No. 09-1220

IN THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

Lyle E. Craker,
Petitioner,

v.

Drug Enforcement Administration,
Respondent.

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

Petitioner's Reply Brief

M. Allen Hopper
ACLU Found. of Northern California
39 Drumm Street
San Francisco, CA 94111
(415) 621-2493 (telephone)
(415) 255-8437 (facsimile)

Sarah R. Wunsch
ACLU of Massachusetts
211 Congress Street, 3rd Floor
Boston, MA 02110
617-482-3170 (telephone)

Theodore P. Metzler*
Henry B. Liu
COVINGTON & BURLING LLP
1201 Pennsylvania Ave. N.W.
Washington, D.C. 20004
(202) 662-5569 (telephone)
(202) 778-5569 (facsimile)

Eugene Gulland
Of Counsel
COVINGTON & BURLING LLP
1201 Pennsylvania Ave. N.W.
Washington, D.C. 20004
(202) 662-6000 (telephone)
(202) 662-6291 (facsimile)

* *Counsel of Record for Petitioner Lyle E. Craker*

May 4, 2012

Table Of Contents

Reply Brief Addendum

Table Of Authorities

Page(s)

Cases

Statutes, Rules, and Legislative Materials

Regulatory Materials

Other Authorities

Summary Of The Argument

1. DEA's belated challenge to the Court's jurisdiction to hear Professor Craker's Petition for Review is meritless. Professor Craker timely filed his petition for review from DEA's final order and the Court expressly held that petition in abeyance while the agency considered Professor Craker's motion for reconsideration. Upon DEA's denial of reconsideration, Professor Craker's petition became ripe and this Court stated that "the appeal can go forward." DEA now urges the Court to adopt a rule that would needlessly require a second petition following the agency's order on reconsideration. DEA's proposed rule should be rejected here as it has been rejected by other courts of appeal. Even if the Court were to adopt DEA's proposed new rule, it should do so only prospectively. The circumstances here—where the Court held a timely petition for review in abeyance and subsequently stated that the appeal could go forward after reconsideration was denied—exemplify circumstances where a litigant is likely to be lulled into noncompliance.

2. The Controlled Substances Act required DEA to register Professor Craker for a license to cultivate marijuana for medical research because his application is consistent with the public

interest and the United States' treaty obligations. 21 U.S.C. § 823(a). DEA's arguments to the contrary are unpersuasive.

a. In considering the public interest, DEA upturned its 30-year interpretation of the first public interest factor of 21 U.S.C. § 823(a)(1). As DEA long held, that factor permits DEA to restrict the registration of new schedule I or II controlled substances manufacturers to a number that provides for adequate supply under adequately competitive conditions only when actually necessary to maintain effective controls against diversion. That interpretation is required by the plain meaning of the statute.

DEA's new interpretation—that petitioners must show *inadequate* supply or competition even where there is no diversion risk—cannot be squared with the text of the statute or its legislative history. Nor has DEA offered any sufficient reason for reexamining its traditional interpretation of § 823(a)(1). With the exception of Professor Craker's application, DEA consistently applied that interpretation for 30 years, and *never* required proof of inadequate supply or competition where there was no diversion risk.

b. In the alternative, DEA arbitrarily and capriciously applied the "adequate supply" and "adequate competition" factors. Under DEA's new interpretation, proof that either is inadequate would be sufficient to grant Professor Craker's application. In fact, both are inadequate.

DEA does not deny that the University of Mississippi holds a monopoly on the supply of research marijuana—the opposite of competition. DEA's contention that it can find "adequately competitive conditions" based solely on price ignores the non-price benefits of competition and the possibility that Professor Craker's costs could be lower than the current supplier's. And DEA's reliance on the bidding process for the NIDA contract is contrary to how its own regulations consider the adequacy of competition.

Nor does DEA deny that the NIDA review process has blocked the supply of marijuana to FDA-approved research. DEA's holding that the supply of research marijuana is nevertheless adequate rests on the faulty premise that FDA-approved research is not "legitimate" unless approved by NIDA. In fact, no statute or regulation requires NIDA to review marijuana research protocols.

3. DEA also misconstrues the United States' obligations under the Single Convention on Narcotic Drugs (the "Single Convention"). Although DEA acknowledges that the Single Convention exempts "medicinal" marijuana from the treaty's system of government controls, the agency nevertheless contends that the exemption does not apply because marijuana has not been approved for medical use by the FDA. DEA's attempt to import a "governmental approval" requirement into the exemption is irreconcilable with the plain language and the purpose of the treaty.

Even without the medicinal marijuana exemption, Professor Craker's application is consistent with the United States' obligations under the Single Convention. The treaty's requirement that national agencies control the domestic trade in marijuana is satisfied by DEA's and FDA's closed system of licensing the manufacture, distribution, and dispensing of schedule I controlled substances.

DEA's claim that NIDA must be the exclusive source for providing marijuana to medical researchers is erroneous. There is no statute, law, or regulation that requires NIDA to regulate the distribution of marijuana for medical research. To the contrary, the

Controlled Substances Act directs HHS to evaluate research protocols for schedule I and II drugs, and HHS has in turn delegated this function to FDA, *not* NIDA. And Professor Craker has consistently maintained that he will distribute marijuana in accordance with DEA and FDA regulations.

