United States Court of Appeals
For the First Circuit

No. 21-1055

DR. LYLE E. CRAKER,

Petitioner,

v.

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION; ANNE MILGRAM,* in her official capacity as Administrator of the Drug Enforcement Administration,

Respondents.

No. 21-1323

SCOTTSDALE RESEARCH INSTITUTE,

Petitioner,

v.

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION; ANNE MILGRAM,* in her official capacity as Administrator of the Drug Enforcement Administration; MERRICK B. GARLAND, Attorney General,

Respondents.

PETITIONS FOR REVIEW OF A FINAL RULE OF THE DRUG ENFORCEMENT ADMINISTRATION

* Pursuant to Fed. R. App. P. 43(c)(2), Administrator Anne Milgram has been substituted for former Acting Administrator D. Christopher Evans in both petitions for review.

Before

Barron, Chief Judge,
Lynch and Kayatta, Circuit Judges.

Shane Pennington, with whom Vicente Sederberg LLP, Michael Perez, Perez Law, Alexandra H. Deal, Paik, Brewington & Deal, LLP, Matthew C. Zorn, and Yetter Coleman LLP were on brief, for petitioners.

Daniel Aguilar, Attorney, Appellate Staff, Civil Division, with whom Brian M. Boynton, Acting Assistant Attorney General, and Mark B. Stern, Attorney, Appellate Staff, Civil Division, were on brief, for respondents.

August 9, 2022

KAYATTA, Circuit Judge. Petitioners -- botany professor Dr. Lyle Craker and clinical research company Scottsdale Research Institute (SRI) -- challenge a rule promulgated by the Drug Enforcement Administration (DEA) that sets the framework through which applicants may register to lawfully manufacture and cultivate cannabis for research purposes. For the following reasons, we deny their petitions for review.

I.

A.

We begin by laying out the statutory and administrative scheme that governs the registration of prospective cannabis growers. The Controlled Substances Act (CSA), 21 U.S.C. § 801 et seq., requires "[e]very person who manufactures . . . any controlled substance" to first register with the federal government. 21 U.S.C. § 822(a)(1). This mandate applies to anyone seeking to "produc[e]" or "cultivat[e]" marijuana, a schedule I substance. Id. § 802(15), (22) (defining "manufacture" to include production and cultivation); see also id. § 812, sched. I(c)(10) (designating "[m]arihuana" as a schedule I controlled substance).[1]

Congress granted the Attorney General the authority to register prospective manufacturers of controlled substances, see id. §§ 822(a), 823(a), and the authority "to promulgate rules and

[1] We use the terms marijuana (or marihuana as the CSA calls it) and cannabis interchangeably throughout this opinion.

regulations . . . relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances," id. § 821. The Attorney General in turn delegated those powers to the Administrator of the DEA. See 28 C.F.R. § 0.100.

Pursuant to this delegated authority, the DEA "shall register an applicant to manufacture controlled substances in schedule I or II if [the agency] determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971." 21 U.S.C. § 823(a). To determine whether registration is consistent with the public interest, the statute enumerates six factors that must be considered, including the "maintenance of effective controls against diversion" of the substance, "compliance with applicable State and local law," the "prior conviction record of [the] applicant," and "such other factors as may be relevant to and consistent with the public health and safety." Id. The statute does not specify how the DEA is to determine that a registration is consistent with the United States' international treaty obligations.

The pertinent treaty obligations to which the parties direct us are those set forth in the Single Convention on Narcotic Drugs, Mar. 30, 1961, 18 U.S.T. 1407, 520 U.N.T.S. 204 (the "Single

Convention"). As relevant here, the Single Convention requires signatories to "prohibit the production, manufacture, export and import of, trade in, possession or use of [substances including cannabis] except for amounts which may be necessary for medical and scientific research only." Id. art. 2.5(b). With respect to cannabis specifically, the treaty adopts the "system of controls as provided in article 23 [of the Single Convention] respecting the control of the opium poppy." Id. art. 28.1. Those controls require that a signatory's designated government agency (here, the DEA): (1) "designate the areas in which . . . cultivation . . . shall be permitted"; (2) authorize only "licensed" cultivators to "engage in such cultivation"; (3) "specify the extent of the land on which the cultivation is permitted"; (4) "purchase and take physical possession of" the cultivated crops; and (5) "have the exclusive right of importing, exporting, wholesale trading and maintaining stocks other than those held by manufacturers of . . . medicinal [cannabis] or [cannabis] preparations." Id. art. 23.2. Article 23 also makes clear that the functions described above must be "discharged by a single government agency if the constitution of the [signatory nation] permits it." Id. art. 23.3.

B.

