing on the total number of registrants of a given substance, while §823(a)(5) addresses diversion control by focusing on the security measures the individual applicant will undertake to prevent diversion from its particular facility. 74 FR at 2128. Dr. Craker's construction of §823(a)(1) would also render largely superfluous the limiting clause of that paragraph. Dr. Craker's reading of §823(a)(1) therefore runs headlong into the canon of statutory construction that courts should

"disfavor interpretations of statutes that render language superfluous." *Connecticut Nat'l Bank v. Germain*, 503 U.S. 249, 253 (1992).

2. None of the other arguments Dr. Craker makes regarding the plain meaning of §823(a)(1) has merit. He first asserts (Brief at 36-37) that "[u]ntil Professor Dr. Craker's application, the DEA had itself applied this reading for more than thirty years," noting that DEA had issued a proposed regulation to that effect in 1974, that DEA had applied this construction in *Johnson Matthey, Inc.*, 67 FR 39041 (June 6, 2002), and had taken this position before the D.C. Circuit in *Noramco*. For two reasons, he is wrong. First, it is well established that "[w]hen the plain wording of the statute is clear, that is the end of the matter," *Saysana*, 590 F.3d at 13, and here, for the reasons set forth above, the Administrator's construction of §823(a)(1) is consistent with, if not compelled by, the plain language of that paragraph.

Second, Dr. Craker fails to appreciate that DEA, in fact, had taken *inconsistent* positions on this question over the years, and it was this nonuniformity in positions that led the Administrator to examine the meaning of §823(a)(1) anew. 74 FR at 2127-32. An agency head "is not estopped from changing a view she believes to have been grounded upon a mistaken legal interpretation," *Thomas Jefferson University v. Shalala*, 512 U.S. 504, 517 (1994), and is free to change its interpretation of a statute as long as it offers a "reasoned analysis" that justifies the change. *See, e.g., Rust v.*

Sullivan, 500 U.S. 173, 187 (1991); *Chevron*, 467 U.S. at 863-64; *see also Mayo Foundation for Medical Educ. & Research v. United States*, 131 S. Ct. 704, 712 (2011) ("We have repeatedly held that [a]gency inconsistency is not a basis for declining to analyze the agency's interpretation under the *Chevron* framework.") (internal quotation omitted). Here, and as set forth in greater detail below, the Administrator's exhaustive reexamination of this question is precisely the type of "reasoned explanation" that can evoke the deference contemplated by *Chevron*.

Dr. Craker also asserts (Brief at 37) that "[t]his plain meaning interpretation of §823(a)(1) has likewise been upheld by the D.C. Circuit," but he badly misreads the decision in *Noramco* in so arguing. In that case, the D.C. Circuit upheld the interpretation of §823(a)(1) taken by DEA in *Johnson Matthey* – in which the "adequate and uninterrupted supply" and "adequacy of competitive conditions" factors were not considered where there was no risk of diversion – as follows:

> Section 823(a)(1) does *not* expressly speak to whether the DEA must consider the number of importers necessary to provide an adequate supply if it determines diversion will be effectively controlled regardless. The stated purpose of section 823(a)(1) is to effectively control against diversion and it expressly directs DEA to limit competition only as a means to achieve "maintenance" of such control. In the absence of an express contrary statutory directive, the DEA reasonably concluded under *Chevron* step 2 that "if DEA determines that there would be no increased difficulty in controlling diversion, the requirements of [section

> 823(a)(1)] are satisfied, and an analysis of adequate competition is not required."

375 F.3d at 1153 (emphasis added) (quoting 67 FR at 39044).

As this passage makes clear, the D.C. Circuit in *Normaco* did *not* hold that DEA's prior interpretation of §823(a)(1) was compelled by the plain language of that paragraph, as Dr. Craker erroneously asserts; rather, the court held that because §823(a)(1) did not "expressly speak" to the question, DEA's construction was a "permissible interpretation" under *Chevron* step two. Indeed, *Noramco* not only fails to support Dr. Craker's assertion that his reading of §823(a)(1) is compelled by the plain language of that paragraph, it does not even stand for the proposition that that construction is the best reading of the provision. That is so because, 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." *Chevron*, 467 U.S. at 843 n.11.

Hence, because the Administrator's construction of §823(a)(1) is consistent with the plain language of that provision, it should be upheld under *Chevron* step one.

