Nos. 21-1055 and 21-1323

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 the United States Drug Enforcement Administration,

Respondents.

No. 21-1323

SCOTTSDALE RESEARCH INTITUTE

Petitioner,

v.

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION; D. CHRISTOPHER EVANS, in his official capacity as Acting Administrator of the United States Drug Enforcement Administration; MERRICK B. GARLAND, Attorney General,

Respondents.

PETITIONERS' REPLY BRIEF

Matthew C. Zorn
Yetter Coleman LLP
811 Main Street, Suite 4100
Houston, Texas 77002
Phone: 713.632.8000
Fax: 713.632.8002
mzorn@yettercoleman.com

Counsel for Petitioner Scottsdale Research Institute

Shane Pennington
Vicente Sederberg LLP
1115 Broadway, 12th Floor
New York, NY 10010
Phone: 917.338.5455
Fax: 303.860.4504
s.pennington@vicentesederberg.com

Michael Perez (No. 1197372)
Perez Law
42 Arlington St.
Medford, MA 02155
617-699-1567
mike@perez-law.com

Alexandra H. Deal (No. 119274)
Paik, Brewington & Deal, LLP
6 Beacon Street, Suite 305
Boston, MA 02108
(617) 439-0150
adeal@pbdlaw.com

Counsel for Petitioner Dr. Lyle E. Craker

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I. DEA Violated the APA Requirements Governing Notice and Comment Rulemaking.

In a pathbreaking publication from her days as a law professor, now-Justice Kagan described "the degree to which the public can understand the sources and levers of bureaucratic action" as a "fundamental precondition of accountability in administration." Elena Kagan, *Presidential Administration*, 114 Harv. L. Rev. 2245, 2332 (2001). And in a passage that speaks directly to this case, she added:

> The lines of responsibility should be stark and clear, so that the exercise of power can be comprehensible, transparent to the gaze of the citizen subject to it. Bureaucracy is the ultimate black box of government--the place where exercises of coercive power are most unfathomable and thus most threatening. To a great extent, this always will be so; the bureaucratic form—in its proportions, its reach, and its distance—is impervious to full public understanding, much less control. But for this very reason, the need for transparency, as an aid to holding governmental decisionmakers to account, here reaches its apex. To the extent possible, consistent with congressional command and other policy objectives, there is good reason to impose clear lines of command and to simplify and personalize the processes of bureaucratic governance.

Id. (quotation marks and citations omitted). DEA's attempt to use 5 U.S.C. § 553's notice-and-comment procedures to convert a policy developed and finalized years ago by a *different* agency *in secret* into a legislative rule is an

affront to the Administrative Procedure Act's ("APA") commitment to public participation and transparency as essential elements of valid agency action.

The government's arguments to the contrary fail to engage meaningfully with petitioners' fundamental objections to DEA's putative rulemaking process. The government emphasizes, for example, that the Proposed Rule "discussed DEA's legal *authority* for the rule at length" and included "detailed analysis of both the Single Convention and the CSA." Govt. Br. 11. From those undisputed premises, it concludes that DEA "complied with its obligations under § 553(b)(2) to adequately explain the legal basis for its rulemaking." *Id.* But § 553(b)(2) doesn't govern DEA's admitted "obligation[ ] … to adequately explain the legal basis for its rulemaking." Section 553(b)(2) requires agencies to include in a Proposed Rule a "reference to the legal authority under which the rule is proposed." 5 U.S.C. § 553(b)(2). Petitioners have never disputed DEA's legal authority to promulgate the rules at issue here. Instead, precisely *because* Congress delegated that legal authority to DEA—and *not* the Office of Legal Counsel ("OLC")—petitioners have argued that DEA's failure to include *its own* legal rationale for the Proposed Rule deprived the public of any meaningful opportunity to comment. Opening Br. 30.