Prior to the initiation of the present petitions for review, the DEA had licensed only a single grower under the registration scheme detailed above -- the National Center for

Natural Products Research (the "National Center"), a division of the University of Mississippi. See Lyle E. Craker; Denial of Application, 74 Fed. Reg. 2101, 2104 (Jan. 14, 2009). The National Center grows cannabis under a contract with the National Institute on Drug Abuse, a component of the Department of Health and Human Services. See id.

In 2016, due in part to greater public interest in research involving cannabis, the DEA announced a new policy designed to increase the number of federally registered cannabis growers. See Applications To Become Registered Under the Controlled Substances Act To Manufacture Marijuana To Supply Researchers in the United States, 81 Fed. Reg. 53,846, 53,847 (Aug. 12, 2016). Under the 2016 program, licensed growers would be "permitted to operate independently, provided the grower agrees . . . that it will only distribute marijuana with prior, written approval from DEA." Id. at 53,848. A number of interested parties, including the petitioners, submitted applications to grow cannabis under this new policy.

Over the next few years, however, the DEA neither approved nor denied any applications pursuant to the 2016 program. Unbeknownst to the applicants, the Department of Justice's Office of Legal Counsel (OLC) -- the entity charged with providing authoritative legal advice to executive branch agencies -- was asked to evaluate the lawfulness of the DEA's existing marijuana

licensing practices, including the 2016 program. In June 2018, the OLC issued a formal legal opinion to the acting chief counsel of the DEA, concluding that the agency "must change its current practices and the [2016 program] to comply with the Single Convention." Licensing Marijuana Cultivation in Compliance with the Single Convention on Narcotic Drugs at 2 (Off. Legal Couns. Jun. 6, 2018), https://www.justice.gov/olc/file/1272131/download (the "Marijuana Cultivation Opinion"). Specifically, the OLC explained that to fulfill the United States' obligations under the Single Convention, the "DEA must adopt a framework in which it purchases and takes possession of the entire marijuana crop of each licensee after the crop is harvested," and the agency "must generally monopolize the import, export, wholesale trade, and stock maintenance of lawfully grown marijuana." Id. The OLC's Marijuana Cultivation Opinion was not released to the public at the time.

To comply with the OLC's directive, the DEA announced in March 2020 a notice of proposed rulemaking, indicating its intent to adopt new rules that would supersede the 2016 program and "ensure that DEA regulations comply with applicable law." Controls To Enhance the Cultivation of Marihuana for Research in the United States, 85 Fed. Reg. 16,292, 16,294 (proposed Mar. 23, 2020) (to be codified at 21 C.F.R. pts. 1301, 1318) (the "Proposed Rule"). In apparent reference to the OLC's Marijuana Cultivation Opinion,

the notice of proposed rulemaking indicated that the "DOJ advised DEA that it must adjust its policies and practices to ensure compliance with the CSA, including the CSA's requirement that registrations be consistent with the Single Convention," but the notice did not include or otherwise incorporate the OLC opinion. Id. The notice identified the relevant provisions of the Single Convention, see id. at 16,293–94, and indicated that the Proposed Rule was needed to "ensure that DEA carries out all five functions under Article 23 and Article 28 of the Single Convention pertaining to marihuana," id. at 16,298. The notice of proposed rulemaking invited comments from the public and interested parties through May 22, 2020. See id. at 16,292.

Seeking to review the advice from the DOJ that was referenced in the notice of proposed rulemaking, SRI sued the DEA and the DOJ under the Freedom of Information Act's affirmative disclosure provision. See 5 U.S.C. § 552(a)(2). That case eventually settled, with the DOJ publishing the OLC's Marijuana Cultivation Opinion to its electronic reading room on April 29, 2020, twenty-three days before the end of the comment period for the Proposed Rule.

Ultimately, after considering public comments, the DEA issued a final rule, adopting the Proposed Rule with one minor modification not relevant to the present petitions. See Controls to Enhance the Cultivation of Marihuana for Research in the United

States, 85 Fed. Reg. 82,333 (Dec. 18, 2020) (codified at 21 C.F.R. pts. 1301, 1318) (the "Final Rule"). The Final Rule addressed, among other things, public comments the agency had received regarding the DEA's obligations to control cannabis under federal law and the Single Convention. See id. at 82,338–40. It also responded to comments pertaining to the agency's proposed definition of the term "medicinal cannabis," see id. at 82,340, which the Final Rule defined to 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 [(FDCA)]," see 21 C.F.R. § 1318.02(b); see also Final Rule, 85 Fed. Reg. at 82,344.