2. *Chevron* Step Two

Even if this Court were to conclude that §823(a)(1) is ambiguous, as did the D.C. Circuit in *Noramco*, the Administrator's construction should be upheld because it is a "permissible interpretation" under *Chevron* step two. As noted above, after concluding that DEA had taken inconsistent positions regarding the meaning of §823(a)(1), the Administrator undertook a panoptic examination of that provision, taking into account the statutory text, legislative history, treaty considerations, DEA regulations, and prior DEA statements. 74 FR at 2127-32. That considered interpretation is entitled to deference.

1. The Administrator first looked to the text of §823(a)(1), and concluded that that paragraph is best read as indicating Congress's direction that in order to maintain effective controls against diversion of schedule I or II controlled substances, DEA must consider limiting the number of registered bulk manufacturers of the substance to that "which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions." *Id.* at 2127 (quoting §823(a)(1)). The Administrator also found that the dictionary definition of the word "limiting" confirmed this meaning. *Id.* The Administrator also noted that this reading of §823(a)(1) was consistent with the overall structure of the CSA, including a

comparison of the purposes of that provision with §§823(a)(5) and 823(d)(1). *Id.* at 2128.

The Administrator next looked to the legislative history of §823(a)(1) and found that it confirms what the text makes clear – that §823(a)(1) 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, and that Congress did not intend for the Attorney General simply to issue such registrations to as many otherwise qualified applicants "as the market will bear." Id. at 2127-29. Among other things, the Administrator noted, a Senate Report regarding the proposed legislation made clear that the 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." *Id.* at 2129 (quoting *Controlled Dangerous Substances Act of 1969: Report of the Comm. on the Judiciary*, United States Senate, 91st Cong. 7 (1969)).

The Administrator next found that her construction of §823(a)(1) was consistent with the Single Convention, and was not inconsistent with existing DEA regulations on the subject. *Id.* at 2129-30. Among other things, the Administrator considered 21 C.F.R. §1301.33(b), which provides that:

> 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.

The Administrator explained that, although somewhat awkwardly phrased, this regulation, broken down into its constituent parts, simply means that the existence of an adequate and uninterrupted supply of a given schedule I or II controlled substances is *not* itself a sufficient basis to deny an application, since inadequately competitive conditions may provide an independent basis for registration under §823(a)(1), and that DEA may not keep the number of 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 the adequacy of competitive conditions. 74 FR at 2130. In other words, the Administrator concluded, §1301.33(b) could be reconciled with the statutory text, as it must be for the regulation to be valid. *Id.*

Finally, the Administrator noted that DEA had taken inconsistent positions regarding the meaning of §823(a)(1) over the years. *Id.* at 2131-33. For example, in *Roxane Laboratories, Inc.*, 63 FR 55891 (Oct. 19, 1998), the Acting Deputy Administrator analyzed the "adequacy of competitive conditions" independently of

diversion, while in *Johnson Matthey*, the final order adopted a proposed regulation in which DEA had proposed to exclude the consideration of "adequately competitive conditions" where the Administrator determined that no impact on diversion would occur. *Id.* at 2131 (citing *Bulk Manufacture of Schedule I and II Substances*, 39 FR 12138 (April 3, 1974)).The Administrator noted, however, that that proposed regulation was withdrawn, never adopted by DEA, and contrary to the statute; thus, she gave it no weight. *Id.* In addition, the Administrator noted, in *Penick Corporation, Inc.*, 68 FR 6947 (Feb. 11, 2003), issued shortly after *Johnson Matthey*, DEA did examine the issue of "adequately competitive conditions" even though no impact on diversion had been shown, and in *Noramco*, the D.C. Circuit upheld both final orders notwithstanding the inconsistency in their analyses. 74 FR at 2132 (citing *Noramco*, 375 F.3d at 1153, 1157 n.8).