In support of their point, petitioners discussed *American Medical Association v. Reno*, 57 F.3d 1129, 1132-33 (D.C. Cir. 1995), at length. Opening Br. 32-35. Like petitioners here, the appellants in *Reno* challenged a DEA rule announcing an increase of controlled substance registration fees on the ground that DEA's Proposed Rule failed to provide the meaningful opportunity to comment the APA requires. 57 F.3d at 1130-31. There, as here, there was no dispute that DEA had the requisite authority to promulgate the rules at issue. *Id.* at 1131 ("DEA is authorized [under the CSA] to register handlers of controlled substances and to collect from them 'reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances" (quoting 21 U.S.C. § 821)). The question was whether DEA's failure to "explain how it determined that a particular cost was properly attributed to [the agency's diversion control program]" deprived the public of any meaningful opportunity to comment on the Proposed Rule. *Id.*

The D.C. Circuit held that it did. By failing to provide "the data underlying" its proposal and "its basis for attributing particular costs to that program," the court explained, DEA had deprived interested persons of "sufficient detail on [the Proposed Rule's] basis in law and evidence to allow for meaningful and informed comment." *Id.* (quoting *Engine Mfrs. Ass'n v.*

EPA, 20 F.3d 1177, 1181 (D.C. Cir. 1984). In their opening brief, petitioners argued that while *Reno* is admittedly out-of-circuit precedent, its reasoning applies with full force here. Opening Br. 35. Tellingly, the government doesn't mention *Reno* in its response brief.

The government's remaining arguments are equally meritless. Petitioners do not argue that DEA must include its "final legal theory" in the Proposed Rule. Govt. Br. 15 (*Telestat v. FCC*, 999F.3d 707, 713 (D.C. Cir. 2021)). On the contrary, petitioners' problem with the Proposed Rule is that DEA *did* in fact include a "final legal theory" in it—just not *DEA*'s. Opening Br. 30 ("DEA's Final Rule did not provide any explanation of *its* reasons for pursuing the rulemaking. Instead, DEA continued to insist that the policy shift was DOJ's idea and that it had no choice in the matter."); Opening Br. 34 ("The APA 'requires the agency to make available to the public in a form that allows for meaningful comment, the data *the agency* used to develop the proposed rule.'" (quoting *Reno*, 57 F.3d at 1133). Instead, DEA "proposed" a legal theory that the OLC Opinion made final nearly two years earlier, *see Licensing Marijuana Cultivation in Compliance with the Single Convention*

on Narcotic Drugs (June 6, 2018) ("OLC Op.").[1] In doing so, DEA emphasized it was merely following DOJ's (OLC's) orders and therefore had no discretion in the matter. *See* 85 Fed. Reg. 16292, 16294 (March 23, 2020) ("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.") (emphasis added); *id.* at 16298 (explaining that because "[t]his proposed rule would amend DEA regulations *only to the extent necessary* to comply with the CSA and to ensure DEA grants registrations that are consistent with the Single Convention as it pertains to marihuana," DEA had no discretion to exercise with respect to the proposed rule and no "alternative approaches would be discussed"). Put simply, the Proposed Rule was a "proposal" in name only.

Nor do petitioners argue that DEA was obligated to concurrently publish "predecisional" "legal advice" DEA received from OLC. Govt. Br. 17. As DEA repeatedly emphasized in the Proposed and Final Rules, the OLC Opinion purported to bind DEA, and DEA treated it as binding:

- OLC Op. 1 ("This opinion considers whether the Drug Enforcement Administration ("DEA") … *must* alter existing

[1] https://www.justice.gov/sites/default/files/opinions/attachments/2020/04/29/2018-06-06-marijuana-cultivation.pdf.

licensing practices to comply with the Single Convention." (emphasis added)).

- OLC Op. 2 ("We conclude that DEA *must change* its current practices and the policy it announced in 2016 to comply with the Single Convention." (emphasis added)).

- OLC Op. 2 ("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. (emphasis added)).

- OLC Op. 2 ("In addition, DEA *must* generally monopolize the import, export, wholesale trade, and stock maintenance of lawfully grown marijuana." (emphasis added)).

- OLC Op. 2 ("There may well be more than one way to satisfy those obligations under the Single Convention, but *the federal government may not license* the cultivation of marijuana without complying with the minimum requirements of that agreement." (emphasis added)).

- OLC Op. 6 (explaining "changes DEA *must* make to conform to the treaty" (emphasis added)).

- OLC Op. 24 ("DEA's licensing procedures *must comply* with those choices. DEA's announced policy, however, *would not* comply with Articles 23 and 28 of the Single Convention." (emphasis added).

