IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

No. 21-1055

DR. LYLE E. CRAKER,

Petitioner,

v.

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION;
D. CHRISTOPHER EVANS, in his official capacity as Acting Administrator of Drug Enforcement Administration,

Respondents.

No. 21-1323

SCOTTSDALE RESEARCH INSTITUTE,

Petitioner,

v.

US DRUG ENFORCEMENT ADMINISTRATION;
D. CHRISTOPHER EVANS, Administrator of Drug Enforcement Administration;
MERRICK B. GARLAND, Attorney General,

Respondents.

ON PETITION FOR REVIEW FROM A FINAL RULE OF THE
U.S. DRUG ENFORCEMENT ADMINISTRATION

BRIEF FOR THE FEDERAL RESPONDENTS

BRIAN M. BOYNTON
Acting Assistant Attorney General

MARK B. STERN
DANIEL AGUILAR
(202) 514-5432
Attorneys, Appellate Staff
Civil Division, Room 7266
U.S. Department of Justice
950 Pennsylvania Ave., NW
Washington, DC 20530

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases:

Statutes and Treaties:

Rules and Regulations:

Other:

STATEMENT OF JURISDICTION

The U.S. Drug Enforcement Administration (DEA) issued a final rule concerning marijuana cultivation and registration on December 18, 2020. 85 Fed. Reg. 82333. Petitioners sought judicial review of that rule in the courts of appeal under 21 U.S.C. § 877. The petitions for review were consolidated, and this Court has jurisdiction under 21 U.S.C. § 877.

STATEMENT OF THE ISSUES

DEA is charged with regulating the manufacture and distribution of controlled substances, including marijuana. Marijuana can be grown for lawful purposes, such as scientific research, and DEA issues registrations to both cultivators and researchers who are engaged in that activity. In the rule at issue here, DEA revised some of the procedures by which it would issue registrations and otherwise regulate the cultivation and distribution of lawfully grown marijuana. Generally speaking, the rule allows DEA to grant multiple registrations to lawfully grow marijuana and allows researchers to grow marijuana for their own research needs. Additionally, the rule identifies several factors that DEA should consider when granting such registrations, including whether the applicant can cultivate a high quality crop and whether the applicant has complied with applicable laws. The rule also sets forth procedures by which DEA will take possession of

cultivated marijuana after it was harvested for distribution to persons who have been registered with DEA. DEA explained that this control of physical marijuana crops and controlling their movement in commerce was necessary to satisfy the United States' obligations under the Single Convention on Narcotic Drugs, 18 U.S.T. 1407.

The issues presented are:

1. Whether DEA complied with the notice-and-comment procedures of 5 U.S.C. § 553.

2. Whether the rule is arbitrary and capricious, or otherwise contrary to law.

STATEMENT OF THE CASE

I. STATUTORY FRAMEWORK

Congress enacted the Controlled Substances Act to regulate the "importation, manufacture, distribution, and possession and improper use of controlled substances." 21 U.S.C. § 801(2). The Act divides controlled substances into five schedules, based on their potential for abuse, medical uses, and risk of physical or psychological dependence. *Id.* § 812(a)-(b). Generally speaking, a schedule I substance has no accepted medical use and a high risk for abuse, while schedule II-V substances have accepted medical uses and decreasing risk of abuse and dependence. *Id.* § 812(b). Congress

designated marijuana as a schedule I substance. *See* Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, title II § 202(c) (sched. I(c)), 84 Stat. 1242, 1249.

Congress required that anyone who seeks to manufacture a controlled substance must first be registered with the federal government. 21 U.S.C. § 822(a)(1). Manufacturing includes "production" and "cultivation," *id.* § 802(15), (22), and so the registration requirements apply to cultivators of marijuana. Congress assigned this registration authority to the Attorney General, who in turn delegated it to the DEA Administrator. 28 C.F.R. § 0.100.

This registration scheme vests DEA with authority to oversee and regulate the manufacture of controlled substances. Before granting any application to manufacture a controlled substance on schedule I or II, DEA must determine whether "registration is consistent with the public interest." 21 U.S.C. § 823(a). To do so, DEA considers whether the applicant maintains "effective controls" against diversion of the substance, has "past experience in the manufacture of controlled substances," complies with State and local laws, whether the applicant has been convicted of crimes related to controlled substances, and "such other

factors as may be relevant to and consistent with the public health and safety." *Id.*

DEA may "inspect the establishment of a registrant or applicant for registration," 21 U.S.C. § 822(f), and may establish quotas for the amount of manufactured substances, *id.* § 826. Registrants must keep records of their inventory available to DEA for inspection and must make periodic reports to DEA regarding all sales and deliveries. *Id.* § 827. And DEA may suspend or revoke a registration if, for example, the manufacturer has materially falsified their application or been convicted of certain felonies. *Id.* § 824(a). Congress further provided that DEA may "promulgate rules and regulations and [] charge reasonable fees relating to the registration and control" of manufacturing controlled substances. *Id.* § 821.

This registration scheme, and other parts of the Controlled Substances Act, implement the United States' obligations under the Single Convention on Narcotic Drugs, a treaty that was ratified by the Senate in 1967. *See* 18 U.S.T. 1407 (Single Convention); 21 U.S.C. § 801(7) (citing the Single Convention as an underlying impetus to enacting the Controlled Substances Act). Indeed, DEA may only register manufacturers of controlled substances on schedule I or II if doing so would be consistent "with United States obligations under international treaties," such as the

Single Convention. 21 U.S.C. § 823(a). The treaty requires, among other things, that signatories "prohibit the production, manufacture" and "trade in, possession or use of" cannabis "except for amounts which may be necessary for medical and scientific research only, including clinical trials." 18 U.S.T. at 1411, art. 2.5(b) (requirements for drugs listed in the treaty's schedule IV).