The Administrator also acknowledged that, in *Chattem Chemicals, Inc.*, 71 FR 9834 (Feb. 27, 2006), she had followed the *Johnson Matthey* approach and declined to consider the issue of adequacy and supply, and the D.C. Circuit thereafter held that, under *Noramco*, this was a permissible reading of §823(a)(1). 74 FR at 2132 (citing *Penick Corp. v. DEA*, 491 F.3d 483, 491 n.11 (D.C. Cir. 2007)). The Administrator stated, however, that for the reasons she had discussed at length, she had now concluded that this approach – although deemed permissible under *Chevron* – was not

the best reading of §823(a)(1) and must be rejected in favor of that which more accurately reflects the statutory text. *Id.*

The Administrator's exhaustive reexamination of this question more than satisfies the requirement that an agency provide a "reasoned explanation" for a change in position, and is the very antithesis of the arbitrary and capricious agency action which Dr. Craker here alleges. Hence, even if the statutory text is deemed ambiguous, the Administrator's considered interpretation is entitled to deference. *See, e.g., River Street Donuts*, 558 F.3d at 115 ("[P]ursuant to *Chevron*, an agency's change in precedent is not invalidating if the agency adequately explains its reasons."); *Berkshire Hathaway, Inc. v. Textile Workers Pension Fund*, 874 F.2d 53, 56 (1st Cir. 1989) ("The agency's current interpretation should not be discounted in this case because it is the result of a more considered examination of the issue.").

2. None of the arguments that Dr. Craker raises (Brief at 39-48) in support of his contention that this is not a permissible reading of §823(a)(1) has merit. Indeed, Dr. Craker implies that his burden is merely to convince this Court has his interpretation of §823(a)(1) is better than that of the Administrator, as if the *Chevron* doctrine did not exist. He also misreads or even omits significant portions of the Administrator's lengthy explanation for her interpretation.

Dr. Craker argues (Brief at 49), for example, that the D.C. Circuit in *Noramco* rejected the contention that a comparison with §823(d)(1) shows that the limiting clause of §823(a)(1) must be applied regardless of the risk of diversion. But *Noramco* – which is not binding on this Court – was decided under *Chevron* step two, and the D.C. Circuit therefore only held that the position taken in *Johnson Matthey* was a permissible reading of §823(a)(1), not that it was the only one that could be reached or even the best one. *See Chevron*, 467 U.S. at 843 n.11. In a similar vein, Dr. Craker cites prior adjudications in which DEA issued inconsistent interpretations of §823(a)(1), without addressing the fact that the Administrator went to great lengths in the 2009 final order to acknowledge and explain these inconsistent prior adjudications. 74 FR at 2131-33. That explanation is precisely the type of "reasoned analysis" that justifies, under *Chevron*, the change in the agency's interpretation.

Equally misplaced (Brief at 41-44) is Dr. Craker's critique of the Administrator's reading of the legislative history. The Administrator explained that although the CSA is admittedly different from its predecessor statute, the Narcotics Manufacturing Act of 1960 (the "1960 Act") – under which diversion was to be controlled by limiting the number of registrants to "the smallest number of establishments" which can produce "an adequate and uninterrupted supply" of narcotic drugs," 74 Stat. 55 (1960) – the CSA also modified the requirement of

"limiting" the number of manufacturers by providing that this limitation be based not only on that which can produce "an adequate and uninterrupted supply," but also on that which provides for "adequately competitive conditions." Thus, the Administrator explained, although the restriction on bulk manufacturers was not as restrictive as under the 1960 Act, as the CSA added the consideration of adequacy of competitive conditions, the legislative history confirmed that the Attorney General was to take into account limiting the number of bulk manufacturers based on the considerations of the adequacy of supply and competitive conditions. 74 FR at 2128-29.

Dr. Craker also confuses matters by asserting (Brief at 46) that "DEA did not provide any reason – much less 'good reasons' – for abandonment of the interpretation of §823(a)(1) it advanced in *Noramco* in favor of the interpretation announced in the order to show cause." It is not the order to show cause that is under review, it is the decisions of the Administrator (to the extent this Court has jurisdiction to consider them), and the Administrator provided more than a reasoned explanation for the change in DEA's position in those decisions.

C. The Administrator's Application of the "Adequately Competitive Conditions" and "Adequate and Uninterrupted Supply" Factors Under §823(a)(1) Was Not Arbitrary and Capricious.

Dr. Craker alternatively contends (Brief at 48-58) that even if DEA were permitted to consider whether "adequately competitive conditions" and an "adequate and uninterrupted supply" of marijuana in evaluating his application, the Administrator's finding that those factors weighed against granting the application was arbitrary and capricious. He is wrong here as well, and he disregards the substantial evidence that supports the Administrator's factual findings.