- OLC Op. 24 ("We conclude that *DEA must alter* the marijuana licensing framework to comply with the Single Convention." (emphasis added)).

- Proposed Rule, 85 Fed. Reg. at 16292 ("Subsequently, the *Department of Justice (DOJ) … determined* that certain changes to its 2016 policy were needed." (emphasis added)).

- Proposed Rule, 85 Fed. Reg. at 16294 ("After the publication of the 2016 policy statement, 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." (emphasis added)).

- Final Rule, 85 Fed. Reg. 82333, 82334 (Dec. 18, 2020) ("Subsequently, the Department of Justice (DOJ) undertook a review of the CSA, including the requirement of section 823(a) that a registration to bulk manufacture a schedule I or II controlled substance must be consistent with United States obligations under international treaties such as the Single Convention, and *determined* that certain changes to its 2016 policy were *needed*. (emphasis added))."

- Final Rule, 85 Fed. Reg. at 82335 ("DOJ reviewed DEA's policies and practices for issuing bulk marihuana manufacturing registrations in light of the CSA and *determined that DEA needed* to amend its policies." (emphasis added)).

- Final Rule, 85 Fed. Reg. at 82335 n.7 ("The Attorney General determined that adjustments were necessary after receiving the aforementioned advisory OLC Opinion.").

- Final Rule, 85 Fed. Reg. at 82339 ("[E]ven if DEA preferred other Federal agencies to carry out these functions, *as DOJ has interpreted the CSA*, including a provision requiring that registrations be consistent with U.S. obligations under the Single Convention, it would be unlawful for DEA to transfer these functions to another Federal agency." (emphasis added)).

- Final Rule, 85 Fed. Reg. at 82339 ("DEA acknowledges some may disagree with these legal conclusions, but *DEA is bound* by the law as DOJ and DEA understand it." (emphasis added)).

- Final Rule, 85 Fed. Reg. at 82346 (explaining that because "[t]his proposed rule would amend DEA regulations *only to the extent necessary* to comply with the CSA and to ensure DEA grants registrations that are consistent with the Single Convention as it pertains to marihuana," DEA had no discretion to exercise with respect to the proposed rule and no "alternative approaches would be discussed").

- Final Rule, 85 Fed. Reg. at 82336 n.8 (citing OLC Op. at 7); *id.* at 82339 n.9 ("The relevant law is briefly summarized here but is discussed in greater depth in the aforementioned OLC Opinion."); *id.* at 82339 n.12 ("These issues are discussed further in the OLC Opinion."); *id.* at 82339 n.13 ("As noted, the relevant legal considerations are explored in greater detail in the aforementioned OLC Opinion.").

The government also argues that DEA "independently explained that the legal basis for the rule rested on various sections of the CSA and its obligations under the Single Convention." Govt. Br. 17. If the government means that DEA followed OLC's orders by regurgitating in the Proposed Rule the legal reasoning made final by the 2018 OLC Opinion, petitioners agree. Indeed, that's precisely problem. *See supra* 12-14 (quoting Kagan, *Presidential Administration*, 114 Harv. L. Rev. at 2332 (describing "the degree to which the public can understand the sources and levers of bureaucratic action" as a "fundamental precondition of accountability in administration")); *see also Alpharma, Inc. v. Leavitt*, 460 F.3d 1, 6 (D.C. Cir. 2006) (Garland, J.) (fundamental administrative-law principles prohibit "judges [from] uphold[ing] agency action on the basis of rationales offered by anyone other than the proper decisionmakers").

To the extent the government means to imply that DEA independently considered OLC's view of the law, found it persuasive, and initiated the rulemaking proceeding at issue here to adopt it as its own, its argument fails

for at least two reasons. First, as already discussed, DEA repeatedly emphasized that OLC had *directed* it to make these changes. *See supra* 12-14 (citing multiple passages from the OLC Opinion). The new policy the Final Rule announced therefore emanated from OLC, not DEA, which is why DEA explicitly underscored its own lack of discretion in the rulemaking process. Proposed Rule, 85 Fed. Reg. at 16298; Final Rule, 85 Fed. Reg. at 82346.