Argument

I. The Court Has Jurisdiction Over Professor Craker's Petition For Review.

DEA contends that this Court lacks jurisdiction because Professor Craker did not file a second petition for review after the agency denied his motion for reconsideration. DEA relies on a jurisdictional rule that "a petition for review filed during the pendency of the motion for reconsideration [is] 'incurably premature and in effect a nullity.'" (DEA Br. 23 (quoting *Gorman v. NTSB*, 558 F.3d 580, 586 (D.C. Cir. 2009).) This "rule" has not been adopted by this Court, and should not be in this case.

The Controlled Substances Act permits "any person aggrieved by a final decision" to obtain review of the decision "upon petition filed with the court." 21 U.S.C. § 877. Professor Craker petitioned for review of a "final decision" of DEA by: (1) filing a timely

petition for review of DEA's January 14, 2009 Final Order; and (2) asking the Court to hold the petition in abeyance until the resolution of his reconsideration motion. The Court granted Professor Craker's motion and suspended any consideration of the merits "until [his] motion for reconsideration is adjudicated." (DEA App. 37.) When DEA denied reconsideration, the Court expressly ordered the case to resume, stating: "*the abeyance is lifted and this case may proceed*." (DEA App. 163 (emphasis added).) As the Court's order implicitly acknowledged, when DEA issued its ruling Professor Craker's petition became ripe for review.

Despite the Court's order that the case proceed, DEA contends that Professor Craker's petition for review is "incurably premature." (DEA Br. 24.) According to DEA, a litigant is required to submit a new petition even if the Court suspends consideration of the initial petition. No court has adopted DEA's proposed jurisdictional rule.

DEA cannot point to any compelling rationale for requiring a party to re-file a petition for review after the court suspends and then resumes consideration of a petition for review. The purpose behind any

finality rule is to prohibit litigants from pressing forward in both the courts and the agency simultaneously. But that problem is solved by holding the appeal in abeyance until the disposition of all reconsideration motions. Because "a stay is as much a refusal to exercise federal jurisdiction as a dismissal," *Moses H. Cone Mem. Hosp. v. Mercury Const. Corp.*, 460 U.S. 1, 28 (1983), both approaches serve the interests of judicial economy.

For that reason, several courts of appeals have rejected the very argument DEA now advances. For example, in *In re Graves*, the Federal Circuit acknowledged that it "cannot exercise jurisdiction over the appeal before the [agency] enters its reconsideration decision." 69 F.3d 1147, 1151 (Fed. Cir. 1995). Yet rather than dismiss the appeal, the court held that its jurisdiction "was, in effect, suspended until the [agency] acted on the [] request for reconsideration and rendered its reconsideration decision." *Id.*[1]

---

[1] The court noted that its decision to suspend the petition for review "finds support by analogy in the treatment afforded by FRAP 4(a)(4)." *Graves*, 69 F.3d at 1151 n.7. The commentary to Rule 4(a)(4) explains that "'[a] notice [of appeal] filed before the filing of one of the specified motions or after the filing of a motion but before disposition of the motion is, in effect, suspended until the motion is disposed of, (continued…)

Similarly, the Seventh Circuit has held that the failure to "amend [the] original petition to reflect the [agency's] order on reconsideration" did not deprive the court of jurisdiction. *Northside Sanitary Landfill, Inc. v. Thomas*, 804 F.2d 371, 379 (7th Cir. 1986). The court reasoned that "[o]nce our jurisdiction has been properly invoked by a petition for review, it makes little sense to require an amendment" after the agency rules a motion for reconsideration. *Id.* Indeed, the court noted that its decision to proceed to the merits "might have 'lulled' [the petitioner] into thinking that its petition need not be amended . . . to sustain our jurisdiction." *Id.* Likewise, here, the Court's decision to suspend consideration of Professor Craker's petition for review provides this Court with jurisdiction to consider it now.

The cases DEA relies on in support of its argument are not on point. DEA cites several cases (at 23-24) holding that a court does not have jurisdiction to consider the merits of a petition for review while a "petition for reconsideration . . . [is] still *pending* before [the agency]."

---

whereupon, the previously filed notice effectively places jurisdiction in the court of appeals.'" *Id.* (quoting Fed. R. App. P. 4(a)(4) advisory committee's notes).

Council Tree Commc'n, Inc. v. FCC, 503 F.3d 284, 287 (3d Cir. 2007) (emphasis added). No request for reconsideration is pending here. There is thus no prospect that this Court will expend judicial resources "while at the same time the petitioner undertakes before the [agency] to get further relief that would make the case moot and [the court's] efforts supererogatory." *Clifton Power Corp. v. FERC*, 294 F.3d 108, 112 (D.C. Cir. 2002).

Here, by contrast, Professor Craker filed his petition for review and simultaneously asked the Court to hold the petition in abeyance because "it would be premature to litigate in this Court" and a stay would "conserve judicial resources during the reconsideration proceedings before the agency." (DEA App.26.) Shortly after DEA issued its ruling, the Court ordered that "the abeyance is lifted and this case may proceed." (DEA App. 163.)

The D.C. Circuit's decision in *TeleSTAR, Inc. v. FCC*, 888 F.2d 132 (D.C. Cir. 1989), does not warrant a different conclusion. In *TeleSTAR*, the court established a "bright line test" that requires *dismissal* in any case where "a petition for review is filed before the challenged action is final." *Id.* at 134. After the court dismisses the

petition, "the challenging party must file a new notice of appeal or petition for review." *Id.* By contrast, this Court expressly allows—as it did in this case—the suspension of a petition for review while a motion for reconsideration is pending. The practical effect of the two approaches is the same.