1. "Adequately Competitive Conditions"

Dr. Craker contends (Brief at 49-54) that the Administrator misapplied the "adequately competitive conditions" factor, asserting that it is undisputed that the University of Mississippi holds a monopoly on the supply of marijuana for medical and scientific research purposes, and that Congress indicated in §823(a)(1) its preference for competition over monopoly. That claim lacks merit.

1. Under §823(a)(1), Congress directed the Attorney General to consider whether "adequately competitive conditions exist," and, as the Administrator concluded, this language cannot be read to "require the registration of an additional bulk manufacturer based merely on the assertion [that] the additional registration will

result in some vague, theoretical incremental increase in competition." 74 FR at 2121. That is so, she explained, because:

> 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.

Id.

Thus, in order to avoid reading the limiting clause in a superfluous manner, the Administrator followed DEA practice of looking to empirical data regarding the historic and present prices charged to those who lawfully acquire the controlled substances from the existing bulk manufacturers, and noted that this approach of focusing on price considerations in evaluating the adequacy of competition was consistent with the CSA's legislative history. *Id.* Applying that standard, the Administrator found that NIDA has always provided marijuana to researchers at cost or for free – privately-funded researchers receive marijuana at NIDA's cost, and HHS-funded researchers, historically the bulk of the marijuana recipients, receive marijuana at no cost. *Id.* The Administrator therefore concluded that there was no evidence to suggest that the cost to any researcher under the existing arrangement would be lower

if Dr. Craker entered the market and, as a result, that Dr. Craker had not demonstrated that competition was inadequate by showing that the prices charged by existing registrants was inadequate. *Id.*

Dr. Craker criticizes this approach, arguing (Brief at 51) that the Sherman Act, for example, reflects a legislative judgment that competition will produce not only lower prices but also better goods and services. This is one of the fundamental flaws in Dr. Craker's brief – analyzing the term "adequately competitive conditions" under §823(a)(1) as if Congress had mandated "competition" as that term is used in the Sherman Act. Regardless, price competition is perhaps the cardinal virtue of the antitrust laws – indeed, "[a]s the legislative history shows, the Sherman Act was enacted to assure customers the benefits of price competition," *Associated General Contractors of California, Inc. v. California State Council of Carpenters*, 459 U.S. 519, 538 (1983) – and the Administrator reasonably construed the term "adequately competitive conditions" to focus on empirical proof regarding historical and present prices charged to those who lawfully acquire a controlled substance from the existing registered bulk manufacturer, rather than on abstract arguments about the theoretical benefits of competition. Dr. Craker makes no effort to show that his entry into the market would result in lower prices to researchers – which his assertion (Brief at 51) that "laws of economics do not require empirical proof in every case in order to

remain true" all but admits. And to the extent he is suggesting that his entry into the market might result in a better *product* as opposed to a better *price*, the Administrator not only found that the quality of marijuana produced by the University of Mississippi was adequate, but also that Dr. Craker had failed to put forth any evidence demonstrating that he is capable of any kind of qualify control relating to the manufacture of marijuana. 74 FR at 2120-22 & n.80.

2. The Administrator also found the fact that the NIDA contract is open for competitive bidding at periodic intervals further supports the conclusion that adequately competitive conditions exist. *Id.* at 2121-22. Dr. Craker asserts (Brief at 52) that this conclusion is not supported by the plain meaning of the statute and is inconsistent with DEA's own regulations, but he is mistaken on both points. Dr. Craker asserts that §823(a)(1) directs the Attorney General to consider "[h]ow many establishments are enough to produce adequate competition," but that is not how that provision reads. Section 823(a)(1) directs the Attorney General to consider the maintenance of effective controls against diversion "by limiting" the number of establishments that can produce a schedule I or II controlled substance to that which can produce "an adequate and uninterrupted supply * * * under adequately competitive conditions," and the Administrator's conclusion that the fact that the NIDA contract is open to periodic competitive bidding supports the conclusion that

"adequately competitive conditions" are present is a reasonable construction of that term. Dr. Craker's reliance on 21 C.F.R. §1301.34(b) also is misplaced; not only does that regulation by its terms deal with importers of schedule I and II controlled substances, but there is nothing in the regulation that prohibits the Administrator from taking into account the competitive bidding process in determining whether "adequately competitive conditions" are present.