Second, even if DEA *did* agree with OLC's view of the law, the Final Rule would still be invalid because an agency announcing a change in policy must acknowledge the change and provide a reasoned explanation for the change. *E.g.*, *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125-26 (2016). Petitioners do not dispute that DEA displayed awareness in the Final Rule that its position was changing. It is DEA's explanation for the change that is problematic.

In the Final Rule, DEA explained that the OLC Opinion declared that DEA *must* amend its regulations before registering additional marijuana manufacturers. *See supra* 12-14 (quoting relevant sources). But because it is DEA's policy that is changing, DEA's explanation is the one that counts. *See, e.g.*, *Encino Motorcars*, 136 S. Ct. at 2122-23 (DOL changing DOL policy); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 506-10 (2009) (FCC changing FCC policy); *Smiley v. Citibank (South Dakota) N.A.*, 517 U.S. 735,

742-43 (1996) (OCC allegedly changing OCC policy). In addressing the effect of another agency's potentially inconsistent position on *Chevron* deference, the Supreme Court reasoned, "even if the position taken by the Department of Energy in [another case] was inconsistent with the [Commerce Department's] position here, it would not speak to the deference owed the Commerce Department under *Chevron*." *United States v. Eurodif S. A.*, 555 U.S. 305, 316 n.7, (2009). The same rationale applies here. *Cf. Alpharma, Inc.*, 460 F.3d at 6 (fundamental administrative-law principles prohibit "judges [from] uphold[ing] agency action on the basis of rationales offered by anyone other than the proper decisionmakers").

DOJ may not use OLC's opinion-writing function to sidestep another agency's obligations under the APA. If DEA considers itself obligated to follow the OLC Opinion, then it must adopt that position as its own, acknowledge its status as the "working law" of the agency, and publish it for public inspection as mandated by the electronic-reading room provisions of the Freedom of Information Act. *See* 5 U.S.C. § 552(a)(2)(A)-(B) (requiring agencies to disclose—even without a request from the public—certain categories of documents, including categories include "final opinions … in the adjudication of cases" and "statements of policy and interpretations which have been adopted by the agency"); *NLRB v. Sears, Roebuck & Co.*,

421 U.S. 132, 153 (1975) (explaining that these categories of records constitute the "working law" of an agency because they "have 'the force and effect of law'" (other citations omitted)). What it can't do is vaguely reference the OLC Opinion as the authoritative law of the Executive Branch that provides the reasoned explanation for its own change in policy, insist that it has no choice but to follow OLC's commands, but then keep that authoritative statement of the law secret from the public.

II. The Final Rule Contravenes the CSA.

A. The Final Rule rests on an impermissible interpretation of the CSA and Single Convention.

Section 823(a). Petitioners dedicated 21 pages of their opening brief to exhausting the traditional tools of statutory construction to demonstrate the many ways in which the Final Rule departs from the plain text of § 823(a). *See* Opening Br. 39-60. The government doesn't even attempt to respond to the vast majority of those arguments.

Petitioners emphasized, for example, that instead of considering "compliance with applicable State and local law" as subsection (a)(2) instructs, the Final Rule focuses on *the applicant's* past "compliance with applicable State and local law." Opening Br. 40 (quoting Final Rule, 85 Fed. Reg. at 82335 (emphasis added)). Had Congress intended subsection (a)(2) to concern the applicant's compliance, petitioners emphasized, there is every

reason to believe it would have said so. Opening Br. 41. After all, other provisions of § 823 *do* key in on "the applicant's" compliance with different laws. Opening Br. 41 (emphasizing that § 823(a)(4) instructs DEA to consider the "prior conviction record *of applicant* under [certain] Federal and State laws" (emphasis added), and § 823(h) directs DEA to consider "compliance *by the applicant* with applicable Federal, State, and local law" (emphasis added)). The government offers no response to these arguments.

Petitioners also emphasized that DEA's focus on an applicant's compliance with federal law renders § 823(a)(4)'s command that DEA consider an applicant's "record of *conviction*" meaningless. Opening Br. 41-42 (discussing 21 U.S.C. § 823(a)(4)). Petitioners even demonstrated how other provisions of § 823—those that *do* in fact require DEA to consider mere violations—underscore Congress's intentionality with respect to § 823(a)(4)'s narrower focus on an applicant's "record of conviction." Opening Br. 42 (citing numerous provisions of § 823).