Moreover, DEA's proposed rule could not fairly be applied retroactively. This court considers three factors in determining whether to give a new rule prospective effect: (1) whether "the court's decision announce[s] a new and unexpected rule of law," (2) whether "the history of the jurisprudence in the affected area of the law, together with the new rule's purpose and effect, counsel for or against retroactive application," and (3) whether "retroactive application give[s] rise to a substantial inequity." *Crowe v. Bolduc*, 365 F.3d 86, 93 (1st Cir. 2004) (citing *Chevron Oil Co. v. Huson*, 404 U.S. 97, 106-07 (1971)). Each of those factors favors giving DEA's proposed jurisdictional rule prospective effect.

First, this Court has not previously required that parties file a new petition for review after the agency denies a motion for reconsideration. To the contrary, the Court's orders holding Professor

Craker's petition in abeyance until DEA acted, and then allowing the case to "proceed," suggest that a new petition for review was unnecessary.

Second, the purpose of DEA's proposed rule counsels against retroactive application in this case. The point of requiring litigants to file a new petition for review is to ensure that they do not pursue administrative and judicial relief simultaneously. Applying the rule retroactively to parties whose petitions for review have been stayed by the Court "does not advance any discernible goal" in judicial economy or fairness. *Crowe*, 365 F.3d at 94.

Third, it would be unjust to apply DEA's proposed rule retroactively. DEA's order denying Professor Craker's application is final and reviewable, and the parties have fully briefed their positions on the merits. The only question is whether Professor Craker should have taken the additional (and unnecessary) step of filing a new petition for review after the Court lifted the stay on the proceedings. Under these circumstances, DEA's proposed rule is a technicality that would "create traps for the unwary" if applied retroactively. *Collins v. NTSB*, 351 F.3d 1246, 1250 (D.C. Cir. 2003). Indeed, DEA's argument

seeks to spring just such a "trap for the unwary." After Professor Craker moved to hold the petition in abeyance, DEA responded that it "does not oppose holding the instant case in abeyance until that motion is resolved." (Reply Br. Add. 1a).

Moreover, other courts of appeals have declined to apply similar jurisdictional rules retroactively. In *TeleSTAR*, the D.C. Circuit held that "subsequent action by the agency on a motion for reconsideration does not ripen the petition for review." 888 F.2d at 134. The court nevertheless concluded that it "will give this rule prospective effect," and "permit[ted] consideration of the originally-premature petition for review." *Id.*

II. DEA's Finding That Professor Craker's Application Is Not In The Public Interest Was Arbitrary And Capricious.

In rejecting Professor Craker's application, DEA applied an interpretation of 21 U.S.C. § 823(a)(1) that assumes an ever present risk of diversion without any individual determination or evidence of such diversion. That interpretation is inconsistent with the text of the statute, its legislative history, and the interpretation that DEA applied for over thirty years.

A. The Plain Language Of 21 U.S.C. § 823(a)(1) Required DEA To Find Professor Craker's Application Was In The Public Interest.

DEA does not dispute that its denial of Professor Craker's application hinged on the first public interest factor of 21 U.S.C. § 823(a). That section required DEA to consider, in determining the public interest, the "maintenance of effective controls against diversion" by limiting licensed manufacturers of marijuana "to a number which can produce an adequate and uninterrupted supply . . . under adequately competitive conditions" for legitimate purposes. 21 U.S.C. § 823(a)(1). In other words, the statute requires DEA to consider whether limiting the number of registered manufacturers would assist in maintaining effective controls against diversion.

Although DEA found no risk of diversion, it weighed this public interest factor against Professor Craker's application. It reached that conclusion only by requiring Professor Craker to affirmatively show inadequate competition or supply even in the absence of any diversion risk. (*See* Final Order, 74 Fed. Reg. 2101, 2123 (Jan. 14, 2009) (Add. 123) ("Thus, every applicant for registration under § 823(a) bears the burden of demonstrating that either the existing supply or

competition is inadequate.").) In doing so, DEA reversed its longstanding interpretation of the first public interest factor and turned the plain language of § 823(a) on its head.

The plain language of § 823(a)(1) compels the interpretation that DEA itself applied for over thirty years—that "[§ 823(a)(1)] permits the Drug Enforcement Administration to restrict entry to a number of registrants constituting adequate competition *only when actually necessary to maintain effective controls against diversion.*" Bulk Manufacture of Schedule I and II Substances, 39 Fed. Reg. 12138 (April 3, 1974) (emphasis added); (*see also* Opening Br. 35-38). As DEA admits, the "*purpose*" of § 823(a)(1) is "to 'maintain effective controls'" against the diversion of schedule I or II controlled substances, and limiting the number of registrants is simply one "*means* by which Congress intended that objective to be achieved." (DEA Br. 32 (emphasis added).) Yet DEA illogically concludes that it therefore "must" require an applicant to prove competition or supply is inadequate *even when there is no risk of diversion.* (*See id.*) That conclusion does not follow from the text. If the purpose of § 823(a)(1)

will be satisfied regardless of competition or supply, then there is no reason to consider those factors.