2. "Adequate and Uninterrupted Supply"

Dr. Craker also asserts (Brief at 54-58) that the Administrator arbitrarily and capriciously applied the "adequate and uninterrupted supply" factor by improperly narrowing the scope of the inquiry to whether NIDA has enough marijuana to satisfy all current and foreseeable research needs in the United States, and failing to consider whether the supply of marijuana was inadequate for another reason – that "NIDA makes marijuana available only to those medical and scientific research projects that it approves." In this regard, Dr. Craker asserts (Brief at 21) that "[t]he undisputed record evidence in this case demonstrates that NIDA's monopoly over the supply of research-grade marijuana has blocked legitimate medical research by qualified medical researchers," pointing to the applications of Dr. Abrams, Dr. Russo, Chemic Laboratories, and the 2011 denial of a research protocol submitted by MAPS. These arguments fail on multiple levels.

1. To begin with, it is important to emphasize what is not at issue. Dr. Craker does not challenge the Administrator's finding that as of the date of the hearing, there were approximately 1055 kilograms of marijuana of various potencies in the NIDA vault, and that this amount not only "far exceeds any present demand for research-grade marijuana as well as any reasonably anticipated demand for such marijuana in the foreseeable future," but also is "more than 90 times the amount of marijuana that [Dr. Craker] proposes to grow." 74 FR at 2119. Dr. Craker also does not renew his claim that the quality of the marijuana produced by NIDA is inferior, nor does he challenge the Administrator's finding that, since HHS changed its policies in 1999 to make marijuana more readily available to researchers, every one of the 17 CMCR-sponsored pre-clinical or clinical studies that requested marijuana from NIDA was provided with marijuana. *Id.*

Dr. Craker also does not renew his claim that the three applications upon which he relies were denied due to "institutional biases" or "political motivations" on the part of NIDA and the Public Health Service, and for good reason. The Administrator considered and rejected that very contention, finding that it was not borne out by the evidence because each of the denials were based on scientific merit, not institutional or political bias, and some of the denials in any event occurred before HHS adopted

its new guidelines for research purposes in 1999. 74 FR2107-08; 76 FR 54107-09.[7] Under §877, the Administrator's findings of fact "are conclusive" if supported by substantial evidence, *Morall v. DEA*, 412 F.3d 165, 176 (D.C. Cir. 2005), and Dr. Craker, unsurprisingly, makes no effort to mount such a challenge here.

2. Dr. Craker's argument thus is entirely dependent on the convoluted claim (Brief at 55) that, because the FDA has the responsibility for evaluating the efficacy and safety of drugs in the context of approval for marketing under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the FDA must be the sole agency to decide – for purposes of the CSA – whether proposed research involving schedule I controlled substances is scientifically meritorious. Building on this mistaken premise, Dr. Craker then asserts that if FDA has allowed certain clinical trials with marijuana to proceed for purposes of the FDCA – in the context of protecting the safety of human research subjects – that action by FDA should constitute a favorable interpretation under §823(f) of the CSA that the Secretary of HHS has blessed the scientific merit of

---

[7] Dr. Craker also asserts (Brief at 25-26, 57) that the denial of MAPS' application to research post-traumatic stress disorder by NIDA further demonstrates the inadequacy of supply. Because that action postdated the proceedings in this case, and because "the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court," *Camp v. Pitts*, 411 U.S. 138, 142 (1973), DEA has moved to strike this decision from the record. Even if it were considered by this Court, it would not change the outcome for the reasons set forth herein.

proposed research with schedule I controlled substances, and should further preclude any other agencies within HHS from making such determination. Continuing with this train of thought, Dr. Craker asserts that if a marijuana research proposal was allowed to go forward from a human research safety perspective for FDCA purposes, but found to be lacking in scientific merit for CSA purposes – by the actual agencies within HHS, NIDA and the Public Health Service, assigned to carry out that function – this constitutes proof that the supply of marijuana is inadequate for purposes of §823(a)(1).

This argument fails on multiple levels. First, there is nothing in the text of §823(a)(1) which remotely suggests that the Administrator has to parse the question of supply in this manner. The Administrator found that NIDA unquestionably has sufficient marijuana to produce "an adequate and uninterrupted supply," and that is all that §823(a)(1) obligates her to consider.