To the extent that cannabis cultivation is permitted, its cultivation must be regulated by "the system of controls [] provided in article 23" of the treaty, which govern opium production. 18 U.S.T. at 1421, art. 28. Those article 23 controls require signatory government agencies to (a) designate areas where cannabis will be cultivated; (b) authorize only licensed entities to cultivate cannabis; (c) specify areas of land to cultivate for each license; (d) "purchase and take physical possession of" the cannabis crops; (e) and have the "exclusive right of importing, exporting, wholesale trading and maintaining" stocks of cannabis, "other than those held by manufacturers of * * * medicinal [cannabis] or [cannabis] preparations." *Id.* at 1419, art. 23. If permitted by domestic law, the Single Convention requires signatories to have all these functions performed by the same government agency. *Id.*

II. RULEMAKING FOR MARIJUANA CULTIVATION AND REGISTRATION

In 2020, DEA proposed new rules regarding marijuana cultivation and registration to ensure "consistency with obligations under international treaties such as the Single Convention." 85 Fed. Reg. 16292, 16293 (Mar. 23, 2020). The rule was part of a review of the Controlled Substances Act undertaken by the Department of Justice, in which DEA is housed. *Id.* DEA explained, in particular, that it currently performed most, but not all, of the functions identified in article 23. DEA (a) designated areas for marijuana cultivation, (b) ensured that only licensed cultivators operated, and (c) specified the areas for growing in the licenses. *Id.* at 16294.

Under the proposed rule, DEA would also (d) purchase and take physical possession of cultivated marijuana, and (e) have the exclusive right of importing, exporting, wholesale trading, and maintain stock of marijuana, other than medicinal marijuana. 85 Fed. Reg. at 16294. Accordingly, DEA proposed rules that would allow DEA to take title and physical possession of cultivated marijuana—which would then be stored in "a secure storage mechanism at the registered location in which DEA may maintain possession" of the marijuana. *Id.* at 16294-95. DEA would also have exclusive importation, exportation, and distribution rights for cultivated marijuana "other than those held by registered manufacturers

and distributors of medicinal cannabis or cannabis preparations." *Id.* at 16295.

The rule proposed definitions for the terms "medicinal cannabis" and "cannabis preparations," as those terms were not defined in the treaty or the Controlled Substances Act. 85 Fed. Reg. at 16295. Cannabis preparation would mean "cannabis that was delivered to DEA and subsequently converted by a registered manufacturer into a mixture * * * containing cannabis, cannabis resin, or extracts of cannabis," but does not include non-marijuana material. *Id.* Medicinal cannabis would mean "a drug product made from the cannabis plant, or derivatives thereof that can be legally marketed under the Federal Food, Drug, and Cosmetic Act," but does not include non-marijuana material. *Id.* In the final rulemaking, DEA explained that this definition would ensure that this subset of marijuana—not subject to DEA's exclusive control for import, export, and distribution—would be approved for medical use under federal law, which was appropriate because "[t]he United States, not State governments, is the relevant party to the Single Convention." 85 Fed. Reg. 82333, 82340 (Dec. 18, 2020).

DEA also proposed a list of factors it would consider when deciding whether to grant an application to register as a marijuana cultivator.

Consistent with the public interest factors in 21 U.S.C. § 823(a), DEA would consider, among other things, whether applicants maintained effective controls against diversion, whether they complied with State and local law, whether they have a prior criminal conviction related to controlled substances, and whether they could "consistently produce and supply cannabis of a high quality and defined chemical composition." 85 Fed. Reg. at 16305-06. DEA would consider these factors for the 35 then-pending applications it had received from entities seeking to register to cultivate marijuana. *Id.* at 16295.

The proposed rule explained how the new registrants would operate under the new system of distribution and control. In most cases, DEA would take title and possession of the marijuana after it was harvested, and the marijuana would be stored on the registrant's site. 85 Fed. Reg. 16295-96. If the registrant sought to use the marijuana for its own scientific research and drug development, then DEA would "distribute a quantity of marihuana that does not exceed the company's DEA-issued procurement quota back to" the registrant. *Id.* If the registrant sought to supply marijuana to other researchers, DEA would either distribute that marijuana directly or would expressly authorize the registrant to distribute the marijuana on DEA's behalf. *Id.* at 16296.

DEA noted that a sub-agency of the Department of Health and Human Services—the National Institute on Drug Abuse—had for many years administered a contract with the University of Mississippi to grow marijuana for research purposes. 85 Fed. Reg. at 16294, 16296. Under the proposed rule, DEA would take possession of that marijuana as well, and then distribute it to researchers as necessary (or authorize the University to act on DEA's behalf). *Id.* at 16296. But since the University was already a registered manufacturer that applies for annual manufacturing quotas from DEA, DEA did "not envision a scenario in which it would deny or delay a distribution to a duly registered schedule I researcher" who sought to obtain marijuana cultivated by the University. *Id.*

Responding to the proposed rule, some commentators asserted that DEA had in the past delayed acting on applications to cultivate marijuana based on "an internal memorandum." 85 Fed. Reg. at 82335. Regarding the "internal memorandum," DEA explained that as part of the Department of Justice's earlier review of the Controlled Substances Act, the Department's Office of Legal Counsel had issued an opinion "examining DEA's policies and practices for granting bulk manufacturing registrations to marihuana growers in light of" the Controlled Substances Act and the Single Convention. *Id.* at 82334. Other commentators suggested that DEA

had misinterpreted the Single Convention, while others argued that "the United States should withdraw from the Single Convention." *Id.* at 82339-40. DEA responded that while commentators may disagree with its "legal conclusions, [] DEA is bound by the law as DOJ and DEA understand it," and must ensure that DEA's regulations "are consistent with U.S. obligations under the Single Convention." *Id.* at 82339.

