United States Court of Appeals
For the First Circuit

No. 09-1220

LYLE E. CRAKER,

Petitioner,

v.

DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

PETITION FOR REVIEW OF AN ORDER OF THE
DRUG ENFORCEMENT ADMINISTRATION

Before

Torruella, Lipez and Howard,
Circuit Judges.

Theodore P. Metzler, with whom Eugene Gulland, Covington & Burling LLP, M. Allen Hopper, ACLU Foundation of Northern California, Sarah R. Wunsch and ACLU of Massachusetts were on brief, for petitioner.

Mark T. Quinlivan, Assistant United States Attorney, with whom Carmen M. Ortiz, United States Attorney, was on brief, for respondent.

April 15, 2013

HOWARD, Circuit Judge. Petitioner Lyle E. Craker, a professor at the University of Massachusetts, seeks review of an order from the Drug Enforcement Administration ("DEA") denying his application for registration to cultivate marijuana for medical research. After review of the administrative record, we deny the petition.

I. Statutory Landscape

In an effort to consolidate the nation's drug laws and increase federal enforcement capabilities, Congress enacted the Comprehensive Drug Abuse and Prevention and Control Act in 1970. See Gonzales v. Raich, 545 U.S. 1, 11-12 (2005). Included within that Act was the Controlled Substances Act ("CSA"), "a comprehensive regime to combat the international and interstate traffic in illegal drugs." Id. at 12. While observing that many drugs within the purview of the CSA "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people," 21 U.S.C. § 801(1), Congress also determined that the health and welfare of Americans were detrimentally affected by "[t]he illegal importation, manufacture, distribution, and possession and improper use of controlled substances." Id. § 801(2).

Consonant with these concerns, "Congress devised a closed regulatory scheme 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 13 (citing 21 U.S.C. §§ 841(a)(1), 844(a)). Under this regime, controlled substances were organized into five schedules, reflective of their accepted medical uses, their potential for abuse, and their psychological and physical effects. Id. at 13-14; 21 U.S.C. § 812. Congress placed marijuana in schedule I, the most stringently controlled group. 21 U.S.C. § 812(c).[1] A schedule I drug "has a high potential for abuse . . . [,] has no currently accepted medical use in treatment in the United States[, and] . . . [lacks] accepted safety for use . . . under medical supervision." Id. § 812(b)(1).

The manufacture of a schedule I substance is a criminal offense unless the manufacturer has registered with the Attorney General. Id. § 822(a)(1).[2] The CSA provides that the Attorney General[3] "shall register an applicant to manufacture substances in

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[1] At the request of the Assistant Secretary of Health, Education and Welfare (now Health and Human Services), marijuana was originally classified under Schedule I on a preliminary basis, pending the "completion of certain studies." Gonzales v. Raich, 545 U.S. 1, 14 (2005). The CSA allows for transfer of substances to, from, or between schedules. 21 U.S.C. § 811. Although considerable efforts have been made to reschedule marijuana, it remains a Schedule I substance. Raich, 545 U.S. at 14-15 n.23; see also Americans for Safe Access v. Drug Enforcement Admin., 706 F.3d 438, 449-452 (D.C. Cir. 2013) (finding that DEA's denial of rescheduling petition was not arbitrary or capricious).

[2] The CSA also contains separate registration provisions relating to "distributors" and "practitioners" that are not implicated in this case.

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

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." Id. § 823(a). The "public interest" determination must be based on the following statutory 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 dispensation of such substances;
>
> (5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion;
>
> (6) such other factors as may be relevant to and consistent with the public health and safety.

Id. § 823(a)(1)-(6). The applicant carries the burden of proof at

any administrative hearing on a registration application. 21 C.F.R. § 1301.44(a).