Second, the premise underlying Dr. Craker's argument – that only the FDA can pass on the scientific merit of research into controlled substances – misses the nail for at least two reasons. First, as the Administrator explained in rejecting this argument on reconsideration, this premise is erroneous as a legal matter because: (1) that FDA's statutory mission lists certain functions did not preclude other agencies within HHS from having overlapping functions; (2) the function of administering the new drug

approval process under 21 U.S.C. §355 is distinct from the determination under §823(f) of the scientific merit of proposed research into schedule I controlled substances; and (3) although the review by FDA of an IND may be similar in certain respects to the review under §823(f) of a schedule I research proposal, the two are distinct administrative functions carried out within HHS. 76 FR at 51408-09. Dr. Craker offers no rebuttal to these findings in his brief on appeal, instead merely repeating the arguments he advanced in his motion for reconsideration.

Third, whatever the merits of Dr. Craker's belief that only the FDA can pass on the scientific merit of research into controlled substances, a petition for review of the denial of an application for registration is not the appropriate forum to raise it. If a researcher believes that NIDA has acted *ultra vires* in declining to provide marijuana because only the FDA can pass on questions of scientific merit, that person can seek to challenge NIDA's action under the APA. But it is not the role of DEA to dictate to the Secretary of HHS how to assign responsibilities amongst the various HHS entities, and Dr. Craker cannot achieve that result through the back door under the guise of a petition for review of the denial of his application for registration.

III. THE ADMINISTRATOR'S DENIAL OF DR. CRAKER'S APPLICATION ON THE ALTERNATE GROUND THAT IT WAS INCONSISTENT WITH THE FEDERAL GOVERNMENT'S OBLIGATIONS UNDER THE SINGLE CONVENTION WAS NOT ARBITRARY AND CAPRICIOUS.

Dr. Craker also argues (Brief at 58-75) that the Administrator's conclusion that his application is inconsistent with the Single Convention is erroneous because the plain language of the treaty exempts "medicinal" marijuana from the control it prescribes, and even if he were not manufacturing "medicinal" marijuana, his compliance with the system of DEA registration and FDA review established by the CSA satisfies the treaty. Both claims lack merit.

A. Standard of Review

This Court reviews the Administrator's interpretation of the Single Convention under the standard set out in *Chevron*. "It is well settled that the Executive Branch's interpretation of a treaty is entitled to great weight." *Abbott v. Abbott*, 130 S. Ct. 1983, 1993 (2010) (internal quotation omitted); *see also Kolovrat v. Oregon*, 366 U.S. 187, 194 (1961) (interpretation of treaties by federal agencies charged with their negotiation and enforcement is given great weight). Moreover, where, as here, the agency is expressly charged by Congress with administering and interpreting a treaty, the agency interpretation must be reviewed under *Chevron*. *See Collins*, 351 F.3d at 1251 (standard of review of agency treaty interpretation "should be guided by

principles similar to those governing statutory interpretation") (internal quotations and citations omitted); *Hill v. Norton*, 275 F.3d 98, 104-05 (D.C. Cir. 2001) (applying *Chevron* to agency's interpretation of treaty and implementing statute); *see generally Auguste v. Ridge*, 395 F.3d 123, 144 n.22 (3d Cir. 2005) (stating that "[w]hether agencies are to be given *Chevron* deference when interpreting and implementing treaties is an unsettled topic," but not deciding the issue).

B. Dr. Craker's Proposed Manufacture of Marijuana is Not Exempt as "Medicinal" Under the Single Convention.

Dr. Craker contends (Brief at 60-66) that the Administrator erred in concluding that the exemption for "medicinal opium" under the Single Convention did not apply because "there currently is no such thing in the United States as 'medicinal cannabis.'" 74 FR at 2116. He is wrong.