The Final Rule does not preclude the DEA from registering more cultivators of cannabis. Indeed, the DEA explained that one of the purposes of the rule was "to increase the number and variety of marihuana growers in order to diversify the supply available to researchers." Final Rule, 85 Fed. Reg. at 82,337. The agency in fact approved SRI's application to manufacture cannabis last fall. The petitioners nonetheless challenge the rule as procedurally deficient, in excess of the DEA's rulemaking authority, and arbitrary and capricious, while Craker (arguing only for himself) also claims the rule is impermissibly retroactive as applied to his still pending application. We address each of these contentions in detail below.

II.

Under the Administrative Procedures Act (APA), we set aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). When an agency seeks to promulgate a legislative rule (like the Final Rule), the APA generally requires the agency to first publish a notice of proposed rulemaking and provide interested parties with a meaningful opportunity to comment on the proposal. See id. § 553. An agency's failure to comply with these procedural requirements renders a rule invalid. See N.H. Hosp. Ass'n v. Azar, 887 F.3d 62, 70 (1st Cir. 2018).

III.

The petitioners begin by raising two perceived procedural defects with the DEA's notice of proposed rulemaking that would demand the Final Rule be set aside. First, they argue that the DEA failed to provide the public with a meaningful opportunity to engage in the notice-and-comment process by declining to disclose the legal basis for the Proposed Rule -- namely, the full reasoning in the then-undisclosed OLC opinion advising the DEA that it must change its registration policies to comply with federal law and the Single Convention. Second, the petitioners assert that the DEA never offered its own reasoned explanation for the rule and instead erroneously characterized

itself as bound to follow the directives of the OLC's Marijuana Cultivation Opinion. We address each contention in turn.

A.

We first consider whether the DEA complied with its procedural obligations under the APA to adequately explain the legal basis of its rulemaking in its March notice. Unless an exception applies, the APA requires federal agencies, when promulgating new legislative rules, to first publish a notice of proposed rulemaking in the Federal Register. 5 U.S.C. § 553(b). This notice must include "reference to the legal authority under which the rule is proposed." Id. § 553(b)(2).

The petitioners argue that the DEA's notice of proposed rulemaking violated the APA's procedural requirements by failing to disclose the agency's legal basis for its new rule. They take aim at the DEA's reference to the OLC's then-unpublished Marijuana Cultivation Opinion advising the DEA that it must adjust its registration practices to ensure compliance with federal law and the Single Convention. This reference, without actual disclosure of the full OLC opinion, the petitioners argue, deprived the public of a meaningful opportunity to participate in the rulemaking process.

The petitioners' reliance on section 553(b)(2) is misplaced. We have explained that section 553(b)(2) primarily "functions to ensure 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). That is, it is designed to make clear to the public the "ostensible basis and scope of the agency's authority." Id.; see also Telesat Can. v. FCC, 999 F.3d 707, 713 (D.C. Cir. 2021) (explaining that the agency met its obligation under section 553(b)(2) by "referencing the relevant legal authority" and "clearly identif[ying] the basic governing statute").

The DEA's notice of proposed rulemaking did just that. It indicated that the Proposed Rule was

> being issued pursuant to the [DEA] Administrator's authority under the CSA "to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances," and to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under [the CSA]."

85 Fed. Reg. at 16,293 (citations omitted and second alteration in original) (first quoting 21 U.S.C. § 821 and then quoting 21 U.S.C. § 871(b)). The notice cited to the relevant provisions of the CSA and described both the registration requirement under section 822(a)(1) and the conditions of registration explicated in section 823(a). See Proposed Rule, 85 Fed. Reg. at 16,293. Indeed, the petitioners concede in reply that they "have never

disputed DEA's legal authority to promulgate the rules at issue here." Accordingly, the public was properly on notice of the provenance of the DEA's rulemaking authority.

Relying primarily on D.C. Circuit law, the petitioners nonetheless contend that section 553(b)(2) requires agencies to make available to the public the "data the agency used to develop the proposed rule." Am. Med. Ass'n v. Reno, 57 F.3d 1129, 1133 (D.C. Cir. 1995) (quoting Engine Mfrs. Ass'n v. EPA, 20 F.3d 1177, 1181 (D.C. Cir. 1994)). But it is unclear how this bears on the present question. A requirement to disclose relevant data sounds more in section 553(b)(3)'s directive that a notice include "either the terms or substance of the proposed rule or a description of the subjects and issues involved," than in section 553(b)(2)'s requirement to include "reference to the legal authority under which the rule is proposed." Cf. Conn. Light & Power Co. v. Nuclear Reg. Comm'n, 673 F.2d 525, 530-31 (D.C. Cir. 1982) (explaining that section 553(b)(3) requires agencies to disclose "the technical basis for a proposed rule").