Since 1968, the National Center for Natural Products Research ("NCNPR") at the University of Mississippi has held the necessary registration and a government contract to grow marijuana for research purposes.[4] Lyle E. Craker, 74 Fed. Reg. 2101, 2104 (Drug Enforcement Admin. Jan. 7, 2009) (Denial of Application) ("Craker II"). The contract 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 the Department of Health and Human Services("HHS"). Id. The contract is opened for competitive bidding every five years. Id. The NCNPR is the only entity registered by the DEA to manufacture marijuana. Lyle E. Craker, Ph.D, No. 05-16 (Drug Enforcement Admin. Feb. 12, 2007) (opinion, recommended ruling and decision) ("Craker I").

Among the "international treaties, conventions or protocols" referred to in section 823(a), the CSA implements the provisions of the Single Convention on Narcotic Drugs, 18 U.S.T. 1407 ("Single Convention"), in an effort "to establish effective control over international and domestic traffic in controlled substances." 21 U.S.C. § 801(7). As relevant to this proceeding,

[4] NCNPR's registration and contract incepted prior to the enactment of the CSA. Lyle E. Craker, 74 Fed. Reg. 2101, 2104 (Drug Enforcement Admin. Jan. 7, 2009) (Denial of Application) ("Craker II").

Article 28 of the Single Convention addresses cultivation of marijuana -- referred to therein by its taxonomic genus, cannabis -- with reference to "the system of controls as provided in article 23 respecting the control of the opium poppy." Pursuant to article 23, any signatory nation that "permits the cultivation of [marijuana or opium]" must designate one or more agencies to: license cultivators and designate where plants may be grown; purchase and take physical possession of each year's crops; and 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.

II. Adjudication of Dr. Craker's Application

Dr. Craker, a professor in the University of Massachusetts' Department of Plant, Soil and Insect Sciences, applied to the DEA for registration to manufacture marijuana for clinical research in 2001. At the DEA's request, he supplemented his application in August 2002. He stated that "a second source of plant material is needed to facilitate privately funded [Food and Drug Administration ("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." Craker II, 74 Fed. Reg. at 2107. Dr. Craker indicated that his production costs would be underwritten by a grant from the Multidisciplinary Association for Psychedelic Studies ("MAPS"), a

non-profit, tax-exempt research and education organization seeking to develop marijuana into an FDA-approved prescription medicine. Id. at 2106.

In December 2004, a DEA official issued an order to show cause, proposing the denial of Dr. Craker's registration application. Id. at 2101; see 21 U.S.C § 824(c); 21 C.F.R. § 1301.37(a), (c). The order first concluded that Dr. Craker's registration "would not be consistent with the public interest as that term is used in 21 U.S.C. § 823(a)." Craker II, 74 Fed. Reg. at 2101. The order also concluded that registration would be inconsistent with the United States' obligations under the Single Convention. Id. Dr. Craker timely requested a hearing, see 21 C.F.R. § 1301.37(d), which was conducted by an administrative law judge ("ALJ") over nine days in August and December 2005. See generally 21 C.F.R. § 1316.41-.67 (outlining hearing procedures).

In February 2007, the ALJ issued an eighty-seven page opinion, recommending that the DEA grant Dr. Craker's application. Craker I. The ALJ first concluded that the Single Convention was not a bar to Dr. Craker's registration, noting that it appeared that marijuana grown by the NCNPR or any other registrant for use in research would qualify as either "medicinal" or "special stocks" under the treaty, and thus not be prohibited by a government monopoly requirement. See Craker I at 82; Craker II, 74 Fed. Reg. at 2102.

The ALJ also found that Dr. Craker's application satisfied the "public interest" requirements of 21 U.S.C. § 823(a). The ALJ first noted a dispute that we will revisit: whether, as Dr. Craker asserts, the "adequately competitive conditions" requirement of section 823(a)(1) must be disregarded if there has been a finding that the applicant can maintain effective controls against diversion. Craker I at 85; Craker II, 74 Fed. Reg. at 2102-03; see Noramco of Del., Inc. v. Drug Enforcement Agency, 375 F.3d 1148, 1152-54, 1157 n.8 (D.C. Cir. 2004) (noting DEA's position that supply and competition can be disregarded if registration does not increase risk of diversion).