The government doesn't dispute any of this. Instead, it insists that the fact that its interpretation contradicts the plain language of these provisions doesn't matter because § 823(a)(6)'s catch-all provision permits DEA to consider "such other factors as may be relevant to and consistent with the public health and safety." Govt. Br. 23 (citing 21 U.S.C. § 823(a)(6)). As

petitioners explained in their opening brief, however, DEA's attempt to read a catch-all provision at the end of a list of specific considerations in a manner that renders the specific considerations meaningless violates fundamental principles of statutory construction. Opening Br. 42-43; *see also* Scalia & Garner, *Reading Law* 199 (West 2012) (explaining that this principle is a classic application of the *ejusdem generis* canon of statutory construction). Despite its continued reliance on § 823(a)(6), Govt. Br. 23, the government doesn't address this argument either.

Section 822(d). The government mischaracterizes petitioners' argument regarding DEA's authority under 21 U.S.C. § 822(d) to waive the CSA's registration requirements. Br. 47-51. Contrary to the government's depiction, petitioners do not argue that DEA should be *required* to grant such waivers. Govt. Br. 37. Rather, they argue that DEA's refusal in the Final Rule even to *consider* the possibility cannot be squared with the plain language of the statute. Opening Br.47-48 (disputing DEA's reasons for concluding that granting any waiver under § 822(d) was not a "legally viable option" (quoting Final Rule, 85 Fed. Reg. at 82336). That point remains unrebutted as well.

Petitioners pressed these same text-focused arguments in comments submitted to DEA on the Proposed Rule. *See* Comments of Scottsdale

Research Institute, LLC 6-12 (May 22, 2020). The informal rulemaking process is supposed to make rules better by exposing agency proposals to public scrutiny. It's one thing for the agency to consider alternative views of the statute and explain why, on balance, it believes it has the better reading. Here, though, DEA and the government consistently refuse to engage with the statutory text even in the face of detailed demonstrations of how their view of the statute contradicts its plain language. If there is a way to defend DEA's interpretation against petitioners' many text-based objections, it does not appear in DEA's response to comments in the Final Rule or the government's response brief in this Court. Such silence from a regulator in the face of good-faith objections from the regulated public undermine the APA's goals in a different way by diminishing public confidence in the agency and the perceived legitimacy of the agency's legal standards. *See, e.g.*, *Dismas Charities, Inc. v. United States Dep't of Justice*, 401 F.3d 666, 678 (6th Cir. 2005) (notice-and-comment procedure promotes quality of agency rules and "ensure[s] fair treatment for persons to be affected by" them).

Medicinal cannabis. DEA's contemporaneous explanation in the Final Rule of its own reasons for its preferred definition of "medicinal cannabis" is as follows:

> DEA understands "medicinal cannabis" to mean drug products derived from cannabis in a form that the United States has approved for medical use, which is most effectively captured in this rule by requiring that the product be able to be legally marketed under the Food Drug and Cosmetic (FD&C Act). The 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, not products States may have approved.

Final Rule, 85 Fed. Reg. at 82340.

In its current effort to defend DEA's definition in this Court, the government offers many additional reasons of its own. Govt. Br. 25-31. But it is a "foundational principle of administrative law" that judicial review of agency action is limited to "the grounds that the agency invoked when it took the action." *Michigan v. EPA*, 576 U.S. 743, 758 (2015) (citing *SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943) (*Chenery I*)). Because most of the government's attempts to prop up DEA's definition of "medicinal cannabis" appear nowhere in the Final Rule itself, they are not properly before this Court. *Id.* Examples of such *post hoc* rationales include the government's discussions of "lawful transportation in interstate or foreign commerce" and "commercial control." Govt. Br. 26-30. The Final Rule must stand or fall on the reasons *DEA* offered at the time. *Michigan*, 576 U.S. at 758.

The government warns that the definition of "medicinal cannabis" should not be "contingent on whether the marijuana could be medically

prescribed under a particular State's law." Govt. Br. 28-29. Petitioners expressly disclaimed any such intention in their opening brief, however, explaining that their point is simply that DEA may not arbitrarily exclude FDA-sanctioned uses of a drug (expanded access) from its definition of medicinal cannabis. Opening Br. 60.