Remarkably, DEA now suggests that its new interpretation is required by the plain language of the statute. (DEA Br. 31-32, 35.) DEA has a thirty-year history of defending the opposite interpretation of § 823(a)(1). For example, in *Noramco of Delaware, Inc. v. DEA*, the agency successfully argued that § 823(a)(1) does not require consideration of competition or supply where there is no diversion risk. 375 F.3d 1148, 1152-53 (D.C. Cir. 2004). As the D.C. Circuit stated, § 823(a)(1) "expressly directs the DEA to limit competition *only* as a means to achieve 'maintenance' of [] control [against diversion]." *Id.* at 1153 (emphasis added).[2]

---

[2] In any case, having prevailed in *Noramco* on the basis that DEA's traditional interpretation of § 823(a)(1) is at a minimum a permissible reading of the statute, the agency is collaterally estopped from now arguing that the plain language requires the opposite interpretation. Collateral estoppel may be applied where "(1) the issue sought to be precluded in the later action is the same as that involved in the earlier action; (2) the issue was actually litigated; (3) the issue was determined by a valid and binding final judgment; and (4) the determination of the issue was essential to the judgment." *Ramallo Bros. Printing, Inc. v. El Dia, Inc.*, 490 F.3d 86 (1st Cir. 2007). The issue here—the proper interpretation of § 823(a)(1)—was litigated, decided, and essential to the judgment in *Noramco*. *See* 375 F.3d at 1152-54.

Nor is DEA's new interpretation even a permissible reading of the statute. The agency's brief repeats several arguments from its Final Order in support of its counter-textual interpretation, but none of those arguments is persuasive.

First, DEA argues that its longstanding interpretation should be abandoned to avoid conflicts with two other subsections of the statute, §§ 823(a)(5) and 823(d)(1). Those arguments fail.

Section 823(d)(1) is the parallel public interest factor to § 823(a)(1) for applications to manufacture controlled substances in schedules III, IV, and V. Like § 823(a)(1), the public interest factor identified is "maintenance of effective controls against diversion," but subsection (d)(1) does not mention limiting registrations on the basis of supply or competition. DEA argues that the presence of the competition and supply language in (a)(1) "suggests that Congress wanted to stipulate in § 823(a)(1) precisely how controls against diversion . . . are to be maintained." (DEA Br. 33.) But DEA fails to explain why Congress would require proof of inadequate supply or competition to maintain effective controls against diversion where the agency has not determined there would be any diversion risk.

DEA also argues that the traditional interpretation of § 823(a)(1) "reduces the scope" of another public interest factor, § 823(a)(5), because subsection (a)(1) was meant to address system-wide diversion whereas (a)(5) was meant to address diversion risks in the particular manufacturing facility. DEA Br. 34. But as Petitioner's opening brief explains, the agency failed to explain why that distinction would require proof of inadequate competition or supply where there is no *system-wide* diversion risk.

Second, DEA's supposed "reexamination" of § 823(a)(1) should also be rejected. Although an agency is not prohibited from revising its interpretation of a statute it administers, it must provide "good reasons" for its new policy. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). Here, the agency claims that its reconsideration was necessary because it "had taken inconsistent positions on this question" before considering Professor Craker's application. (DEA Br. 35.) DEA's assertion is inaccurate.

In 1974, DEA interpreted § 823(a)(1) "as requiring the registration of otherwise qualified applicants to manufacture any controlled substance, as long as the total number of registrants remains

within the effective control [of] the Administration." *Bulk Manufacture*, 39 Fed. Reg. at 12,138. DEA stated that it "believe[s] that the statute permits the DEA to restrict entry to a number of registrants only when actually necessary to maintain effective controls against diversion." *Id.* DEA also noted that the statute "requires the DEA to register an applicant who meets all the other statutory requirements, without regard to the adequacy of competition, if the Administrator determines that registering another manufacturer will not increase the difficulty of maintaining effective controls against diversion." *Id.*

In 1980, a DEA Administrative Law Judge applied this same interpretation. DEA explained that "all the statute requires is that the administrator determine whether or not the number which would exist if the pending application granted is a number which can produce the desired result [*i.e.*, adequate competition and supply] and be effectively controlled so as to prevent diversion." *In re McNeilab*, No. 78-13 at 24 (Aug. 20, 1980) (cited in Antitrust Div. Amicus Br., *In re Johnson Matthey, Inc.*, http://www.justice.com/atr/public/comments/8014.htm, at 4-6). DEA continued to apply this interpretation right up to—and indeed even while it was considering—Professor Craker's application.

(Opening Br. 45-47); *see Penick Corp. v. DEA*, 491 F.3d 483, 491 n.11 (D.C. Cir. 2007); Chattem Chemicals, Inc., 71 Fed. Reg. 9834, 9838 (Feb. 27, 2006); *Noramco*, 375 F.3d at 1152-53; Johnson-Matthey, Inc., 67 Fed. Reg. 39041, 39043-44 (June 6, 2002).

DEA claims that it applied a different interpretation of the statute in two cases, but that is incorrect. Before Professor Craker's case, DEA *never* required an applicant to prove inadequate competition where did not find any risk of diversion. The agency says that in Roxane Laboratories, Inc., 63 Fed. Reg. 55891 (Oct. 19, 1988), it "analyzed the 'adequacy of competitive conditions' independently of diversion." (DEA Br. 40-41.) But *Roxane* involved a registration to import cocaine, and an examination of competitive conditions was required *by an entirely separate statute.* Roxane proposed to import cocaine under 21 U.S.C. § 952(a)(2)(B), which allows importation only where "the Attorney General finds that competition among domestic manufacturers of the controlled substance is inadequate." The agency *did not* examine competition under § 823(a)(1) in *Roxane.* Indeed, 952(a)(2)(B) shows that Congress knew well how to draft a statute that requires proof of inadequate competition.