The government's position with respect to Dr. Craker's application was and is that both the diversion and supply/competition criteria must be satisfied. Without resolving the issue, the ALJ considered both factors, concluding that Dr. Craker had adequately proven that there is minimal risk that any marijuana he cultivated would be diverted. With respect to supply, the ALJ found that NIDA-approved researchers had not experienced difficulty obtaining marijuana from NCNPR when it was needed. Nevertheless, the ALJ found the supply to be inadequate because NIDA refused to supply some researchers who held DEA registrations and approvals from HHS. Finally, the ALJ concluded that the competitive bidding process for renewing the single extant NIDA

marijuana contract did not amount to "adequate competition" within the meaning of the statute.

After finding that Dr. Craker satisfied all but one of the remaining statutory factors -- promotion of technical advances under section 832(a)(3) -- the ALJ recommended that his application be granted.

In January 2009, the DEA Deputy Administrator ("Administrator") rejected the ALJ's recommendation and denied Dr. Craker's application. Craker II, 74 Fed. Reg. at 2133. Turning first to the Single Convention, the Administrator concluded that Dr. Craker's application evinced an intent "to distribute marijuana outside the HHS system." Id. at 2114. In support of this finding, the Administrator noted that one of Dr. Craker's putative colleagues, MAPS president Rick Doblin, testified that "[w]hat we're trying to do is get the [Public Health Service] and NIDA out of the picture." Id. at 2114-15. Dr. Craker's intent, the Administrator ruled, is to elide "the very Government monopoly over the wholesale distribution of marijuana that the Single Convention demands. Thus, from the outset . . . [Dr. Craker]'s proposed registration cannot be reconciled with United States obligations under the treaty." Id. at 2115.

The Administrator additionally rejected Dr. Craker's assertion that his plans fell within the Single Convention's "medicinal opium" exception both because marijuana currently has no

accepted use in the United States, id. at 2116-17, and that even if considered analogous to medicinal opium, Dr. Craker's proposal would run afoul of the Single Convention's "central theme," that a single national agency must control the distribution and production of raw marijuana used for research. Id. at 2117.

Next, the Administrator found that granting Dr. Craker's application would not be within the public interest, as required by 21 U.S.C. § 823(a). In so doing, the Administrator first agreed with the ALJ that the DEA had inconsistently construed section 823(a)(1) in the past, at times calling for consideration of supply and competition regardless of the potential for diversion and at other times ignoring adequacy of supply and competition if effective diversion controls were in place. Id. at 2118. After a lengthy disquisition on the issue, id. at 2127-32, the Administrator determined that a registrant must prove both that effective controls against diversion are in place and that supplies and competition are inadequate. Id. at 2133 ("The alternative interpretation, though found to be permissible, . . . provides no mechanism to prevent the proliferation of bulk suppliers . . . beyond that necessary to adequately supply . . . these materials under adequately competitive conditions. [This] heightens the risk of oversupply, which, in turn increases the risk of diversion.").

The Administrator then concluded that the existing supply and quality of marijuana was adequate, observing that NIDA had been

able to successfully supply research efforts and that the NIDA denials cited by Dr. Craker were not due to insufficient supply, but rather were due to lack of scientific merit. Id. at 2119. The Administrator further accepted the ALJ's finding that the existing marijuana supply was of sufficient quality to meet the research community's needs, id. at 2102, observing further that Dr. Craker's opposing anecdotal evidence of shortcomings in taste, potency and freshness was countered by evidence of researchers' "overall satisfaction" with marijuana received from NIDA. Id. at 2120.

In addressing the "adequately competitive conditions" criterion, the Administrator focused on cost, noting that NIDA provided marijuana either at cost (to privately-funded researchers) or for free (to HHS-funded researchers), at no profit to NIDA. Id. at 2121. Thus, Dr. Craker could not claim that his entry into manufacturing would lower costs to researchers, beyond a generalized reference to the idea that more competition would lead to lower costs, a claim which itself was belied by the fact that, as MAPS's president Mr. Doblin noted, MAPS's costs would be affected by its own profit-making motivation. Id. As a final consideration under section 823(a)(1), the Administrator accepted the government's reasoning that the process by which the NIDA marijuana contract was opened periodically for competitive bidding helped to ensure adequate competition. Id. at 2121-22.