DEA noted that it "is working to expand the number of DEA-registered bulk manufacturers of marijuana, including through the finalization of this rule." 85 Fed. Reg. at 82335. That registration process is ongoing, but DEA has initially approved several applications to register as a marijuana cultivator and has sent memoranda of understanding to those applicants as "the next step in the approval process." DEA, *DEA Continues to Prioritize Efforts to Expand Access to Marijuana for Research in the United States* (May 14, 2021), https://go.usa.gov/xMDeE.

In May 2021, petitioner Scottsdale Research Institute received preliminary approval of its application and a memorandum of understanding from DEA. Science, *United States Set to Allow More Facilities to Produce Marijuana for Research*, https://www.science.org/news/2021/05/us-set-allow-more-facilities-produce-marijuana-research (quoting petitioner's president and principal

investigator as saying "We were euphoric. This is a victory for scientific freedom."). Petitioner's application to manufacture marijuana was granted on September 7, 2021. DEA, *Bulk Manufacturers Notice of Registration – 2021*, https://go.usa.gov/xMPJ7 (granting application published at 84 Fed. Reg. 54926 (Oct. 11, 2019)).

SUMMARY OF ARGUMENT

DEA's rule implements the United States' obligations under the Single Convention and furthers the underlying purposes of the Controlled Substances Act. The rule allows DEA to move forward with the registration of additional marijuana cultivators and will allow DEA-registered researchers to obtain higher quality crops for scientific research. DEA explained the legal basis for the rule, what it sought to achieve, and how those goals were consistent with governing law. In all aspects, DEA acted in a reasoned and appropriate manner.

I. The proposed rule discussed DEA's legal authority for the rule at length, with detailed analysis of both the Single Convention and the Controlled Substances Act. DEA thus complied with its obligations under 5 U.S.C. § 553(b)(2) to adequately explain the legal basis for its rulemaking. Petitioners contend that DEA should have also concurrently published a memorandum from the Office of Legal Counsel that expounded upon this

legal analysis, but petitioners identify no authority to support that requirement.

II. A. In considering whether to grant an application to manufacture marijuana, DEA considers the applicant's compliance with applicable law and what effect an increase in the number of marijuana manufacturers may have on efforts to curtail illegal diversion of marijuana. Those factors are specifically enumerated in 21 U.S.C. § 823(a), and Congress further provided DEA authority to consider "such other factors as may be relevant to and consistent with the public health and safety," *id.* § 823(a)(6). Although petitioners claim that DEA acted in violation of the Controlled Substances Act in considering these factors, the plain text of the Act grants DEA the authority to do so.

B. In the rulemaking, DEA defined the term "medicinal cannabis," which is not expressly defined in either the Single Convention or the Controlled Substances Act. DEA explained that "medicinal cannabis" would not be subject to DEA's otherwise exclusive right to control the import, export, and wholesale trading of legally cultivated marijuana. Reflecting that intersection of interstate commerce and a medicinal product, DEA defined "medicinal cannabis" to mean a drug derived from cannabis that could be lawfully marketed in interstate commerce. That is a

reasonable definition for that undefined term and warrants deference under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

C. DEA explained that it would evaluate pending applications to manufacture marijuana under the framework of the new rule. Petitioner Craker alleges that this is impermissibly retroactive, but that contention is foreclosed by this Court's decision in *Pine Tree Medical Associates v. Secretary of Health & Human Services*, 127 F.3d 118, 121-22 (1st Cir. 1997), which held that an agency may properly evaluate pending license applications under new substantive standards.

D. Petitioners further claim that DEA acted arbitrarily and capriciously by declining to exempt marijuana manufacturers from registering with DEA and by precluding DEA-registered researchers from purchasing marijuana grown by manufactures who are not registered with DEA. Neither contention has merit. DEA explained, consistent with common sense, that to carry out the system of controls laid out by the Controlled Substances Act, it would require lawfully manufactured marijuana to be grown by individuals and entities who are registered with DEA.

STANDARD OF REVIEW

In reviewing the final rule under the Administrative Procedure Act (APA), the Court considers whether the rule is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). In reviewing DEA's construction of the Controlled Substances Act, the Court employs the familiar framework under *Chevron*. *Craker v. DEA*, 714 F.3d 17, 26 (1st Cir. 2013). If the statute is ambiguous "*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.*

ARGUMENT

I. DEA PROVIDED ADEQUATE NOTICE OF THE LEGAL AUTHORITY FOR THE PROPOSED RULEMAKING

The APA generally requires that when agencies promulgate legislative rules, they must first publish a notice of proposed rulemaking that "refer[s] to the legal authority under which the rule is proposed." 5 U.S.C. § 553(b)(2). That requirement "ensure[s] that the agency considers whether it actually has the authority to make the rule it is proposing, and to give interested parties a chance to comment on that question." *United States v. Whitlow*, 714 F.3d 41, 46 (1st Cir. 2013). Thus, an agency's invocation of a particular enabling statute suffices to "place[] interested

parties on notice of the [agency's] intent and enable[s] them to offer comment and argument about [the agency's] authority." *Id.* While the agency can choose to elaborate this point and explain all underlying legal concerns, "[a] notice need not explicate a rule's final legal theory." *Telesat Canada v. FCC*, 999 F.3d 707, 713 (D.C. Cir. 2021).