Nor did the agency apply a different interpretation of § 823(a)(1) in Penick Corp., 68 Fed. Reg. 6947 (Feb. 11, 2003). DEA points to its discussion of competition in that case, but the agency has never said that it was *prohibited* from discussing competition, only that it need not do so unless there is a risk of diversion. In *Penick*, the parties contested both whether the registration would result in increased diversion and whether competition was adequate. *Id.* at 6949. The agency found no diversion risk and inadequate competition, but it could well have included the discussion of competition as "belt and suspenders" in case its holding on diversion were not upheld. Indeed, on appeal the D.C. Circuit noted that no finding on competition was even required. *Noramco*, 375 F.3d at 1157 n.8. Unlike here, there is no indication in *Penick* that DEA would have denied the application if it had found adequate competition even though it also found no diversion risk.

The *only* time that DEA applied a different interpretation of the statute was in its 2004 order to show cause directed to Professor Craker. (*See* App. 14 ¶ 9.) DEA gave no reason for abandoning its traditional interpretation of the statute in that order. In fact the

agency continued to apply its traditional interpretation even after the order to show cause. See *Penick*, 491 F.3d at 491 n.11; Chattem Chemicals, Inc., 71 Fed. Reg. at 9838.

Third, DEA's examination of the legislative history of § 823(a) is flawed. In response to Petitioner's brief (at 41-43), the agency now abandons its reliance on language from the Narcotics Manufacturing Act of 1960, *see* 74 Fed. Reg. 2128 (Add. 128), and with good reason. The 1960 Act stated that DEA should consider limiting new registrants to "the smallest number of establishments which will provide an adequate an uninterrupted supply," but Congress *removed* the "smallest number of establishments" language when it passed the Controlled Substances Act. The statute now states that DEA should "consider" limiting registrants to "a number"—not the smallest one—that can produce adequate supply under competitive conditions. *See Stone v. INS*, 514 U.S. 386, 397 (1995) (amendments to a statute are presumed to have "real and substantial effect").

DEA now attempts read "the smallest number" back into the statute by quoting language from the Senate Report from a draft (and not enacted) version of the Controlled Substances Act. The draft states

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 an uninterrupted supply under adequately competitive conditions for legitimate purposes." (DEA Br. 39 (quoting S. Rep. No. 91-613 at 7).)

DEA fails to mention that the quoted language specifically responded to the concern that new registrations could "add[] to the danger of diversion." S. Rep. No. 91-613 at 7. DEA also fails to mention that in *the very next sentence*, the Report states, "In effect, the Attorney General must seek out a balance between safeguarding against diversion and allowing for sufficient competition among manufacturers." *Id.* Where there is no diversion risk, that balance weighs toward registration.[3]

As DEA acknowledged in 1974, the legislative history confirms the plain import of § 823(a)(1), that Congress intended DEA to

---

[3] In an amicus brief, DOJ's Antitrust Division agreed with DEA's traditional interpretation of § 823(a) and analyzed this legislative history as supporting that interpretation. Antitrust Div. Amicus Br., *In re Johnson Matthey, Inc.*, http://www.justice.com/atr/public/comments/8014.htm, at 4-6.

limit the number of suppliers only when necessary to ensure controls against diversion. *Bulk Manufacture*, 39 Fed. Reg. at 12138. DEA consistently applied that interpretation for 30 years—until it came to Professor Craker. DEA's new interpretation is not a permissible reading of § 823(a)(1) and its proposed rationalizations for changing course all fail. DEA's application of such a wholly unsupported interpretation of the statute is arbitrary and capricious.

B. In The Alternative, DEA's Application Of The "Adequate Supply" And "Adequate Competition" Factors Was Arbitrary And Capricious.

Under DEA's new interpretation, § 823(a)(1) would weigh in favor of Professor Craker's application upon a showing of either inadequate competition or inadequate supply. Even if § 823(a)(1) could be read to permit DEA to require such a showing, DEA applied the competition and supply factors contrary to their plain meaning. Under any reasonable definition, the supply of marijuana for medical research purposes is inadequate, and is provided under monopolistic conditions, which are inherently uncompetitive.

1. A Monopoly On The Supply of Marijuana For Medical Research Is Not Adequate Competition.

DEA does not deny that the University of Mississippi (as controlled by NIDA) currently holds a monopoly on the supply of marijuana for medical research and that accordingly there is no competition whatsoever for the supply of research marijuana. Indeed, DEA makes no effort to explain how a monopoly can be "adequately competitive." Instead, DEA contends that the supply of marijuana is sufficient because Professor Craker cannot provide marijuana at lower cost to researchers, even though his production costs have yet to be determined and could well be less than NIDA's costs. Under DEA's reasoning, conditions are "adequately competitive" simply because when NIDA chooses to supply marijuana for a privately-funded research project, it provides the material at its cost.[4]

But there is no question that competition provides benefits other than lower prices to consumers. *See, e.g.*, *Noramco*, 75 F.3d at 1158 ("[E]xpanding the playing field may yield other [non-price]

[4] Of course, when NIDA refuses to provide marijuana to FDA-approved projects, it is not available at any price for those projects and the cost is infinite; Professor Craker's costs would necessarily be lower for those projects.

benefits," such as "improved product quality, reliability of supply, financial terms and conditions and order lead times."). The legislative history of § 823(a)(1), moreover, shows that Congress intended competition to go *beyond* price. The 1969 draft of § 823(a)(1) referred to the number of establishments that can produce an adequate and uninterrupted supply "at reasonable prices." S. Rep. No. 91-613 at 18. That version was not enacted, however, and Congress instead chose the more expansive term "adequately competitive conditions." DEA's focus on price failed to give effect to the non-price benefits of competition.