The Administrator next accepted the ALJ's recommendations concerning sections (2), (3) and (4) of 823(a), agreeing that Dr. Craker had adequately demonstrated that he would abide by applicable laws, that he had failed to demonstrate that his proposed activities would promote scientific advancements in the field, and that he had never been convicted of violating any controlled substance law. Id. at 2123-25. With respect to section 821(a)(5), the Administrator noted that while Dr. Craker had no experience in the manufacture of controlled substances, he would have satisfactory diversion control in place. Id. at 2125-26. Finally, the Administrator concluded that Mr. Doblin's admission that he regularly smoked marijuana in violation of federal drug laws and that he was to play a central role in the proposed manufacturing operation was another factor weighing against Dr. Craker's application. Id. at 2126-27; 21 U.S.C. § 821(a)(6).

The Administrator ultimately concluded that any one of three negative findings could provide a "compelling" basis to deny the application: conflict with the Single Convention; existing adequate supply and competition; and Mr. Doblin's conduct and involvement. Craker II, 74 Fed. Reg. at 2133. Concurrent with the denial, however, the Administrator also granted Dr. Craker fifteen days in which to file a motion for reconsideration to refute any facts of which the Administrator had taken official notice during the proceedings. Id. at 2108 n.24; see 21 C.F.R. § 1316.59(e).

Availing himself of the opportunity, Dr. Craker filed a motion for reconsideration in January 2009. He also requested that the hearing be reopened for him to call additional witnesses. On February 9, 2009, the Administrator issued an order permitting further briefing and stating that she would decide on the basis of those submissions whether to grant Dr. Craker's request to reopen the administrative hearing or grant his request for reconsideration. In December 2010, the Administrator denied the request to reopen the hearing, but allowed Dr. Craker to further supplement the record and to raise new arguments. In August 2011, the Administrator denied the motion for reconsideration. Lyle E. Craker, Ph.D, 76 Fed. Reg. 51403, (Drug Enforcement Admin. Aug. 8, 2011) (order regarding officially noticed evidence and motion for reconsideration) ("Craker III").

The Administrator rejected claims that Dr. Craker had made alleging political and institutional bias, as well as his argument that the FDA, rather than NIDA, should assess registration applications under 21 U.S.C. § 823. Id. at 51406-08. The Administrator also reiterated the finding that Dr. Craker's registration would be inconsistent with the Single Convention. Id. at 51410. At the same time, the Administrator backed away somewhat from the previous conclusion with respect to Mr. Doblin, observing that some controls could conceivably be put into place to alleviate concerns over his personal use of marijuana, but that the other

grounds for denial of the application rendered analysis of that issue unnecessary. Id. at 51411-12.

The final pieces of the background puzzle emerge from Dr. Craker's initial filing with us after the DEA issued Craker II. On February 13, 2009, while his motion for reconsideration was pending, Dr. Craker filed a petition for review of Craker II in this court, pursuant to 21 U.S.C. § 877. At the same time, he filed a motion to stay the appellate proceedings and hold them in abeyance, which we granted on March 12, 2009, until such time as the motion for reconsideration before the Administrator was acted on. In his appellate motion, Dr. Craker indicated that the goal of the motion was to preserve his appeal rights in the event that Craker II was deemed to be a "final decision" within the meaning of 21 U.S.C. § 877, thus triggering the statute's 30-day deadline for seeking judicial review. On August 24, 2011, after receiving notification that Craker III had been issued, we lifted the abeyance and permitted the petition for review to proceed.

III. Analysis

A. Jurisdiction

The government argues that we are without jurisdiction to address the merits of Dr. Craker's petition. Its jurisdictional theory starts with the fact that Congress has permitted judicial review only of "final" agency decisions. 21 U.S.C. § 877; see also John Doe, Inc. v. Drug Enforcement Admin., 484 F.3d 561, 565 (D.C.