Here, DEA explained the legal authority for the rule at some length. The proposed rule cited 21 U.S.C. § 822(a)(1) for the requirement that everyone who seeks to manufacture controlled substances must be registered with DEA, including entities planning to cultivate controlled substances under 21 U.S.C. § 802(15), (22).[1] DEA then cited 21 U.S.C. § 823(a) and this Court's decision in *Craker v. DEA*, 714 F.3d 17 (1st Cir. 2013) in explaining that prospective cultivators of marijuana must be registered with DEA.[2] It further explained that under § 823(a), a registration may only be granted if "(1) The registration is consistent with the public interest (based on the enumerated criteria in section 823(a)), and (2) the registration is consistent with U.S. obligations under the Single Convention on Narcotic Drugs, 1961 ('Single Convention' or 'Treaty'), 18 U.S.T. 1407."[3]

[1] 85 Fed. Reg. at 16293.
[2] *Id.*
[3] *Id.*

DEA explained that it was promulgating the rule under its rulemaking authority in 21 U.S.C. §§ 821, 871(b), to ensure "consistency with obligations under international treaties such as the Single Convention."[4] In particular, DEA cited articles 23 and 28 of the Single Convention and stated that the proposed rule would ensure compliance with the Single Convention by allowing DEA to have the exclusive right of importing, exporting, and distributing marijuana grown by registered cultivators and taking physical possession of their crops after harvest.[5] The proposed rule explicated DEA's consideration of the public interest factors in 21 U.S.C. § 823(a),[6] how the agency would apply the Agriculture Improvement Act of 2018, Pub. L. No. 115-334, 132 Stat. 4490,[7] and the agency's obligation to charge fees to offset costs under 21 U.S.C. § 886a(1)(C).[8] That lengthy explanation and citation to specific aspects of DEA's legal authority "complied with both the letter and the spirit of § 553(b)(2)." *Whitlow*, 714 F.3d at 46 (rejecting argument that Attorney General failed to provide adequate notice of a rule's legal basis because he "identif[ied] a statutory provision that gave him the power to issue [the] rule * * * which is what § 553(b)(2) required").

---

[4] *Id.*
[5] 85 Fed. Reg. 16294-95.
[6] *Id.* at 16296-97.
[7] *Id.* at 16297.
[8] *Id.*

Petitioners mistakenly argue that DEA failed to provide adequate notice for the proposed rule because the agency did not concurrently publish an opinion by the Office of Legal Counsel that construed the Single Convention and advised DEA to amend its policies to conform to the treaty. Br. 33-36. Petitioners cite no authority for the proposition that if an agency consults with the Office of Legal Counsel about potential rulemaking, it must publish those communications in a notice of proposed rulemaking in order to comply with the APA. That is unsurprising. The Office of Legal Counsel often provides legal advice to government agencies, including during rulemaking, and works with agencies to ensure that rules comply with controlling legal principles. *See Citizens for Resp. & Ethics in Washington v. U.S. Department of Justice*, 922 F.3d 480, 484 (D.C. Cir. 2019). There is no need for those opinions—which are often predecisional and deliberative documents—to be included in proposed rules as a matter of law under 5 U.S.C. § 553(b)(2). That is particularly true here, where DEA independently explained that the legal basis for the rule rested on various sections of the Controlled Substances Act and its obligations to control marijuana cultivation under the Single Convention (which is implemented by DEA under the Controlled Substances Act, *see* 21 U.S.C. §§ 801(7), 823(a)).

Petitioners also err in asserting that DEA "did not offer a reasoned explanation" for the rule. Br. 37. To the contrary, DEA explained that the rule was necessary "to ensure that DEA complies with the [Controlled Substances Act] and grants registrations that are consistent with relevant treaty provisions, namely articles 23 and 28 of the Single Convention." 85 Fed. Reg. at 16294. Accordingly, DEA proposed to carry out the functions identified in Single Convention art. 23(2)(d) and (e) by taking physical possession of registered, cultivated marijuana crops after harvest and by having exclusive control over "importing, exporting, wholesale trading, and maintaining stocks of" marijuana. *Id.* DEA went on to elucidate how its new rules would apply to different cultivation scenarios, *id.* at 16295-96, how it would apply the public interest factors in 21 U.S.C. § 823(a) to "most efficiently supply the lawful needs of the U.S. market in terms of quantity and quality," *id.* at 16297, and how it would construct an administrative fee schedule to support the program, *id.* And in the final rule, DEA described at length its understanding that the Single Convention and the Controlled Substances Act required DEA to carry out the functions it had previously identified. 85 Fed. Reg. 82338-39. DEA explained that it "has no authority to assign these functions to another agency or a private contractor outside

the government. Rather, DEA must perform the functions itself, and this rule will enable DEA to do so more effectively." *Id.* at 82339.