In all events, the government's argument is also self-defeating. It says that the listing of "opium alkaloids" refers to drugs like "morphine, codeine, and papervine," which is listed separately from "medicinal opium." Govt. Br. 27. Yet that is precisely petitioners' point: These drugs are FDA-approved. Medicinal *opium* listed in Article 23 of the Single Convention, by contrast, is opium that has been adapted for medical use but isn't processed into a conventional pharmaceutical.

Contrary to the government's depiction, petitioners do not claim that "medicinal cannabis" refers to any kind of marijuana that might have potential medical applications. Govt. Br. 27. Rather, their point is that cannabis that is eligible for expanded access has actual medical applications according to FDA, and that DEA's definition arbitrarily excludes them. Opening Br. 61.

The government offers no colorable reason that medicinal cannabis that is eligible for limited medical use under an FDA program should not

qualify as "medicinal cannabis" simply because FDA has not approved it for interstate marketing. The government insists that DEA "rightly" looked to the federal level. Govt. Br. 30. As petitioners explained, however, at the federal level, even non-FDA-approved drugs can be medically used under expanded access. Opening Br. 56-59. The government's attempt to distinguish this Court's decision in *Grinspoon v. DEA*, 828 F.2d 881, 891 (1st Cir. 1987). After all, if DEA cannot define "medical use" as "FDA approved," then how can it define "medicinal" as FDA approved? The government attempts to explain this problem away by stating that "medicinal" in the treaty bears different consequences than "medical use" in the CSA, *i.e.* legislation that implements the treaty. Govt. Br. 30 (discussing "follow-on effect"). But consequences cannot change the meaning of words.

Finally, the government's discussion of *Sisley v. DEA*, 2021 WL 3853049, at *1-2 (9th Cir. Aug. 30, 2021) is a non-sequitur. Govt. Br. 31. Petitioners do not seek rescheduling. Their grievance is with DEA's impermissible interference with the regulation of the medical practice by arbitrarily excluding a medical use for cannabis that FDA itself has blessed. Opening Br. 56-61. The fact that marijuana remains in schedule I does not preclude its use in an expanded access protocol. Tellingly, the government does not contend otherwise.

B. *Chevron* does not apply.

The government invokes *Chevron* deference. *See Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). For the reasons already explained, however, the government's interpretation would be impermissible and therefore would not pass muster even under *Chevron*. In any case, *Chevron* does not apply in this case for several reasons, which petitioners discuss next.

First, nowhere in the Proposed Rule or Final Rule did DEA claim the statute is ambiguous. Indeed, it disclaimed any discretion to interpret the statute differently. *See supra* 12-14 (quoting passages from Proposed and Final Rules). *Chevron* deference doesn't apply to agency interpretations of unambiguous statutes. *Chevron*, 467 U.S. at 843. Nor is it available when an agency mistakenly *believes* a statute is unambiguous. *See* Daniel J. Hemel and Aaron L. Nielson, Chevron *Step One-and-a-Half,* 84 U. Chi. L. Rev. 757, 764 (2017) (deference in appropriate where an agency's explanation for a statutory interpretation demonstrates that the agency failed to recognize a statutory ambiguity because "[i]f agencies are entrusted with discretionary power on the grounds that they are more accountable than courts, then judicial review should encourage agencies to take responsibility for their decisions.")

Third, *Chevron* does not apply to a law-enforcement agency's interpretation of a dual-application statute like the CSA. *See Esquivel-Quintana v. Lynch*, 810 F.3d 1019, 1027-32 (6th Cir. 2016) (Sutton, J.) (concurring in part, dissenting in part).