Cir. 2007) (final decision requirement under § 877 is jurisdictional in nature); Fry v. Drug Enforcement Admin., 353 F.3d 1041, 1044 (9th Cir. 2003); Nutt v. Drug Enforcement Admin., 916 F.2d 202, 203 (5th Cir. 1990) (same). The government's position is that the only final decision is Craker III, from which Dr. Craker did not seek review. While the government acknowledges that Dr. Craker did seek review of Craker II, it argues that the pendency of the motion for agency reconsideration of that decision deprived the order of finality, and thus us of jurisdiction. The premature petition for review, the government further contends, did not ripen so as to vest us with jurisdiction once the agency issued its final decision on reconsideration.

The government relies on a rule, established by the D.C. Circuit and adopted by others, whereby a petition for review filed during the pendency of a motion for agency reconsideration is "incurably premature and in effect a nullity." Gorman v. NTSB, 558 F.3d 580, 586 (D.C. Cir. 2009) (internal quotation omitted); accord Council Tree Commc'ns, Inc. v. FCC, 503 F.3d 284, 287 (3d Cir. 2007). In the cases in which that rule has been applied, however, either the governing statute or the implementing regulations expressly provided for agency reconsideration. See, e.g., Council Tree Commc'ns, 503 F.3d at 286 (petition for reconsideration of FCC order pursuant to 47 C.F.R. § 1.106); Clifton Power Corp. v. FERC, 294 F.3d 108, 110 (D.C. Cir. 2002)

(motion for rehearing and reconsideration of FERC order pursuant to 16 U.S.C. § 825(b)). No similar procedural guarantee existed here, which is why Dr. Craker filed his protective petition with us. Nevertheless, the government argues that the facts of this case still favor applying the "incurably premature" rule. The Administrator expressly afforded Dr. Craker the opportunity to refute the facts of which she had taken official notice by filing a motion for reconsideration and, after Dr. Craker availed himself of that opportunity and also sought broader reconsideration of the order, permitted him to file supplemental briefing. Accordingly, the government argues, Dr. Craker's appeal was premature despite the fact that neither the CSA nor DEA's implementing regulations provide for a motion for reconsideration.[5]

It is not clear that even those courts that have adopted the maturation rule would apply it here, where the opportunity granted to the petitioner was limited to contesting facts of which the agency had taken official notice, while broader reconsideration of the factual and legal bases for the agency's final order remained only, at the time of the filing of the petition for review, a mere possibility. See supra p. 13 (noting that the Administrator's February 9, 2009 order withheld judgment on the propriety of Dr. Craker's motion for reconsideration). In

[5] The parties do not dispute that motions for reconsideration of DEA orders are not contemplated. We assume, without deciding, the correctness of that position.

concluding that, where a party's original petition for review of an agency order was unripe, that party must file a new petition upon disposition of its motion for reconsideration, the D.C. Circuit explained:

> We develop this bright line test to discourage the filing of petitions for review until after the agency completes the reconsideration process. If a party determines to seek reconsideration of an agency ruling, it is a pointless waste of judicial energy for the court to process any petition for review before the agency has acted on the request for reconsideration.

TeleSTAR, Inc. v. FCC, 888 F.2d 132, 134 (D.C. Cir. 1989).

The D.C. Circuit has, however, declined to apply the rule where the motion for reconsideration was not timely filed. That is because, "at least where . . . the agency does not consider the merits of the tardy request," there is no "possibility that the order complained of will be modified in any way which renders judicial review unnecessary." See Gorman, 558 F.3d at 587 (internal quotation omitted). Similarly, the possibility of concurrent jurisdiction and the judicial economy concerns that arise from it, while not wholly eliminated, are considerably diminished in cases, such as this one, in which reconsideration may or may not have been permitted in the agency's discretion. See Craker III, 76 Fed. Reg. at 51405 (explaining the decision to permit reconsideration as an "exercise of [the Administrator's] discretion"); see also City of Colo. Springs v. Solis, 589 F.3d 1121, 1131 (10th Cir. 2009) (concluding that the rule announced in

ICC v. Bhd. of Locomotive Eng'rs, 482 U.S. 270, 284 (1987), whereby the timely filing of a motion for administrative reconsideration renders the underlying order non-final for purposes of judicial review, "is not applicable in this case because the [agency] has not established a rehearing or reconsideration procedure for [the type of order at issue]").