In contrast to those mandatory legal obligations, DEA elsewhere recognized where it had discretion in formulating its rule to implement those mandates. For instance, DEA confirmed that it "has discretion to weigh the statutory factors" in 21 U.S.C. § 823(a) when considering an application to cultivate marijuana, and explained that DEA will generally consider "an applicant's prior compliance with federal law." 85 Fed. Reg. at 82335. Elsewhere, DEA explained that it has "discretion * * * in setting a fee structure to recover the cost of this rule," but lacked "sufficient information at this time to discuss alternatives for either the future registration fees or the fees for the sale of marihuana," since the agency lacked previous experience buying and selling marijuana from registered cultivators. *Id.* at 82346. That said, DEA anticipated that it would address changes to those fees in a future rulemaking, which would "includ[e] a discussion of alternative approaches" once it had more data. *Id.*

DEA's rulemaking thus "articulat[ed] a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.' " *Grosso v. Surface Transportation Board*, 804 F.3d 110, 116 (1st Cir. 2015). The agency explained where it was required to take specific

action to comply with the law, where it retained discretion to choose how to best implement those legal requirements, and how it would do so. That is all the APA requires.

II. THE REVISED REGISTRATION SCHEME IS A VALID EXERCISE OF DEA'S RULEMAKING AUTHORITY

A. DEA Can Reasonably Consider An Applicant's Compliance With Controlled Substances Law And The Total Number Of Registered Marijuana Cultivators Before Granting A New Application To Manufacture Marijuana

Under 21 U.S.C. § 823(a), DEA must consider the public interest factors identified by Congress to determine whether the agency should grant an application to manufacture a controlled substance like marijuana. Those factors are:

> (1) maintaining effective controls against diversion by limiting the manufacture of the substance "to a number of establishments which can produce an adequate and uninterrupted supply" under "adequately competitive conditions for legitimate" purposes;
>
> (2) "compliance with applicable State and local law";
>
> (3) promoting technical advances and developing 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 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. § 823(a) (emphasis added).

The final rule implements these statutory factors as authorized. *See* 85 Fed. Reg. 82353-54 (promulgating 21 C.F.R. § 1318.05). In subsection (a) of the regulation, DEA repeated the factors Congress had enumerated by statute. In subsection (b), DEA identified considerations of "particular emphasis" for granting registrations to cultivate marijuana. First, DEA would consider "[w]hether the applicant has demonstrated prior compliance with the [Controlled Substances] Act and this chapter" of DEA's regulations. 21 C.F.R. § 1318.05(b)(1). Second, DEA would consider the "applicant's ability to consistently produce and supply cannabis of a high quality and defined chemical composition." *Id.* § 1318.05(b)(2). Third, DEA would consider whether the applicant could cultivate marijuana "in quantities and varieties that will satisfy the anticipated demand of researchers and other registrants in the United States who wish to obtain" marijuana for lawful purposes. *Id.* § 1318.05(b)(3)(i). And last, if an applicant sought to grow marijuana for their own research, DEA would consider "the holding of an approved marihuana research protocol by a registered schedule I researcher * * * as evidence of the necessity of the applicant's registration." *Id.* § 1318.05(b)(3)(ii).

Petitioners urge that these considerations are prohibited by the statute, arguing that DEA may not consider whether an applicant has previously violated the law unless the applicant has certain criminal convictions. Br. 40-44. But nothing in 21 U.S.C. § 823(a) precludes DEA from considering whether an applicant has violated federal, state, or local laws in determining whether to grant an application. Indeed, Congress directed DEA to specifically consider an applicant's "compliance with applicable State and local law," and whether the applicant had a "prior conviction" for a controlled substances offense. 21 U.S.C. § 823(a)(2), (4). Congress further provided that in assessing any application to manufacture controlled substances, DEA may consider "such other factors as may be relevant to and consistent with the public health and safety." *Id.* § 823(a)(6).

Consistent with that authority, DEA will consider whether an applicant "has demonstrated prior compliance with the Act and this [regulatory] chapter." 21 C.F.R. § 1318.05(b)(1). As DEA explained in the rulemaking, "prior conduct in violation of the [Controlled Substances Act] is relevant to determining whether the applicant can be entrusted with the responsibilities associated with being a DEA registrant." 85 Fed. Reg. at 82335. And while neither the statute nor DEA's rulemaking distinguish

being an applicant's current or past compliance with state and local laws, both past and current compliance would certainly be relevant considerations in determining whether the grant an application.

Petitioners also argue (at 44-47) that DEA erred in rejecting a commenter's suggestion that "the number of applicants selected to bulk manufacture marihuana should be unlimited." 85 Fed. Reg. 82336. But petitioners do not seriously argue that there should be an unlimited number of registrants for controlled substances. Congress instructed DEA to evaluate applications to manufacture controlled substances in light of the "maintenance of effective controls against diversion * * * by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply." 21 U.S.C. § 823(a)(1). As DEA has explained in earlier rulemaking, that provision "does not allow DEA simply to register as many bulk manufacturers * * * as the market will bear." 74 Fed. Reg. 2101, 2127 (Jan. 14, 2009). Instead, DEA must "consider disallowing additional entrants * * * unless DEA concludes that [the] addition of a particular applicant is necessary to produce" sufficient supply of the controlled substance "under adequately competitive conditions." *Id.* And this Court

has affirmed DEA's understanding of that provision. *Craker*, 714 F.3d at 28.