In any event, the DEA's notice of proposed rulemaking did disclose the legal reasoning behind the Proposed Rule, albeit not at the same fulsome level of detail as in the OLC's Marijuana Cultivation Opinion. For instance, the notice of proposed rulemaking describes the five requirements in article 23(2) of the Single Convention for the supervision, licensing, and distribution

of marijuana. See Proposed Rule, 85 Fed. Reg. at 16,294. And it explains that while the DEA "already directly performs [three of the listed] functions," "[i]n order to ensure that DEA complies with the CSA and grants registrations that are consistent with . . . articles 23 and 28 of the Single Convention," the "proposed rule would amend DEA's regulations so that DEA directly carries out [the] remaining two functions." Id. This fairly gave notice to the public, including the petitioners, that issuing the Proposed Rule was motivated by the conclusion that the DEA's current marijuana registration scheme did not fully comply with the relevant articles of the Single Convention as required by the CSA.

Even if we were to agree with the petitioners that the APA requires the DEA to have disclosed the OLC's Marijuana Cultivation Opinion in its notice of proposed rulemaking, the petitioners can point to no prejudice resulting from this supposed failure to include more detail about the legal basis of the Proposed Rule. See 5 U.S.C. § 706 ("[D]ue account shall be taken of the rule of prejudicial error."); see also Am. Radio Relay League, Inc. v. FCC, 524 F.3d 227, 237 (D.C. Cir. 2008) (noting that the failure to disclose information for public comment is subject to the rule of prejudicial error). The OLC's opinion was publicly disclosed during the comment period, and various commenters -- including SRI and an entity affiliated with Craker

-- had an opportunity to raise issues relating to the document. See, e.g., Final Rule, 85 Fed. Reg. at 82,340-41 (responding to "some commenters['s] suggest[ion] that DEA and DOJ misinterpreted the Single Convention"). The petitioners do not explain what additional, concrete commentary they would have introduced had the OLC's opinion been disclosed sooner.

B.

The petitioners also argue that the DEA's rule must be set aside because the agency failed to provide its own reasoned explanation for the rule by impermissibly substituting the OLC's interpretation for its own. The petitioners, however, point to no authority supporting their view that an agency cannot justify an action based on its adoption of the OLC's controlling legal advice. The OLC's purpose, after all, is to provide such authoritative guidance to executive branch agencies. And bound or not, there is no indication that the DEA did not itself agree with the OLC's view on the interpretation of the CSA in the Final Rule. See, e.g., Final Rule, 85 Fed. Reg. at 82,340 (noting that the "DEA is bound by the law as DOJ and DEA understand it" (emphasis added)). Accordingly, there is no merit to the petitioners' argument that this dooms the DEA's rule.

IV.

The petitioners next contend that the Final Rule exceeds the DEA's rulemaking authority. First, they argue that the Final

Rule contravenes the CSA by imposing requirements that are different from the six enumerated "public interest" factors. See 21 U.S.C. § 823(a). Second, they assert that the Final Rule impermissibly limits the DEA's statutory authority to waive section 823(a)'s registration requirements. See id. § 822(d). And, third, they argue that the DEA's definition of "medicinal cannabis" in the Final Rule is unduly narrow because it requires cannabis products be legally marketable under the FDCA to qualify. The petitioners instead contend that the term "medicinal" must be given a broader meaning. We consider each argument in turn.

A.

The petitioners argue that the Final Rule exceeds the DEA's rulemaking authority because it is contrary to Congress's express instruction to register applicants to manufacture cannabis if doing so is "consistent with the public interest." 21 U.S.C. § 823(a). Section 823(a) lists six factors that the DEA must consider when determining the public interest:

> (1) maintenance of effective controls against diversion of particular controlled substances . . . by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;
>
> (2) compliance with applicable State and local law;

> (3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;
>
> (4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;
>
> (5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and
>
> (6) such other factors as may be relevant to and consistent with the public health and safety.

Id. § 823(a).[2] The Final Rule references these six factors verbatim. It also identifies considerations of "particular emphasis" for determining the public interest. See 21 C.F.R. § 1318.05(b); see also Final Rule, 85 Fed. Reg. 82,353–54. These considerations include "[w]hether the applicant has demonstrated prior compliance with [the CSA] and this chapter [of the DEA's regulations]." 21 C.F.R. § 1318.05(b)(1).

The petitioners assert that the Final Rule nevertheless contravenes section 823(a) for two main reasons.

1.