DEA also attempts to defend its reliance on the competitive bidding process for the NIDA contract as support for "adequately competitive conditions," but DEA's own regulation, 21 C.F.R. § 1301.34(d), shows that (outside of applications to cultivate marijuana), DEA itself considers "adequately competitive conditions" to mean conditions in the market to supply the drug; that is, competition among two or more firms to sell the drug, not to be a monopoly provider. *See Roxane*, 63 Fed. Reg. at 55895 (the regulation "clearly contemplate[s] that there are at least two manufacturers of the controlled substance in question.").

DEA claims its own regulation is not relevant because it deals with importers of schedule I and II controlled substances rather than manufacturers. And indeed, the regulation implements 21 U.S.C. § 952(a)(2)(B)—the statute at issue for the importation of cocaine in *Roxane*, 63 Fed. Reg. 55891. But § 952(a)(2)(B) requires a finding of inadequate competition specifically where registration of additional domestic manufacturers under § 823 would not render competition adequate. DEA offers no reason why, if § 823(a)(1) required an analysis of competition—which it does not—that analysis should be any different than the analysis under § 952(a)(2)(B).

2. The University Of Mississippi Cannot Supply All Legitimate Research Needs.

DEA does not deny that the University of Mississippi—the only licensed producer of marijuana for medical research—is prohibited from releasing its supply of the drug except at the authorization of NIDA. Nor does the agency deny that NIDA has refused to supply FDA-approved research projects. DEA nevertheless insists that the supply of research marijuana is "adequate," but in doing so the agency misstates the legislative and regulatory scheme in which its own determinations are made.

The supply of research marijuana is inadequate because the only provider of that drug operates under a contractual restraint that prevents it from fulfilling the needs of the research community. (Opening Br. 55-57.) Congress has directed FDA to be the agency responsible for evaluating the efficacy and safety of drug research. 21 U.S.C. § 303(b) (*see also* Opening Br. 55). But the University of Mississippi cannot provide marijuana to FDA-approved research unless that research is also approved by NIDA. And NIDA has in fact failed to approve several FDA-approved research projects. (*See* Opening Br. 23-26.[5]) In those cases, NIDA's review blocked the supply of marijuana for legitimate medical research.

DEA counters that "nothing in the text § 823(a)(1) remotely suggests that the Administrator has to parse the question of supply in this manner." (DEA Br. 52.) But DEA is wrong. The text of § 823(a)(1) expressly states that the supply that must be adequate is the supply

---

[5] As explained in Petitioner's opposition to DEA's motion to strike, the argument at pages 25-26 of Petitioner's opening brief is offered as background to show that NIDA's review impedes the supply of marijuana for FDA-approved research, a fact that DEA does not dispute. *See Asarco, Inc. v. EPA*, 616 F.2d 1153, 1160 (9th Cir. 1980).

"for legitimate medical, scientific, research, and industrial purposes," and FDA-approved research is a obviously a legitimate purpose whether approved by NIDA or not.

DEA also asserts that NIDA's review is mandated by 21 U.S.C. § 823(f), which requires the Secretary of HHS to review the qualifications of researchers who propose to study schedule I and II controlled substances as well as "the merits of the research protocol." In fact, NIDA does not review the research protocols for *any* privately-funded FDA-approved research other than marijuana. Moreover, DEA fails to acknowledge that NIDA *never* performs § 823(f) review because HHS has delegated its responsibility under that section to FDA. (*See* Opening Br. 56 & n.16; FDA Staff Manual Guides Vol. II 1410.10(1)(A)(8).) Instead, DEA simply reiterates several statements from its Final Order—that FDA's "statutory mission" does not prevent other agencies from having overlapping functions and that FDA's approval processes are different from review under § 823(f). But those statements are not responsive to the argument that HHS has in fact delegated its responsibility under § 823(f) to FDA.

DEA's circular reasoning—that the NIDA supply of research marijuana is adequate so long as it is adequate for NIDA-approved research—should thus be rejected because NIDA-approved research does not comprise all legitimate purposes under § 823(a).

III. Professor Craker's Application Is Consistent With The United States' Obligations Under The Single Convention.

DEA has repeatedly taken the view that "the primary goals of the Single Convention are to limit the manufacture, trade, and consumption of narcotic drugs to *legitimate medical and scientific purposes*; and *ensuring availability of these drugs for medical use*." *Penick*, 68 Fed. Reg. at 6949 (emphasis added). Although Professor Craker seeks to cultivate marijuana solely for legitimate medical research, DEA asserts that his registration would be inconsistent with the United States' obligations under the treaty. None of DEA's arguments has merit.

A. DEA's Interpretation Of The Single Convention Is Not Entitled To Deference.

DEA first asserts that this Court must afford the agency's interpretation of the Single Convention *Chevron* deference. Neither the Supreme Court nor this Court has adopted DEA's view. To the contrary, the Supreme Court has consistently held that "[t]he clear

import of treaty language controls unless 'application of the words of the treaty according to their obvious meaning effects a result inconsistent with the intent or expectations of its signatories.'" *Sumitomo Shoji America, Inc. v. Avagliano*, 457 U.S. 176, 180 (1982) (quoting *Maximov v. United States*, 373 U.S. 49, 54 (1963)). Because DEA's interpretation of the Single Convention is at odds with the treaty's plain language, the Court owes no deference to the agency's views.