Accordingly, DEA explained in this rulemaking that it "must perform an analysis of each application to determine whether the addition of the applicant is necessary to provide the adequate and uninterrupted supply of marihuana for research needs or whether the legitimate need will be met by the registration of others." 85 Fed. Reg. at 82336. Contrary to petitioners' suggestions, DEA did not promulgate any regulations setting a cap on the number of marijuana cultivators, and did not set forth a policy automatically denying an applicant's registration if the marijuana supply was barely adequate. Instead, the regulation simply reiterates the statutory language verbatim. *Compare* 21 U.S.C. § 823(a)(1), *with* 21 C.F.R. § 1318.05(a)(1). And elsewhere in the rulemaking, DEA explained that under § 823(a)(1), "DEA must weigh, as one of the registration factors, the need to maintain effective controls against diversion by limiting the number of registered bulk marihuana growers." 85 Fed. Reg. at 82344. Moreover, to alleviate any concerns about the availability of marijuana for research, DEA provided that if an applicant has a "bona fide supply agreement" with a DEA-registered researcher, or if the manufacturer "propos[es] to grow marihuana to supply its own research," then the

applicant will be "deemed to have satisfied this aspect of" § 823(a)(1). *Id.* at 82344-45; *accord* 21 C.F.R. § 1318.05(b)(3) (codifying this provision).

B. DEA Reasonably Defined "Medicinal Cannabis"

The Single Convention requires that marijuana must be controlled under the treaty's "article 23 respecting the control of the opium poppy." 18 U.S.T. at 1420, art. 28(1). Article 23, in turn, requires DEA to "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.* at 1419, art. 23(2)(e). The treaty defines "medicinal opium" to mean "opium which has undergone the processes necessary to adapt it for medicinal use," and "preparation" as "a mixture, solid or liquid, containing a drug." *Id.* at 1410, art. 1(1)(*o*), (s).

In its rulemaking, DEA had to adapt those treaty provisions for use in regulating marijuana, in some cases by adopting analogous requirements when the specific strictures regarding opium were not directly applicable. For instance, article 23 discusses the regulation of "opium alkaloids"—such as morphine and codeine—which have no comparable analogue for "cannabinoids derived from the cannabis plant." 85 Fed. Reg. at 16294 n.7. And as relevant here, while the Single Convention defined "medicinal opium" as opium that "has undergone the processes necessary to adapt it

for medicinal use," it did not define what those processes were. Some known processes for manufacturing medicinal opium—as distinct from morphine and heroin—are not obviously applicable to marijuana. *See* International Opium Convention, 38 Stat. 1912, 1932 (1912) (defining medicinal opium as "raw opium which shall have been heated to 60 degrees centigrade, whether or not powdered or granulated, or whether or not mixed with neutral substances, and which shall not contain less than 10% of morphine").

Accordingly, DEA was faced with a choice of how to apply a phrase that had a particular meaning for opium but had no corresponding meaning to marijuana. DEA's decision on how to apply that phrase would affects its lawful transportation in interstate and foreign commerce, since DEA would not have exclusive control over the import, export, and wholesale trading of "medicinal cannabis." 85 Fed. Reg. at 82340. In keeping with that focus on commercial control, DEA reasonably chose to define "medicinal cannabis" as "drug products derived from cannabis in a form that the United States has approved for medical use, which is most effectively captured" by determining whether the product is "able to be legally marketed under the Food Drug and Cosmetic [Act]." *Id.*

Petitioners argue that this definition and is irreconcilable with the term "medicinal." Under petitioners' view, "'[m]edicinal cannabis' means 'cannabis that is adapted to the cure or alleviation of bodily disorders,'" Br. 52, and DEA cannot impose any further limitations on that definition. That is incorrect, because the Single Convention does not use the term "medicinal" as a catch-all to mean any possible medical applications for a controlled substance. Instead, article 23 of the Single Convention discusses "medicinal opium " in conjunction with particular kinds of preparation and formulation of opium drug. "[O]pium alkaloids," for instance, refer to drugs like "morphine, codeine, and papervine." Charles G. Hoff, *Drug Abuse*, 51 Mil. L. Rev. 147, 151 & n.24 (1971). And an opium "preparation" specifically refers to a "mixture" that contains a drug. 18 U.S.T. at 1410, art. 1(1)(s). Because "medicinal opium" does not refer to all potential medical applications for opium—which also includes opium alkaloids and opium preparations—"medicinal cannabis" similarly need not refer to any kind of marijuana that might have potential medical applications. Beyond that, neither the Single Convention nor the Controlled Substances Act shines any more light on how "medicinal cannabis" should be understood.

In those circumstances, deference to DEA's reasonable choice to define "medicinal cannabis" is appropriate. DEA's administers the

Controlled Substances Act, which "implements" the Single Convention. *Craker*, 714 F.3d at 20. Accordingly, DEA's interpretation is entitled to "great weight," *Sumitomo Shoji America, Inc. v. Avagliano*, 457 U.S. 176, 184-85 (1982), and can appropriately receive deference under *Chevron*. *See Hill v. Norton*, 275 F.3d 98, 104 (D.C. Cir. 2001) (applying *Chevron* to agency's interpretation of treaty and implementing statute);[9] *Sohappy v. Hodel*, 911 F.2d 1312, 1316-17 (9th Cir. 1990) (applying *Chevron* to "an agency's construction of a statute or treaty it administers"). Thus, the Court may sustain DEA's "reasonable interpretation[] of ambiguous or unclear" terms. *De Vega v. Gonzales*, 503 F.3d 45, 48 (1st Cir. 2007).