First, the petitioners contend that the Final Rule impermissibly allows the DEA to consider factors not expressly

[2] The petitioners make no argument that section 823(a) is itself beyond Congress's legislative authority.

enumerated in section 823(a) -- namely, an applicant's past compliance with state and local laws (as opposed to its current compliance) and an applicant's compliance with federal law (as opposed to, more narrowly, its "prior conviction record"). In support of this narrow reading, the petitioners point out that section 823(a)(2) only lists "compliance with applicable State and local law" as a factor to be considered, without any express mention of past compliance. And they contrast the more specific reference to an applicant's "prior conviction record under Federal and State laws" in section 823(a)(4) with more general references to "compliance . . . with applicable Federal, State, and local law" elsewhere in the section, see 21 U.S.C. § 823(h)(2); see also id. § 823(f)(4). These language choices, the petitioners argue, demonstrate that Congress did not intend for the DEA to consider these other factors.

But the petitioners' reading of the CSA finds limited support in the text of the statute. The CSA expressly vests the DEA with the authority to register an applicant to cultivate cannabis "if [the agency] determines that such registration is consistent with the public interest," listing six factors the agency must consider. 21 U.S.C. § 823(a). While Congress required the DEA to assess specific factors such as "compliance with applicable State and local law" and the "prior conviction record of [an] applicant under Federal and State laws," id. § 823(a)(2),

(4), the statute also directs the DEA to consider "such other factors as may be relevant to and consistent with the public health and safety," id. § 823(a)(6). The question then is whether considerations like the applicant's past compliance with state and local laws and compliance with federal law are "such other factors."

The DEA thought so, and so do we, even without the benefit of any deference to the DEA's interpretation that might be called for. The statute expressly authorizes the DEA to consider "other factors as may be relevant to and consistent with the public health and safety." Id. Congress itself has concluded that "[t]he illegal . . . distribution[] and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people." Id. § 801(2). Given these considerations, the petitioners make no serious argument that past compliance with federal, state, or local laws is not "relevant to and consistent with the public health and safety." Id. § 823(a)(6). And, indeed, the Final Rule explained that, among other things, prior compliance is "relevant to past experience in the manufacture of a schedule I controlled substance, past experience in preventing diversion of a controlled substance from other than DEA-authorized sources, and the promotion and protection of public health and safety," as well as "determining whether the applicant can be entrusted with the

responsibilities associated with being a DEA registrant." 85 Fed. Reg. at 82,335. We see nothing in the DEA's explanation that conflicts with section 823(a) or would lead us to part company with the agency's reading of the statute.

2.

The petitioners next complain that the Final Rule misconstrues section 823(a)(1), which directs the DEA to "consider[]" the "maintenance of effective controls against diversion of [cannabis] by limiting the importation and bulk manufacture of [cannabis] to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes." 21 U.S.C. § 823(a)(1). They contend that the DEA impermissibly reads the provision to require the agency to limit the number of manufacturers to only the number of establishments that can produce an adequate and uninterrupted supply of cannabis under adequately competitive conditions. See Final Rule, 85 Fed. Reg. at 82,336–37. And they argue that the DEA's interpretation of that provision to mandate (rather than merely "consider") an upper limit to the number of registrants conflicts with both the CSA and the DEA's prior interpretation of the relevant provision.

Contrary to the petitioners' contentions, however, the Final Rule does not purport to apply a specific cap on the number

registrants. First, with respect to the CSA, the regulation as codified simply restates the statutory language verbatim. Compare 21 C.F.R. § 1318.05(a)(1), with 21 U.S.C. § 823(a)(1). To the extent the petitioners find fault with the DEA's further explanation that it is "not allowed to register an unlimited amount of manufacturers" and "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," Final Rule, 85 Fed. Reg. at 82,336, those statements are consistent with both the CSA and the DEA's prior rulemakings.

In particular, the petitioners fasten attention to a footnote in a past DEA action that acknowledged that "the CSA . . . does not unambiguously impose an absolute ceiling on the number of registered manufacturers." Lyle E. Craker; Denial of Application, 74 Fed. Reg. at 2128 n.105. But that same footnote also explained that "[n]onetheless," section 823(a)(1) "can be construed to mean that DEA . . . must consider keeping as the upper boundary on the number of manufacturers that which can produce an adequate and uninterrupted supply under adequately competitive conditions." Id. That is, the DEA interpreted the CSA in its earlier action as "retain[ing] the concept of an upper limit on the number of manufacturers as a factor to be considered when evaluating an

application for registration under § 823(a)." Id. The Final Rule neatly follows the DEA's prior interpretation as well as the text of section 823(a)(1) -- which, again, the Final Rule incorporates verbatim. We therefore do not read this portion of the Final Rule as contrary to either the CSA or the DEA's own interpretive precedent.

B.