Moreover, such jurisdictional concerns are further alleviated here, because we suspended and then resumed consideration of a petition for review upon completion of the reconsideration process. As the Supreme Court has observed, "a stay is as much a refusal to exercise federal jurisdiction as a dismissal." Moses H. Cone Mem. Hosp. v. Mecury Const. Corp., 460 U.S. 1, 28 (1983); see also In re Graves, 69 F.3d 1147, 1151 (Fed. Cir. 1995) (concluding that although the court "cannot exercise jurisdiction over the appeal before the [agency] enters its reconsideration decision," its jurisdiction "was, in effect, suspended until the [agency] acted"); Northside Sanitary Landfill, Inc. v. Thomas, 804 F.2d 371, 379 (7th Cir. 1986) ("Once our jurisdiction has been [timely] invoked by a petition for review, it makes little sense to require an amendment to the petition to preserve that jurisdiction only because the agency has ruled on the motion for reconsideration.").

Given that, in the circumstances of this case, holding the petition in abeyance served equally the interests of judicial

economy, we are not persuaded that we should impose a bright line test requiring dismissal or amendment of a petition filed during the pendency of a motion for reconsideration, at least where the reconsideration process is ad hoc, as here. We also hesitate to apply such a rule retroactively in any event. See TeleSTAR, Inc., 888 F.2d at 134 (giving newly adopted "incurably premature" rule prospective effect only); see generally Crowe v. Bolduc, 365 F.3d 86, 93 (1st Cir. 2004) (noting that in determining whether to give a new rule prospective effect, we consider, among other factors, whether "retroactive application give[s] rise to a substantial inequity"). Accordingly, we conclude that we have jurisdiction to consider Dr. Craker's petition for review and turn to the merits.[6]

B. Chevron Analysis

In reviewing the Administrator's decision, we first address whether Congress has unambiguously spoken to the precise question that is at issue, Chevron, U.S.A. Inc. v. Natural Resources Defense Council Inc., 467 U.S. 837, 842-43 (1997). If it turns out that the statute is ambiguous, then Chevron deference must be afforded; the agency's interpretation of the statute will be upheld as long as it is "based on a permissible construction of the statute." Id. at 843. In the end, we may set aside the

[6] As previously noted, Dr. Craker is seeking review of Craker II, the Administrator's original decision, and not Craker III, the decision on reconsideration. Given our ultimate disposition, we needn't consider the agency's order in Craker III.

Administrator's decision if it is arbitrary, capricious, an abuse of discretion, not supported by substantial evidence, or otherwise not in accordance with the law. NLRB v. Reg'l Home Care Servs., 237 F.3d 62, 71 (1st Cir. 2001); see also 5 U.S.C. § 706(2)(A), (E). A decision is arbitrary and capricious "if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). We may not substitute our judgment for that of the agency, even if we disagree with its conclusions. River Street Donuts, LLC v. Napolitano, 558 F.3d 111, 114 (1st Cir. 2009). Here, to set the stage for the Chevron analysis, we engage in a more detailed review of the decision at issue.

As previously noted, the Administrator rejected Dr. Craker's application both because it was inconsistent with the Single Convention and because it did not meet the "public interest" requirement of 21 U.S.C. § 823. Because we resolve the matter under section 823, we need not review the arguments relative to the Single Convention, since failure to satisfy either is fatal to Dr. Craker's claim. 21 U.S.C. § 823(a).