Here, DEA considered how best to define "medicinal cannabis," when that term was used in the context of explaining which subsets of marijuana would not be subject to DEA's "exclusive right [to] import[], export[], wholesale trad[e] and maintain[] stocks" of legally manufactured marijuana. 18 U.S.T. at 1419, art. 23(2)(e). Rather than define "medicinal cannabis" based on vague principles of medical use, or contingent on whether the marijuana could be medically prescribed under a particular State's laws, DEA reasonably sought to define the term in a way that would

[9] Superseded by statute on other grounds, Migratory Bird Treaty Reform Act, Pub. L. No. 108-447, § 143, 118 Stat. 2809, 3071-72 (2004).

be consistently applied in exporting, importing, and interstate commerce. As DEA explained, "[t]he United States, not State governments, is the relevant party to the Single Convention, and thus 'medicinal cannabis' should only include cannabis-derived products that the United States has approved for medical use." 85 Fed. Reg. at 82340. Accordingly, DEA defined "medicinal cannabis" to mean a drug derived from cannabis that could be legally marketed in interstate commerce under the Federal Food, Drug, and Cosmetic Act. *Id.*

Petitioners misread this Court's decision in *Grinspoon v. DEA*, 828 F.2d 881 (1st Cir. 1987) in arguing that DEA's definition is impermissible. *Grinspoon* did not discuss the Single Convention or the term "medicinal cannabis." Instead, *Grinspoon* concerned whether and how DEA could decide whether to reschedule a controlled substance under 21 U.S.C. § 812(b). That statute requires that a schedule I substance may have "no currently accepted medical use in treatment in the United States," while all other schedules of controlled substance do have such an accepted medical use. *Grinspoon* held that the statutory phrase "accepted medical use in treatment *in the United States*" did not require that a drug be approved for interstate marketing by the Food and Drug Administration, because the statutory phrase did not "require a finding of recognized medical use in

every state or * * * approval for interstate marketing of the substance." 828 F.2d at 886 (emphasis added). That understanding, combined with the particular reticulated scheme for assessing the appropriate schedule for a controlled substance, *see id.* at 883 & nn.2-3 (citing 21 U.S.C. § 811(b)-(c)), indicated that Congress did not intend for a drug's placement on schedule I to turn solely on FDA approval, *id.* at 891-92.

Grinspoon's considerations are inapposite here. Unlike a decision to place a substance on a particular schedule—which can have many other follow on effects—the only effect of marijuana being classified as "medicinal cannabis" is to exempt it from DEA's exclusive control over imports, exports, and shipment in interstate commerce. *See* 18 U.S.T. at 1410, art. 1(1)(m) (defining "import" and "export" as drugs in foreign commerce and "the physical transfer of drugs * * * from one territory to another territory of the same State"). DEA rightly then looked to define that term on the federal level and determine whether the cannabis "can be legally marketed under the Federal Food, Drug, and Cosmetic Act." 85 Fed. Reg. at 82340.

And to the extent petitioners argue that this definition affects the practice of medicine (at 60-62), they are mistaken. Marijuana is a controlled substance because Congress designated it as a schedule I substance. 21 U.S.C. § 812(c), sched. I(c)(10). If petitioners would like

marijuana's schedule to be changed, they may petition DEA to do so. *Sisley v. DEA*, --- F.4th ---, 2021 WL 3853049, at *1-2 (9th Cir. Aug. 30, 2021). But the definition of "medicinal cannabis" here affects only whether that defined subset of marijuana must be exclusively controlled by DEA when shipped in interstate commerce.

C. The Rule Permissibly Applies To Pending Applications

In the proposed rule, DEA explained that after promulgation of the new rule, it would not consider additional applications to manufacture marijuana until it had completed its review if the "approximately 35 such applications currently pending." 85 Fed. Reg. at 16297. That was codified at 21 C.F.R. § 1318.05(c), which required DEA to act on all applications pending as of January 19, 2021, before processing new applications.

Petitioner Lyle Craker contends that this it would be impermissibly retroactive for DEA to evaluate pending applications under the new rule. Br. 62-66. This Court, however, has rejected that argument and explained that agencies may consider pending applications for a license under newly promulgated substantive standards. *Pine Tree Medical Associates v. Secretary of Health & Human Services*, 127 F.3d 118, 121-22 (1st Cir. 1997).

In *Pine Tree*, the Court held that "the mere filing of an application is not the kind of completed transaction in which a party could fairly expect

stability of the relevant laws as of the transaction date." *Pine Tree*, 127 F.3d at 121. To illustrate the point, the Court contrasted an agency changing the format of an application with changing the substantive standards under which it would be evaluated. If the agency rejected a pending application because it did not satisfy a newly required format, that would raise retroactivity concerns because the applicant would lack "fair notice" about the proper form of the application that they had already submitted. *Id.* at 122. By contrast, the Court found "no support * * * for the proposition that filing an application with an agency essentially fixes an entitlement to the application of those *substantive* regulations in force on the filing date." *Id.*

Other courts of appeals have relied upon *Pine Tree* to similarly hold that evaluating a pending license application under new substantive standards is not impermissibly retroactive. "[F]iling an application with an agency does not generally confer upon the applicant an inviolable right to have the agency rule on the application pursuant to the regulations in effect at the time of filing." *BellSouth Telecomms., Inc. v. Southeast Tel., Inc.*, 462 F.3d 650, 660-61 (6th Cir. 2006) (citing *Pine Tree*, 127 F.3d at 121); *accord Durable Mfg. Co. v. U.S. Department of Labor*, 578 F.3d 497, 503-04 (7th Cir. 2009) (quoting *Pine Tree*, 127 F.3d at 121). Accordingly, DEA may evaluate pending applications under the new framework.