The petitioners argue next that the Final Rule impermissibly circumscribes the DEA's authority under the CSA to waive registration requirements in certain circumstances. The statute permits the DEA to, "by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if [the agency] finds it consistent with the public health and safety." 21 U.S.C. § 822(d). During the public comment period, various commentors urged the DEA to exercise its authority under section 822(d) to waive registration requirements for growers who supply cannabis to researchers. In the Final Rule, the DEA explained why it declined to do so. See 85 Fed. Reg. at 82,335–36.

The petitioners' primary argument appears to be that the DEA erred by refusing to even consider the possibility that it could grant waivers of the registration requirement for cannabis growers who supply researchers. This characterization, however, is belied by the fact that the agency did consider the issue in

its rulemaking; it simply decided not to exercise its authority in the way that the petitioners hoped it would. See id. And while the petitioners suggest that the DEA's justifications in the Final Rule for declining to so waive the registration requirements are insufficient, they never explain how section 822(d) in any way compels the DEA to exercise its waiver authority in this instance.

Take, for example, the petitioners' dissatisfaction with the DEA's explanation that "waiving the requirement of registration for marihuana growers who supply researchers would be inconsistent with U.S. obligations under the Single Convention." Id. at 82,336. To be sure, the petitioners are correct that it is only section 823(a) -- the provision laying out the registration requirements -- that instructs the DEA to consider compliance with the Single Convention. But that does not mean the DEA was off-base in determining that it would nonetheless be unwise to grant a waiver of registration that would violate the United States' treaty obligations. The petitioners' rejoinders at best establish that the agency was not obliged to decline to so exercise its authority; they do not demonstrate that the agency erred in making a discretionary decision to not waive registration.

C.

The petitioners next argue that the DEA's definition of the term "medicinal cannabis" in the Final Rule should be set aside. To recap, the DEA's rule defines "medicinal cannabis" as

"a drug product made from the cannabis plant, or derivatives thereof, that can be legally marketed under the Federal Food, Drug, and Cosmetic Act." 21 C.F.R. § 1318.02(b); see also Final Rule, Fed. Reg. at 82,340. The petitioners contend that the agency's definition is inconsistent with the plain meaning of "medicinal" and contrary to both the structure and scheme of the Single Convention and federal law.

To explain why the petitioners miss the mark, we begin by tracing how the DEA arrived at its definition of medicinal cannabis. In the Final Rule, the agency observed that "the Single Convention does not define medicinal cannabis." 85 Fed. Reg. at 82,340. At the same time, the DEA did not reject the petitioners' view that the Single Convention's understanding of "medicinal cannabis" is informed by its definition of "medicinal opium." See, e.g., id. at 82,344 n.17 (noting that the definition for "medicinal opium" in the Single Convention "appl[ies] to cannabis through Article 28"). Because the Single Convention defines "medicinal opium" to mean "opium which has undergone the processes necessary to adapt it for medicinal use," Single Convention, art. 1, § 1(o), there is support for the petitioners' position that the Single Convention would embrace a broader definition of "medicinal cannabis" than what the DEA put forward.

However, rather than borrowing verbatim whatever definition of "medicinal cannabis" could be gleaned from the Single

Convention, the DEA chose instead to "adapt[] the Single Convention's definition[] to reflect federal law, including the [FDCA] and the CSA." Final Rule, 85 Fed. Reg. at 82,344 n.17. That is, while the agency's definition of medicinal cannabis "track[ed]" the Single Convention's definition, the DEA also "adapted" that definition "to account for Federal law." Id. at 82,344. The question then is whether the DEA's decision to "adapt" the definition in the Single Convention to include only products approved for marketing under the FDCA was a reasonable exercise of its rulemaking authority.

As an initial matter, there is no question that the DEA has the authority to establish its own definition of "medicinal cannabis" in the context of the federal registration scheme. The CSA grants the DEA the power to "promulgate rules and regulations . . . relating to the registration and control of the manufacture, distribution, and dispensing of [cannabis]." 21 U.S.C. § 821. And it specifies that the DEA shall register applicants to manufacture cannabis if the agency "determines that such registration is consistent with the public interest and with United States obligations under international treaties," including the Single Convention. Id. § 823(a). Accordingly, it is well within the DEA's statutory mandate to define a term that implicates its control over stocks of cannabis and that relates to both the

public interest and the United States' obligations under the Single Convention.

As for whether the definition the DEA arrived at is arbitrary or capricious, the petitioners point us to nothing that demonstrates that the agency's understanding of "medicinal cannabis" contravenes the CSA, violates the United States' obligations under the Single Convention, or is otherwise contrary to law. Beginning with the CSA, we observe that the statute has no definition of "medicinal cannabis" of its own and never even uses the term. The CSA classifies cannabis as a schedule I drug. See 21 U.S.C. § 812, sched. I(c)(10); see also Gonzales v. Raich, 545 U.S. 1, 14 (2005). And it mandates that the DEA in registering cultivators consider the "maintenance of effective controls against diversion." 21 U.S.C. § 823(a)(1). Given this regulatory scheme, it is hardly arbitrary or capricious for the DEA to define "medicinal cannabis" -- as that term is used by the DEA in its own rule -- in a way that keeps stocks of cannabis produced by registered growers within the agency's exclusive control, at least until any such cannabis intended for medicinal use can be legally marketed under federal law.