Even if the Court concludes that the text of the Single Convention is ambiguous, deference is only given to the "*reasonable* views of the Executive Branch concerning the meaning of an international treaty." *El Al Israel Airlines, Ltd. v. Tsui Yuan Tseng*, 525 U.S. 155, 168 (1999) (emphasis added). The agency's views are "not conclusive." *Sumitomo*, 457 U.S. at 184. Here, the Court owes no deference to DEA's fundamental misunderstanding of the United States' implementation and compliance with the treaty.

B. Professor Craker's Application Is Exempt From The Single Convention Under The "Medicinal Marijuana" Exemption.

DEA no longer disputes that the Single Convention exempts "medicinal" marijuana from the treaty's system of government controls. Indeed, as Petitioner's opening brief explains (at 60-62), the text, structure, and purpose of the Single Convention make clear that the "medicinal" marijuana exemption serves to protect legitimate medical research. DEA nevertheless contends that the exemption does not apply in the United States because "marijuana has not been approved for medical use by the FDA." (DEA Br. 56.) DEA's interpretation of the medicinal marijuana exemption is erroneous.

First, DEA's attempt to import a "government approval" requirement into the exemption is irreconcilable with the plain language of the treaty. The Single Convention broadly defines "medicinal cannabis" as marijuana "which has undergone the processes necessary to adapt it for medicinal use." Single Convention, Art. 1, ¶¶ 1(o), 28 (Add. 8, 12). As the commentary to the Single Convention makes clear, that language refers to the *physical* and *chemical*

processes needed to adapt a drug for medicinal use—there is no government approval requirement. (App. 95).

Second, DEA's interpretation of the "medicinal" marijuana exemption would render it meaningless. DEA acknowledges that the purpose of the exemption is to reduce government barriers to legitimate medical research, but claims (at 57) that marijuana is not "medicinal" until approved as a new drug by FDA. But to obtain FDA approval a new drug's safety and effectiveness must be shown through an adequate number of controlled studies. *See* 21 C.F.R. § 314.126. DEA's interpretation of the treaty thus places medical researchers in a "catch-22"—the medicinal marijuana exemption does not apply without FDA approval, but without the exemption researchers cannot obtain marijuana to conduct the necessary studies to obtain FDA approval.

Third, DEA's argument is inconsistent with the structure and purpose of the treaty as a whole. As DEA itself has explained, "the primary goals of the Single Convention are to limit the manufacture, trade, and consumption of narcotic drugs to legitimate medical and scientific purposes; and ensuring availability of these drugs for medical use." *Penick*, 68 Fed. Reg. at 6949; *see also Penick*, 491 F.3d at 492;

Single Convention, Art. 2, ¶ 5(b) (Add. 9). Because Professor Craker's application seeks to manufacture marijuana solely for federally-regulated medical research, it is not prohibited by the Single Convention.

Finally, DEA also claims that the medical research exemption does not apply to marijuana because it does not have "an accepted medical use in humans." (DEA Br. 57.) Once again, the text of the Single Convention contains no such limitation. And the treaty drafters expressly considered the possibility of manufacturing medicinal marijuana. In the commentary to Article 28, the drafters explained that "the production of cannabis and cannabis resin must not be undertaken for other than medical and scientific purposes." Commentary, Art. 28, ¶ 7 (App. 115).

C. Professor Craker's Application Satisfies The Single Convention's Requirement Of Government Controls Over Marijuana Distribution.

Even if the medicinal marijuana exemption did not apply, Professor Craker's application is consistent with the United States' obligations under the Single Convention. Articles 23 and 28 of the treaty call for a single government agency to have "the exclusive right of

importing, exporting, wholesale trading and maintaining stocks" of marijuana. Single Convention, Art. 23, ¶ 2 & Art. 28, ¶ 1 (Add. 11-12). Professor Craker's application satisfies this condition by adhering to DEA's stringent regulations for manufacturing, distributing, and dispensing controlled substances. *See* 21 C.F.R. § 1301 *et seq.*

DEA asserts that Professor Craker's proposal "is inconsistent with the Single Convention's requirement of a government monopoly on the wholesale trade in the drug." (DEA Br. 59.) That is inaccurate. The Controlled Substances Act establishes a closed system of distribution whereby any "person who manufactures, distributes, dispenses, imports, or exports any controlled substance" must be registered with DEA. *See* 21 U.S.C. § 822-823; 21 C.F.R. § 1301.11.

If an individual wishes to obtain marijuana for conducting medical research, the individual must register with DEA *and* submit a research protocol to FDA. *See* 21 C.F.R. § 1301.32; *see also* FDA Staff Manual Guides Vol. II 1410.10(a)(8) (App. 124). FDA has the authority to "determine the qualifications and competency of the applicant," and must "consult with [DEA] as to effective procedures to safeguard adequately against diversion of such controlled substances from

legitimate medical or scientific use." 21 C.F.R. § 1301.32(a). Thus, any individual who seeks to obtain marijuana from Professor Craker will be required to register with DEA, obtain FDA approval of its research protocols, and, in the case of human research, be approved by an Institutional Review Board ("IRB") operating under regulations created by the HHS Office of Human Research Protections. *See* 45 C.F.R. § 46.101 *et seq*. These steps ensure that the government will maintain control over Professor Craker's wholesale distribution of marijuana.