D. Petitioners' Remaining Objections Lack Merit

1. DEA Is Not Required To Waive The Registration Requirement For Marijuana Cultivators

Under 21 U.S.C. § 822(d), DEA has the general authority to waive "by regulation" the Controlled Substances Act's registration requirements for "certain manufacturers, distributors, or dispensers" of a controlled substance if waiver is "consistent with the public health and safety." DEA has previously used this authority, for example, to waive registration for doctors who administered the radioactive diagnostic drug product DaTscan if they possessed "a valid medical use license or permit issued by the United States Nuclear Regulatory Commission." 79 Fed. Reg. 70085, 70089 (Nov. 25, 2014).

In the rulemaking here, commentators suggested that DEA should categorically waive the registration requirement for marijuana manufacturers who sought to supply marijuana to researchers. 85 Fed. Reg. at 82335-36. DEA declined to do so, and petitioners contend that DEA's refusal to waive registration requirements is contrary to law. Br. 47-50. But DEA provided an adequate explanation for its decision, because "waiving the requirement of registration for marihuana growers who supply researchers would be inconsistent with U.S. obligations under the Single Convention." 85 Fed. Reg. at 82336. That is because the Single Convention

requires DEA to "prohibit the production [and] manufacture" of marijuana "except for amounts which may be necessary for medical and scientific research only." 18 U.S.T. at 1411, art. 2.5(b). And for those amounts lawfully grown, "all cultivators * * * shall be required to deliver their total crops" to DEA after harvesting. *Id.* at 1419, art. 23(2)(d). It is difficult to conceive of a scheme in which DEA could limit the amount of marijuana lawfully grown and be sure to take possession of all of it unless DEA required marijuana manufacturers to be registered with the agency and subject to production quotas and record-keeping requirements. *See* 21 U.S.C. § 826(c) (production quotas for registered manufacturers); *id.* § 827 (record-keeping and reporting requirements for registered manufacturers). And petitioners have offered no theory for how DEA could realistically satisfy these requirements if it were to waive registration requirements for a large swath of marijuana manufacturers.

2. DEA Reasonably Required Registered Researchers To Use Marijuana Cultivated By Registered Manufacturers

Under the Controlled Substances Act, it is unlawful for any person to knowingly "manufacture, distribute, or dispense" a controlled substance without DEA authorization. 21 U.S.C. § 841(a)(1). And DEA registrants—including researchers—may "possess, manufacture, distribute, or dispense"

controlled substances only "to the extent authorized by their registration and in conformity with the other provisions" of the Controlled Substances Act. *Id.* § 822(b). If an entity is not registered with DEA and nevertheless knowingly manufactures a controlled substances, that activity is unlawful. And it makes good sense to discourage that kind of unlawful activity by ensuring that such illegally manufactured substances cannot be laundered to DEA-registered entities for further distribution.

Thus, as DEA explained in the rule, receiving "a schedule I substance from a non-registrant, distributed in violation of § 841(a)," is not an activity "'in conformity with the other provisions' of [Controlled Substances Act] as required of registrants by § 822(b)." 85 Fed. Reg. at 82338. And so, DEA declined to permit researchers from using their DEA registration to possess and potentially dispense marijuana manufactured without a DEA registration. *Id.* (recognizing that this would "be inconsistent with the requirements of other Federal laws, as well as DEA's broader obligation to authorize controlled substances research in a manner consistent with the public safety").

Petitioners argue that this decision is arbitrary and capricious because DEA permits researchers to conduct studies on marijuana cultivated by the University of Mississippi, but does not permit researchers

to obtain marijuana grown by manufacturers who are registered with States but not with DEA. Br. 67. But there is no contradiction; the University is a DEA-registered manufacturer of marijuana. *See* DEA, *Bulk Manufacturers Notice of Registration–2019* (Dec. 3, 2019), https://go.usa.gov/xMK7n. Under the rule, researchers may obtain marijuana for study from a registered manufacturer, and there is no threshold impediment that would prevent a prospective manufacturer who is currently licensed by a state from also seeking DEA registration. And if a registered researcher seeks to cultivate their own marijuana for study, they may apply to be registered as a manufacturer and their anticipated research will be sufficient to demonstrate a need for their production. 21 C.F.R. § 1318.05(b)(3)(i).[10]

[10] In passing, petitioners assert that "DEA overlooked several viable alternatives" to the framework it adopted. Br. 66. Petitioners fail to explain what these alternatives might have been or how petitioners were prejudiced by DEA's choice not to promulgate these unnamed alternatives. *See* 5 U.S.C. § 706 (under the APA "due account shall be taken of the rule of prejudicial error).

CONCLUSION

The petitions for review should be denied.

Respectfully submitted,

BRIAN M. BOYNTON
Acting Assistant Attorney General

MARK B. STERN
/s/ Daniel Aguilar
DANIEL AGUILAR
(202) 514-5432
Attorneys, Appellate Staff
Civil Division, Room 7266
U.S. Department of Justice
950 Pennsylvania Ave., NW
Washington, DC 20530

SEPTEMBER 2021

CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(A)

I hereby certify that the certify that this brief complies with the requirements of Fed. R. App. P. 32(a)(5) and (6) because it has been prepared in 14-point Georgia, a proportionally spaced font.

I further certify that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 7,406 words, excluding the parts of the brief exempted under Rule 32(a)(7)(B)(iii), according to the count of Microsoft Word.

/s/ Daniel Aguilar
DANIEL AGUILAR

CERTIFICATE OF SERVICE

I hereby certify that on September 29, 2021, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the First Circuit by using the appellate CM/ECF system. The participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

/s/ Daniel Aguilar
DANIEL AGUILAR