As for the Single Convention, all parties agree that the DEA's definition of "medicinal cannabis" is no broader than the treaty's definition of the term. For that reason, we see no conflict between the DEA's chosen definition and the United States'

obligations under the Single Convention. The Single Convention allows the United States to forego asserting exclusive control over "medicinal cannabis" as that term is used in the treaty. See Single Convention, art. 23, § 2(e) ("Parties need not extend this exclusive right to medicinal [cannabis]."). But nothing in the Single Convention requires a signatory to forego that control over any stock of cannabis, including medicinal cannabis. And for the reasons already explained, the DEA's justification for retaining its exclusive rights over a broader stock of cannabis than the Single Convention arguably requires -- "to ensure compliance with the CSA," Final Rule, 85 Fed. Reg. at 82,340 -- is neither arbitrary nor capricious.

Trying an alternative approach, the petitioners also argue that the DEA's definition of "medicinal cannabis" is contrary to our prior decision in Grinspoon v. DEA, 828 F.2d 881 (1st. Cir. 1987). In Grinspoon, we had occasion to examine the CSA's statutory requirements for classification of schedule I substances, specifically the condition that the substance "has no currently accepted medical use in treatment in the United States," 21 U.S.C. § 812(b)(1)(B). The DEA promulgated a rule that essentially sought to interpret the statutory phrase "accepted medical use in treatment in the United States" in the CSA to mean "approved for interstate marketing by the [Food and Drug Administration (FDA)] under the FDCA." See Grinspoon, 828 F.2d at

884. We concluded that the DEA's limiting construction was contrary to congressional intent because it was "plainly possible that a substance may fail to obtain interstate marketing approval even if it has an accepted medical use." Id. at 887–88.

Here, though, the DEA was not engaged with defining a statutory term. And the statutory direction was simply to register prospective cannabis cultivators based on the public interest and the need to comply with the nation's treaty obligations, see 21 U.S.C. § 823(a), and to promulgate rules "relating to the registration and control of [cannabis]," id. § 821. And as we have discussed, nothing in the definition exceeded the agency's statutory authority or put the United States in breach of its treaty obligations.

The petitioners also assert that the DEA's definition of "medicinal cannabis" conflicts with various FDA regulations indicating the FDA's endorsement of research and medical treatments involving federally regulated substances that have not been approved for interstate marketing under the FDCA. This supposedly demonstrates that the FDA understands that such substances may be "medicinal" even if they have not undergone the relevant approval process. But here we are not weighing the wisdom of competing interpretations by different federal agencies over the same statutory provisions. Just because the FDA might reasonably construe the statutes it administers to provide for a

broader definition of "medicinal cannabis" does not mean that the DEA acts arbitrarily or capriciously when it defines "medicinal cannabis" more narrowly for its own purposes. It is no surprise -- and no mark of unreasonableness -- that the FDA might have a different definition of "medicinal cannabis" in one context than the DEA does for its work in other contexts.[3]

In sum, the DEA has for its purposes crafted its own definition of medicinal cannabis that is based on, but not wholly equivalent to, that in the Single Convention. That definition neither breaches any treaty obligation of the United States nor violates federal law. And the DEA did not act arbitrarily or capriciously in concluding that it must maintain exclusive control over stocks of a schedule I drug produced under federal law until medicinal products containing that substance are approved for marketing by the FDA. For these simple reasons, we reject the petitioners' challenge to the DEA's definition of "medicinal cannabis."

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[3] The above reasoning also explains why the petitioners are incorrect to assert that the DEA's definition of "medicinal cannabis" in the context of interpreting its authority under the CSA impermissibly regulates medical practice. The DEA's definition relates to what subset of cannabis must be exclusively controlled by the DEA -- something the CSA and the Single Convention requires the agency to consider. It does not concern what activities are or are not permissible aspects of medical practice. Accordingly, we do not view the agency's actions as exceeding its congressionally delegated authority in this way.

v.