DEA contends that its regulations are insufficient to satisfy the Single Convention because "NIDA is the exclusive source for providing marijuana to medical researchers." (DEA Br. 60.) But DEA cannot point to any authority that permits or requires NIDA to regulate the distribution of research marijuana. To the contrary, the Controlled Substances Act delegates authority to review research protocols to HHS, which has delegated this function in turn to FDA, *not to* NIDA. *See* FDA Staff Manual Guides Vol. II 1410.10(1)(A)(8) (App. 124). And Professor Craker has consistently maintained that he will distribute marijuana in accordance with DEA and FDA regulations (and IRB approval for research involving humans).

DEA also ignores that NIDA's own representative testified that NIDA is not responsible for implementing the Single Convention. (Gust Test., Dec. 14, 2005, Tr. at 1732:5-14). NIDA's Director has likewise stated that "it is not NIDA's role to . . . contribute to DEA licensing procedures." (App. 193).

Moreover, DEA's contention that NIDA must maintain control over the distribution of research marijuana is inconsistent with the practice of other nations. In the United Kingdom, the National Cannabis Agency grants licenses to private entities to "produce, possess, or supply marijuana" under the government's supervision, satisfying the Single Convention as "a form of constructive purchase and possession" by the agency. (Add. 87). Professor Craker's registration would likewise be subject to DEA's supervision over all levels of the production and distribution of the drug.

DEA does not dispute that the U.K.'s system is analogous, but instead asserts (at 61) that "the Attorney General [is not required] to rely upon or consider how other nations interpret the Single Convention." But the question is not whether DEA is *required* to rely other countries' interpretation of the Single Convention, but whether

DEA is forbidden from registering Professor Craker under the plain terms of the Single Convention. *See* 21 U.S.C. § 823(a). The experience of the U.K. demonstrates that DEA is well within its authority to grant private entities a license to manufacture and distribute marijuana. *See Medellin v. Texas*, 552 U.S. 491, 507 (2008) ("[W]e have also considered as aids to its interpretation the negotiation and drafting history of the treaty as well as the postratification understanding of signatory nations." (internal citation and quotations omitted)).

Finally, DEA suggests that the International Narcotics Control Board has rejected the U.K.'s method for implementing the Single Convention. But the Board has never stated that the United Kingdom's method of compliance violates the treaty. To the contrary, the Board has *commended* the U.K. for its medical marijuana research. *See* INCB 2001 Annual Report 25, ¶ 158, http://www.incb.org/pdf/e/ar/2001/incb_report_2001_2.pdf.

DEA's conclusion that NIDA must control the distribution of marijuana for medical research is contrary to the text and purpose of the Single Convention and should be rejected.

Conclusion

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

Respectfully submitted,

/s/ Theodore P. Metzler

M. Allen Hopper
ACLU Found. of Northern California
39 Drumm Street
San Francisco, CA 94111
(415) 621-2493 (telephone)
(415) 255-8437 (facsimile)

Sarah R. Wunsch
ACLU of Massachusetts
211 Congress Street, 3rd Floor
Boston, MA 02110
(617) 482-3170 (telephone)

Theodore P. Metzler*
Henry B. Liu
COVINGTON & BURLING LLP
1201 Pennsylvania Ave. N.W.
Washington, D.C. 20004
(202) 662-5569 (telephone)
(202) 778-5569 (facsimile)

Eugene Gulland
Of Counsel
COVINGTON & BURLING LLP
1201 Pennsylvania Ave. N.W.
Washington, D.C. 20004
(202) 662-6000 (telephone)
(202) 662-6291 (facsimile)

* *Counsel of Record for Petitioner Lyle E. Craker*

May 4, 2012

CERTIFICATE OF RULE 32(a) COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because the brief contains 6,993 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

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

Date: May 4, 2012

/s/ Theodore P. Metzler

Theodore P. Metzler
Attorney for Petitioner
Lyle E. Craker

CERTIFICATE OF SERVICE

I hereby certify that on May 4, 2012, I electronically filed the foregoing document with the United States Court of Appeals for the First Circuit by using the CM/ECF system. I certify that the following parties or their counsel of record are registered as ECF Filers and that they will be served by the CM/ECF system:

Mark T. Quinlivan
US Attorney's Office
1 Courthouse Way
Suite 9200
Boston, MA 02110
Attorney for Respondent
Drug Enforcement Administration

Date: May 4, 2012

/s/ Theodore P. Metzler

Theodore P. Metzler
Attorney for Petitioner
Lyle E. Craker

Reply Brief Addendum

No. 09-1220

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

2009 MAR -2 P 3:46

FILED IN CLERKS OFFICE
US COURT OF APPEALS
FOR THE FIRST CIRCUIT

LYLE E. CRAKER, Ph.D.,
Petitioner,

v.

DRUG ENFORCEMENT ADMINISTRATION,
Respondent.

GOVERNMENT'S RESPONSE TO MOTION TO STAY AND HOLD APPELLATE PROCEEDINGS IN ABEYANCE

Respondent, through its undersigned counsel, hereby responds to Petitioner's Motion to Stay and Hold Appellate Proceedings in Abeyance. As Petitioner notes, a motion to reconsider is currently pending before the Deputy Administrator of the Drug Enforcement Administration. Therefore, Respondent does not oppose holding the instant case in abeyance until that motion is resolved.

Respectfully Submitted,

Teresa A. Wallbaum

TERESA A. WALLBAUM (First Circuit Bar # 33038)
Acting Deputy Chief for Policy & Appeals
U.S. Department of Justice
Narcotic and Dangerous Drug Section
1400 New York Ave., NW (Bond Building)
Washington, D.C. 20005
Tel: (202) 616-5193
Fax: (202) 514-6112
Teresa.Wallbaum@usdoj.gov