In analyzing the CSA, the Administrator first compared Congress' treatment of Schedule I and II substances in section 823(a)(1) with that of Schedule III, IV and V substances, as set forth in section 823(d). Notably, the two statutory sections contain identical public interest factors, except that in section (d) -- which deals with substances that Congress regards as less dangerous -- there is no reference as there is in section (a)(1) to "limiting supply" and "competitive conditions." Unlike considerations with respect to less dangerous drugs, then, according to the Administrator, section 823(a)(1) explicitly sets out both Congress' stated purpose (to maintain effective controls against diversion) and how it intends that the objective is to be achieved (by limiting the number of manufacturers to that which can produce an adequate and uninterrupted supply under adequately competitive prices). Craker II, 74 Fed. Reg. at 2118-23. Moreover, the Administrator also found that section 823(a)(5)'s mandate to consider "the existence in the establishment of effective control against diversion" suggests that section (a)(1)'s reference to diversion is directed toward preventing diversion by limiting the number of manufacturers. Id. at 2128.

The Administrator also detailed the legislative history of the CSA to buttress her conclusion, observing that the CSA's predecessor, the Narcotics Manufacturing Act of 1960, called for the limitation of manufacturers to the smallest number that could

produce an adequate, uninterrupted supply, without referencing competition. Id. Thus, the Administrator concluded, in enacting the CSA, Congress increased the potential number of approved manufacturers from that which can produce an adequate and uninterrupted supply to that which can do so under adequately competitive conditions. Id.

The Administrator acknowledged that the 1960 Act, unlike the CSA, referred to allowing only "the smallest number of establishments that can produce an adequate and uninterrupted supply," and that the CSA dropped the "smallest number" formulation. Nevertheless, she concluded that the CSA's continued use of the term "limiting" retained the concept of an upper limit on manufacturers as a consideration. Id. at 2128-29 n.105.

Finally, the Administrator cited Justice Department written testimony which noted the "primary objective" of "effective control" and that additional manufacturers could be licensed if the additional licenses do not significantly affect drug control. Id. at 2129.

1. Chevron Step One

At the outset, we reject each party's contention that section 823(a)(1) unambiguously supports its respective position. It is not clear from the text of the section whether, as Dr. Craker argues, limiting supply is allowed only where diversion is a concern, or, as the Administrator contends on appeal, the statute

must be construed to require that limiting supply be the means by which effective controls against diversion are implemented. Indeed, as the Administrator observed, 74 Fed. Reg. 2127-32, and as the DEA concedes, the DEA itself has taken inconsistent positions on this question. Compare Noramco, 375 F.3d at 1153 (observing that the DEA argued in one registration (Johnson Matthey) that no analysis of competition is required), with id. at 1157 (noting that in a different registration (Penick) the DEA addressed competition and supply factors). As it does not appear that the statute either mandates or excludes either side's view, we turn to step two and resolve whether the administrator's interpretation is a reasonable one. We hold that it is.

2. Chevron Step Two

We conclude that the government's view prevails at Chevron's second step. Dr. Craker advances three reasons why this should not be the outcome. We address them in turn.

First, he argues that the court in Noramco squarely rejected the DEA's present view. But contrary to this assertion, the court in Noramco did not hold that section 823(a)(1) unambiguously required the DEA to forego consideration of supply and competition if it found no increased difficulty in controlling diversion. Instead, the court held that the statute did not directly answer the question, but that the Agency's interpretation of the statute -- that analysis of competition and supply was

unnecessary -- was reasonable. Noramco, 375 F.3d at 1153; see also Chevron, 467 U.S. at 843 n.11 ("The court need not conclude that the agency construction was the only one it permissibly could have adopted . . . or even the reading the court would have reached if the question initially had arisen in a judicial proceeding.").[7]

Dr. Craker next takes aim at the Administrator's assessment that section (a)(1) speaks to diversion on a "registrant-wide" scale, whereas section (a)(5) refers to an individual registrant. He argues that even if this dichotomy is permissible, the Administrator failed to demonstrate any diversion concern. We disagree, as the Administrator cited legislative history noting Congress' recognition that the risk of diversion increases with the addition of new manufacturers. 74 Fed. Reg. at 2129.