Fourth, in the Final Rule, DEA admitted that the policy it announced rested on OLC's construction of the CSA and treaty—not DEA's. *See supra* 12-14 (quoting several passages of Final Rule). OLC has no statutory authority to construe the CSA or the treaty with the force and effect of law. As such, its interpretation is ineligible for *Chevron*. *E.g.*, *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001) (deference available only "when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority"). Moreover, DEA has never given any indication that it actually agrees with OLC's interpretation. This Court should not defer to DEA regarding an interpretation that (1) isn't DEA's in the first place and (2) DEA may very well disagree with. *Id.*

The government also claims "DEA's interpretation" of the Single Convention is entitled to deference. Govt. Br. 28 (citing *Sumitomo Shoji America, Inc. v. Avagliano*, 457 U.S. 176, 184-85 (1982)). As just explained,

however, DEA admits that the Final Rule is the result of *OLC*'s interpretation—not its own. *See supra* 12-14 (quoting Proposed Rule and Final Rule). And because the government never argues that OLC's interpretation is entitled to deference, judicial deference cannot apply. *See Mead Corp.*, 533 U.S. at 226-27 (deference not appropriate when agency lacks delegated authority to make rules carrying the force of law).

Furthermore, neither DEA nor OLC argued that any of the relevant treaty provisions is ambiguous. That, too, forecloses deference. *See Chevron*, 467 U.S. at 843; *Martinez v. United States*, 828 F.3d 451, 475 (6th Cir. 2016) ("Only if the language of a treaty, when read in the context of its structure and purpose, is ambiguous may courts 'resort to extraneous information like the history of the treaty, the content of negotiations concerning the treaty, and the practical construction adopted by the contracting parties.'") (quoting *Kreimerman v. Casa Veerkamp, S.A. de C.V.*, 22 F.3d 634, 638 (5th Cir. 1994)).

III. The Final Rule Is Arbitrary and Capricious.

The government doesn't respond to most of petitioners' arguments that the Final Rule is arbitrary and capricious. Opening Br. 62-67. Rather than repeat undisputed points here, Petitioners limit themselves to the rebuttals and clarifications made necessary by the government's response.

Failure to Consider Alternatives. The government does not dispute DEA's failure to consider alternatives to the policy adopted in the Final Rule. Instead, in a footnote, it claims that petitioners failed to identify any viable alternatives, making DEA's failure to consider alternatives was harmless error. Govt. Br. 36 n.10. That argument misconceives DEA's duty as an agency announcing a change in longstanding policy. *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1913 (2020) (requiring agency to consider alternatives "within the ambit of the existing policy" before rescinding that policy and without prompting in the form of public comment).

That said, petitioners did suggest relevant alternatives—several in fact. SRI Comments at 15-16. SRI also emphasized that OLC had flagged certain options for DEA to consider when changing its regulations and explained that "[n]ormally, an agency rule would be arbitrary and capricious if the agency has … entirely failed to consider an important aspect of the problem …." SRI Comments at 16 (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983)). Petitioners made the same point in their opening brief. Opening Br. 63.

To be sure, petitioners would have preferred to offer even more suggested alternatives and to have included even deeper analysis. As

petitioners made clear in their opening brief, however, the government's failure to disclose authoritative statement of law underlying the proposed rule forced petitioners to squander the majority of the comment period locked in the emergency litigation to force the government to disclose the secret OLC Opinion at the heart of this case. Br. 50-51 & n.10.

Treating Similar Cases Dissimilarly. The government does not deny that *all* marijuana grown under the NIDA contract since the enactment of the CSA in 1970 was grown in violation of federal law and the Single Convention. Opening Br. 67 (citing OLC Op. 24). Nor does it deny that DEA lets researchers use that illegally grown marijuana for research anyway. Opening Br. 67. In light of these facts, petitioners argued that DEA's refusal to let researchers study the state-dispensary marijuana people across the country are using every day because it was grown in violation of federal law was arbitrary and capricious. Opening Br. 67.

In response, the government claims there is "no contradiction" because unlike the state operators petitioners reference, the University of Mississippi is a DEA-registered manufacturer. Govt. Br. 36. But petitioners are not saying that the University of Mississippi and the state operators in question are all registered to manufacture marijuana. Rather, they're drawing attention to the fact that, registered or not, both have indisputably been

growing marijuana in violation of state and federal law. Petitioners insisted that if DEA wants to treat some violations of law differently than others, it must provide a reasoned explanation for doing so—especially where, as here, an urgent issue of public health and safety is involved. Opening Br. 67; *see also Regents*, 140 S. Ct. at 1913. DEA didn't offer such an explanation in the Final Rule, and the government does not offer one here.