1. As set forth above, article 28 of the Single Convention provides that if a party permits the cultivation of cannabis, "it shall apply thereto the system of controls as provided in article 23 respecting the opium poppy." Single Convention, art. 28, ¶1. Article 23 of the Single Convention, in turn, provides that a signatory party shall establish one or more agencies for carrying out the purposes of the treaty, and 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." *Id.* art. 23, ¶2(e). The Convention allows, however, that the "Parties need not extend this exclusive right to medicinal opium and opium preparations." *Id.*

2. In this case, the Administrator noted that not only was the term "medicinal opium" now obsolete, but its description in the various older Pharmacopoeias indicates that there were recognized standards for the substance's manufacture and that the drug had an accepted medical use in humans. 74 FR at 2116. By contrast, there are no recognized standards with respect to herbal marijuana, it has not been approved for medicinal use in the United States and most other countries, and neither marijuana, cannabis, or THC is listed in the various pharmacopeias. *Id.* As noted above, when it enacted the CSA in 1970, Congress classified marijuana as a schedule I controlled substance – which means, *inter alia*, that it "has no currently accepted medical use in treatment in the United States," 21 U.S.C. §812(b)(1)(B) – and it remains a schedule I controlled substance to this day, *see Raich*, 545 U.S. at 14-15, as marijuana has not been approved for medical use by the FDA. 76 FR at 51410.

Dr. Craker thus errs (Brief at 62) in asserting that "[m]arijuana used for bona fide medical research is necessarily being used 'medicinally.'" To the contrary, marijuana used in bona fide medical research is being tested to determine *if* it might someday be used medicinally. It is theoretically possible, as the Administrator noted,

that a marijuana-derived drug might be approved by the FDA in the future that would qualify as "medicinal cannabis" within the meaning of the Single Convention. 76 FR at 51410. But that day has not come close to arriving; indeed, as the Administrator noted, no clinical trials involving marijuana – even the 17 CMCR-sponsored studies – have advanced beyond Phase 1 of the three phases required for FDA approval of a new drug. 74 FR at 2107 n.23; 76 FR 51407 n.5. Hence, marijuana is not akin to "medicinal opium" under the Single Convention, as "medicinal opium" already had an accepted medical use in humans as evidenced by its inclusion in the various medical pharmacopeia. 74 FR at 2116.

Dr. Craker likewise errs in placing reliance on paragraph 2 of the Single Convention, which provides, *inter alia*, that with respect to drugs in marijuana's class:

> 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, possess 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.

Single Convention, art. 2, ¶5(b). This paragraph merely states that if a signatory nation elects to take the more draconian measure of banning production and distribution of marijuana entirely, that nation must still allow research with the drug;

it nowhere modifies the meaning"medicinal opium" under article 23 of the Single Convention – much less suggests that marijuana produced for research is "medicinal" under the treaty.

C. Dr. Craker's Registration is Not Otherwise Exempt Under the Single Convention.

Dr. Craker also contends (Brief at 66-74) that even if he were not manufacturing "medicinal" marijuana within the meaning of the Single Convention, "his proposed registration would be consistent with the Single Convention because it complies with governmental controls restricting the wholesale trade in marijuana." Here, too, he is mistaken.

1. As noted above, article 23 of the Single Convention provides 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, ¶2(e). 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 * * * grant its national cannabis agency *the exclusive right of wholesale * * * trade in these drugs*." Commentary on the Single Convention on Narcotic Drugs ("Commentary") at 314 (emphasis added). The Commentary further explains that:

> 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. * * *

Id. at 263. The Commentary additionally notes that "it may be advisable or even essential to keep to a minimum the number of * * * manufacturers and international traders (importers as well as exporters) * * * engaged in these activities." *Id.* at 264.

2. Here, the Administrator correctly determined that Dr. Craker's proposed registration – in which he sought to not simply grow marijuana, but distribute it outside the HHS system – is inconsistent with the Single Convention's requirement of a government monopoly on the wholesale trade in the drug. 74 FR at 2114-15; 76 FR 51409-11. As the Administrator explained, since 1968, HHS has implemented this aspect of the Single Convention by providing for a system under which NIDA enters into a contract with a private grower, with the grower being obligated under the contract to produce the amount and quantity of marijuana specified by NIDA and to produce marijuana cigarettes to supply researchers as directed by NDA. 76 FR at

51409. In his second supplemental brief in support of his motion for reconsideration, Dr. Craker expressly acknowledged that "[i]t is certainly true Dr. Dr. Craker seeks to cultivate marijuana outside of *NIDA's* monopoly," [App.124 (emphasis in original)], and that concession dooms his contention that his registration would be consistent with the Single Convention, as the system under which NIDA is the exclusive source for providing marijuana to medical researchers implements the Single Convention's requirement of a government monopoly on the wholesale trade in the drug.