Finally, Dr. Craker argues that the Administrator did not adequately explain why the DEA was changing its position from the one that it had advocated in Noramco. To the contrary, and as previously noted, Craker II contains a lengthy analysis of that very issue. 74 Fed. Reg. at 2127-33. "[P]ursuant to Chevron, an agency's change in precedent is not invalidating if the agency adequately explains its reasons. The agency's explanation must be

[7] We note that Dr. Craker's brief truncates a quote from the Noramco opinion to make it appear that the DEA's interpretation of section 823(a)(1) is actually the court's holding of how the statute must be read.

accompanied by some reasoning that indicates that the shift is rational and, therefore, not arbitrary and capricious. This is not a difficult standard to meet." River Street Donuts, LLC, 558 F.3d at 115 (internal citations and quotation marks omitted). Here, the Administrator addressed the agency's prior positions, including that taken in an opinion that was issued while the instant matter was pending before the DEA[8] -- and explained that the interpretation now urged better effectuated the CSA. We find its reasoning sufficient.

Accordingly, we conclude that the Administrator's interpretation of 21 U.S.C. § 823(a)(1) is a reasonable one, to which we defer.

3. Administrator's Decision

Dr. Craker's final claim is that, even if the DEA is permitted to consider supply and competition, the Administrator erred because Dr. Craker demonstrated that both competition and supply are inadequate. On the contrary, the Administrator's findings are supported by the record.

a. Competition

Dr. Craker's argument with respect to competition is essentially that there cannot be "adequately competitive conditions" when there is only one manufacturer of marijuana.

[8] See Penick Corp. v. Drug Enforcement Admin., 491 F.3d 483 (D.C. Cir. 2007).

Invoking anti-trust doctrine, he asserts that a monopoly cannot constitute competition within the meaning of the statute.

The Administrator addressed competition through the lens of price, and observed that NIDA had provided marijuana manufactured by the University of Mississippi either at cost or free to researchers, and that Dr. Craker had made no showing of how he could provide it for less, especially when his associate Mr. Doblin acknowledged MAPS' profit motive in its manufacturing enterprise. 74 Fed. Reg. at 2121. Additionally, the Administrator noted that Dr. Craker is free to bid on the contract when it comes up for renewal. Id.

We see nothing improper in the Administrator's approach. The statutory term "adequately competitive conditions" is not necessarily as narrow as the petitioner suggests. This is not an anti-trust case, and Dr. Craker does not point to any authority suggesting that anti-trust laws must guide the "adequacy of competition" inquiry or that price considerations must not. That the current regime may not be the most competitive situation possible does not render it "inadequate."

b. Adequate and Uninterrupted Supply[9]

In finding that Dr. Craker failed to demonstrate that the current supply of marijuana was not adequate and uninterrupted, the

[9] Dr. Craker does not renew on appeal his argument that the current marijuana supply is lacking in quality.

Administrator observed that there were over 1000 kilograms of marijuana in NIDA possession, an amount which far exceeds present research demands and "any foreseeable" future demand. Id. at 2119. Dr. Craker does not dispute this finding, or that the current amount is more than ninety times the amount he proposes to supply. Id. Instead, he argues that the adequacy of supply must not be measured against NIDA-approved research, but by whether the supply is adequate to supply projects approved by the FDA. But even if we were to accept his premise -- which we don't -- Dr. Craker fails to demonstrate that the supply is inadequate for those needs, either. He merely states that certain projects were rejected as "not bona-fide" by NIDA, a claim which does not address the adequacy of supply. The fact that Dr. Craker disagrees with the method by which marijuana research is approved does not undermine the substantial evidence that supports the Administrator's conclusion or render that conclusion arbitrary or capricious.

IV. CONCLUSION

Because the Administrator's interpretation of the CSA is permissible and her findings are reasonable and supported by the evidence, the petition for review is **denied**.