Finally, the petitioners argue that the DEA's new regulatory framework for registrations, even if it is within the agency's rulemaking authority, must be set aside as arbitrary, capricious, or otherwise contrary to law. The petitioners begin by contending that the DEA failed to consider relevant alternatives. When promulgating new regulations, an agency must consider alternatives "within the ambit of the existing [policy]," but it need not "consider all policy alternatives in reaching [its] decision." Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 51 (1983); see also DHS v. Regents of the Univ. of Cal., 140 S. Ct. 1891, 1914–15 (2020) ("Agencies are not compelled to explore 'every alternative device and thought conceivable by the mind of man.'" (quoting Vt. Yankee Nuclear Power Corp. v. NRDC, 435 U.S. 519, 551 (1978)). The key question is whether the agency "entirely failed to consider an important aspect of the problem." State Farm, 463 U.S. at 43.

The petitioners devote all of three sentences in their opening brief to this argument. They do not identify any specific aspect of the problem that the DEA missed and make no argument for why the DEA's supposed failure to consider the alternatives the petitioners point to should doom the entire rule. Instead, the petitioners vaguely gesture towards two documents -- the OLC's Marijuana Cultivation Opinion and SRI's comments to the agency

during the notice-and-comment period -- as sources for the purported alternatives the DEA declined to consider. And in so doing, the petitioners make no attempt to explain why these records indicate that the agency "entirely failed to consider an important aspect of the problem." Id. We therefore treat this argument as waived. United States v. Zannino, 895 F.2d 1, 17 (1st Cir. 1990) ("[I]ssues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived.").

The petitioners also argue that the Final Rule arbitrarily discriminates between cannabis supplied by the National Center -- the only federally registered cannabis grower at the time the rule was promulgated -- and cannabis supplied from other sources, including cannabis grown in states that allow it under their laws. During the notice-and-comment period, various commentors suggested that federally registered researchers should be allowed to obtain cannabis from state-authorized dispensaries. See Final Rule, 85 Fed. Reg. at 82,338. The DEA rejected this proposal, explaining that "[s]tate licenses to manufacture marijuana do not satisfy the requirements of Federal law," and, therefore, allowing researchers to use state-authorized cannabis would violate the CSA. Id. The petitioners assert that this decision is arbitrary and capricious because it fails to treat "like cases alike." Namely, it permits researchers to obtain

cannabis from the National Center but not from state-permitted dispensaries.

But this argument misses a crucial detail: the National Center and state dispensaries are not "like cases." As the DEA explains, the National Center is a federally registered grower under the CSA, while state dispensaries are not. And federal law requires that "[e]very person who manufactures or distributes [cannabis] . . . shall obtain annually a registration issued by the [DEA]." 21 U.S.C. § 822(a)(1). It is hardly arbitrary and capricious for the DEA to allow federally registered growers to supply cannabis while precluding non-federally registered growers from doing the same.

The petitioners point out that, under the OLC's and the DEA's reading of the CSA, all of the National Center's historic growing activity was also in violation of federal law and the Single Convention. But the petitioners never explain why that makes the National Center somehow equivalent to the proposed state dispensaries. Nor do they establish that, after the Final Rule's implementation, the National Center's activities would continue to be contrary to federal law.

Lastly, Craker, not joined by fellow petitioner SRI, argues that the Final Rule is impermissibly retroactive because it applies to pending applications before the DEA. He explains that because he (and 30-some-odd others) had already sent in

applications in response to the DEA's call for applications for the 2016 program, it is unfair to pull the rug out from under him by applying the new rule to the application he prepared in reliance on the prior regime.

While we have acknowledged generally that "the retroactive application of an agency rule is disfavored," we have also explained 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 Med. Assocs. v. Sec'y of Health and Hum. Servs., 127 F.3d 118, 121 (1st Cir. 1997). Particularly where a change involves "the substantive standards for granting the application on the merits," it does not typically raise the kind of "fair notice and retroactivity concerns" that Craker complains of. Id. at 122. Previously, we 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. (emphasis omitted). Craker musters up no such support now. And while Craker points to factual differences between his case and Pine Tree, he makes no argument as to why those distinctions demand a different legal rule be applied. Thus, Craker has not identified any notice or retroactivity problem that would render the application of the

Final Rule to his application arbitrary, capricious, or otherwise contrary to law.[4]

VI.

For the foregoing reasons, we deny the petitioners' petitions for review.

[4] Craker also argues that the rule suddenly changed the status of pending applications from "complete" to "incomplete" because of a requirement to submit a new form. But this too does not render the rule impermissibly retroactive. Although we have noted that "rejecting an application because it fails to meet a new regulation governing the proper format or preparation of applications that was promulgated after that application was filed" could raise notice and retroactivity concerns, Pine Tree, 127 F.3d at 122, changing an application's status to "incomplete" to account for a new filing requirement is not equivalent to a denial, at least without some evidence that the new filing requirement essentially effects a rejection. Here, Craker has raised no claim of prejudice from the requirement except that a new form must be submitted.