Dr. Craker's assertion (Brief at 72) that he has consistently maintained that he will distribute the marijuana he grows exclusively to researchers holding DEA registration and with the concomitant FDA approval therefore is beside the point. As the Administrator reasonably concluded, this contention is at odds with one of the central provisions of the Single Convention, under which the wholesale trade in drugs such as marijuana cannot be entrusted to private individuals because the effectiveness of the signatory nation's control regime would be weakened:

> 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 regime 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 on the wholesale and international trade in the agricultural product in question in the country which authorizes its production.

Commentary at 278.

Finally, Dr. Craker's reliance (Brief at 69-70) on the experience in the United Kingdom is misplaced. As the Administrator explained, not only does the CSA nowhere call upon the Attorney General to rely upon or consider how other nations interpret the Single Convention as a basis for the Attorney General's determination of the government's obligations under that treaty, but if the government were to look to an outside entity for guidance on how to interpret the Single Convention, it would be the International Narcotics Control Board – the United Nations organ created by the Single Convention to implement, and monitor compliance with, the Convention – which has stated that, *inter alia*, that "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," and that the standards under the Single

Convention "require, *inter alia*, the control of cultivation and production of cannabis by a national cannabis agency." 74 FR 2115-16.

CONCLUSION

For these reasons, DEA respectfully requests that the Court dismiss the petition for review for lack of jurisdiction or, in the alternative, deny the petition for review.

Respectfully submitted,

CARMEN M. ORTIZ
United States Attorney

By: /s/ *Mark T. Quinlivan*
MARK T. QUINLIVAN
Assistant U.S. Attorney

CERTIFICATE OF COMPLIANCE WITH
Rule 32(a)

Certificate of Compliance with Type-Volume Limitation
Typeface Requirements, and Type Style Requirements

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains **13,953** words (an opening or answering brief may not exceed 14,000 words, a reply brief may not exceed 7,000 words), excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) (*i.e.*, the corporate disclosure statement, table of contents, table of citations, addendum, and certificates of counsel).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in proportionally spaced typeface using Times New Roman 14 point, in Word Perfect X4.

/s/ *Mark T. Quinlivan*
MARK T. QUINLIVAN
Dated: March 22, 2012

CERTIFICATE OF SERVICE

I, Mark T. Quinlivan, AUSA, certify that on March 22, 2012, I electronically served a copy of the foregoing document on the following registered participants of the CM/ECF system:

Theodore P. Metzler
Counsel of Record
Eugene Gulland
1201 Pennsylvania, Ave., N.W.
Washington, D.C. 20004

M. Allen Hopper
ACLU Found. of Northern California
39 Drumm Street
San Francisco, CA 94111

Sarah R. Wunsch
ACLU of Massachusetts
211 Congress Street, 3rd Floor
Boston, MA 02110

/s/ Mark T. Quinlivan
MARK T. QUINLIVAN

No. 09-1220

IN THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

LYLE E. CRAKER,
PETITIONER

v.

DRUG ENFORCEMENT ADMINISTRATION,
RESPONDENT

Addendum Table of Contents

21 U.S.C. §823(a)

Registration requirements

(a) Manufacturers of controlled substances in schedule I or II
The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

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

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

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

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

21 U.S.C. §823(d)

Registration requirements

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

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

(2) compliance with applicable State and local law;

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

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

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

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

21 U.S.C. §877

Judicial review

All final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

SINGLE CONVENTION

ON

NARCOTIC DRUGS, 1961

As amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961,

UNITED NATIONS

G.Add.4

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

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

Article 22

SPECIAL PROVISION APPLICABLE TO CULTIVATION

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

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

Article 23

NATIONAL OPIUM AGENCIES

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

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

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

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

Article 24

LIMITATION ON PRODUCTION OF OPIUM FOR INTERNATIONAL TRADE

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

Article 26

THE COCA BUSH AND COCA LEAVES

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

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

Article 27

ADDITIONAL PROVISIONS RELATING TO COCA LEAVES

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

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

Article 28

CONTROL OF CANNABIS

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

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

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

Article 29

MANUFACTURE

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

2. The Parties shall:

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

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