The government's focus on registration fails for another reason. DEA has a long, documented history of permitting the University of Mississippi to grow (and registered researchers to study) illegally grown marijuana seized by law enforcement. Claudia Dreifus, *Growing Marijuana with Government Money*, N.Y. Times (Dec. 22, 2008), *available at* https://www.nytimes.com/2008/12/23/health/23conv.html. Thus, whatever DEA's reasons for refusing to permit registrants to access state-dispensary marijuana may be, principled opposition to violations of the CSA's registration requirements isn't one of them.

The principle that courts and agencies must "[t]reat like cases alike" is "the central precept of justice." H.L.A. Hart, *The Concept of Law* 164 (3d ed. 2012) (quotation marks omitted); *see also* Aristotle, *Ethica Nicomachea* V.3.1131a–1131b (W.D. Ross trans. 1925) ("[T]hings that are alike should be

treated alike."). Regulated parties in similar situations should be able to expect similar outcomes. That is not happening here.

Retroactivity.[2] The government claims this Court's decision in *Pine Tree Medical Associates v. Secretary of Health & Human Services*, 127 F.3d 118 (1st Cir. 1997), forecloses petitioners' claim that the Final Rule is impermissibly retroactive. Govt. Br. 31-32. That argument overlooks key distinctions between this case and *Pine Tree*, including the following:

> 1. Unlike in *Pine Tree*, petitioners face a competitive application process before DEA. As petitioners explained in their opening brief, changes to the standards applicable to those applications will predictably impact the applicant pool petitioners must compete against for registration. *See* SRI Comments 18.
>
> 2. DEA increased the fees associated with growing marijuana under federal registration. SRI Comments 18 (discussing fees); Proposed Rule, 85 Fed. Reg. at 16297 (discussing fees). This, too, affects competition and the applicants' business arrangements. Opening Br. 18.
>
> 3. DEA's need to apply the Final Rule retroactively caused it to delay adjudication of petitioners' long-pending applications for years, which amounts to attaching a new disability with respect to a transaction already passed. Opening Br. 64 (citing *Ass'n of Accredited Cosmetology Schs. v. Alexander*, 979 F.2d 859, 864 (D.C. Cir. 1992))

For these reasons, which the government leaves unrebutted, the Final Rule is impermissibly retroactive and must be set aside.

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[2] Petitioner SRI does not join this argument.

CONCLUSION

Petitioners request that the Court grant the Petitions for Review, hold the Final Rule unlawful, and set it aside.

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Matthew C. Zorn
YETTER COLEMAN LLP
811 Main Street, Suite 4100
Houston, Texas 77002
Phone: 713.632.8000
Fax: 713.632.8002
mzorn@yettercoleman.com

Counsel for Petitioner Scottsdale Research Institute

/s/ Shane Pennington
Shane Pennington
Vicente Sederberg LLP
1115 Broadway, 12th Floor
New York, NY 10010
Phone: 917.338.5455
Fax: 303.860.4504
s.pennington@vicentesederberg.com

Michael Perez (No. 1197372)
Perez Law
42 Arlington St.
Medford, MA 02155
617-699-1567
mike@perez-law.com

Alexandra H. Deal (No. 119274)
Paik, Brewington & Deal, LLP
6 Beacon Street, Suite 305
Boston, MA 02108
(617) 439-0150
adeal@pbdlaw.com

Counsel for Petitioner Dr. Lyle E. Craker

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1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 5,358 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-tyle requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Georgia font.

/s/ Shane Pennington

Shane Pennington
Vicente Sederberg LLP
1115 Broadway, 12th Floor
New York, NY 10010
Phone: 917.338.5455
Fax: 303.860.4504
s.pennington@vicentesederberg.com

Counsel for Petitioner Dr. Lyle E. Craker

CERTIFICATE OF SERVICE

I hereby certify that on November 3, 2021, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the First Circuit by using the appellate CM/ECF system.

/s/ Shane Pennington
Shane Pennington
Vicente Sederberg LLP
1115 Broadway, 12th Floor
New York, NY 10010
Phone: 917.338.5455
Fax: 303.860.4504
s.pennington@vicentesederberg.com

Counsel for Petitioner Dr. Lyle E. Craker