No. 21-70544

In the United States Court of Appeals for the Ninth Circuit

ADVANCED INTEGRATIVE MEDICAL SCIENCE INSTITUTE, PLLC, *et al.*,

Petitioners,

v.

U.S. DRUG ENFORCEMENT ADMINISTRATION, *et al.*,

Respondents.

PETITIONERS' REPLY BRIEF

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This dispute arises out of DEA's determination that "[a]bsent an explicit statutory exemption to the Controlled Substances Act (CSA), [it] has *no authority* to waive any of the CSA's requirements pursuant to [Right to Try ("RTT") laws]." In turn, that determination raises an important legal question: does the CSA permit DEA to allow discrete therapeutic uses of Schedule I drugs?

Just this month, writing for the court in *Judge Rotenberg Educ. Ctr., Inc. v. U. S. Food & Drug Admin.*, No. 20-1087, 2021 WL 2799891, (D.C. Cir. July 6, 2021), Judge Sentelle provided the answer in a related context. First, the court explained that 21 U.S.C. § 396 of the Food, Drug, & Cosmetic Act ("FDCA") constrains the FDA's authority by prohibiting it from regulating the practice of medicine. That statute "expressly denies the FDA authority to construe any part of the [FDCA] … to permit the FDA to 'limit[ ] or interfere[ ]' with practitioners' authority to prescribe or administer 'legally marketed device[s]' to patients." *Id.* at *4. Then, the court noted how essential aspects of federalism, as articulated by the Supreme Court, supported this conclusion—principles that apply "with equal force to the so-called modern administrative state." *Id.* at *6 ("States, not the federal government, traditionally have regulated the practice of medicine. Choosing what

treatments are or are not appropriate for a particular condition is at the heart of the practice of medicine.") *Id.* (citations omitted).

These same principles resolve this case. What the *Judge Rotenberg* Court explained as to FDA, the use of shock therapy, and § 396, applies with even greater force as to DEA, the facts here, and § 902. DEA is a law enforcement agency, with even *less* authority than FDA to regulate medical practice. In response to Petitioners' inquiry, DEA determined it has no authority to permit an FDCA sanctioned use of a Schedule I drug under RTT. But as FDA's actions clashed with § 396 of the FDCA in *Judge Rotenberg*, DEA's construction of the CSA runs afoul of § 902 and principles of federalism. Therefore, under the Administrative Procedure Act ("APA"), it must be set aside.

DEA wants this Court to avoid reaching this judgment in two ways.

First, DEA argues this Court lacks jurisdiction because the conclusion the agency rendered in its letter is not "final agency action" under *Bennett v. Spear*, 520 U.S. 154 (1997). This argument might have superficial appeal, as the agency determination in this case was sent via letter. But on examination, DEA elevates form over substance. Precedent establishes that letters often give rise to reviewable agency action. In this case, DEA's letter contains all the hallmarks of finality: an official, delegated authority by the agency to

interpret the CSA in a definitive manner, did so to the detriment of Petitioners, leaving Petitioners no further avenue to pursue that squares with RTT. Applying the pragmatic approach to finality as the Supreme Court instructs and § 877, this Court has jurisdiction.

Second, on the merits, DEA asks this Court to embrace its construction of the CSA that all access to Schedule I drugs is denied except for research. The Response cites little text or pertinent case law to support this interpretation, which is contrary to § 902, precedent, and principles of federalism. Instead, DEA resorts to hyperbole and slippery slopes, as well as undermining positions Petitioners never argued.

I. DEA's Determination and Conclusion About Its Authority Is Final and Reviewable.

The APA "embodies the basic presumption of judicial review." *Abbott Lab'y v. Gardner*, 387 U.S. 136, 140 (1967). Under 5 U.S.C. § 704, "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review." Here, 21 U.S.C.' § 877 makes DEA's conclusion reviewable.

In response to Petitioners' inquiry, and with delegated authority to speak on the agency's behalf, DEA's Deputy Assistant Administrator of Diversion Control concluded that "[a]bsent an explicit statutory exemption to the Controlled Substances Act (CSA), DEA has *no authority* to waive any

of the CSA's requirements pursuant to RTT." SER 3 ("Letter") (emphasis added). That conclusion was definitive. It gave no indication that it was tentative or subject to reconsideration. Under the APA and § 877, Petitioners are entitled to judicial review.

Bennett's two-part test reinforces this conclusion. 520 U.S. at 177-78. Equating "final decision" in § 877 with "final agency action" in § 704, DEA says its determination was not "final agency action" because it neither (1) was rendered in any decisionmaking context, nor did it (2) determine any rights or obligations or give rise to any legal consequences. But faithful application of the pragmatic approach to that standard that the Supreme Court has repeatedly endorsed compels the opposite conclusion. *E.g.*, *U.S. Army Corps of Eng' v. Hawkes Co.* 136 S. Ct. 1807, 1813 (2016) (noting the Court has taken a "pragmatic" approach to the issue of finality since the 1950s).

A. The Letter's Conclusion Was Neither Tentative nor Interlocutory.

DEA does not argue that the Letter's legal conclusion was tentative. Nor does it claim that judicial review of that conclusion would interfere with some other decisionmaking process already underway to address this question. To the contrary, the Response appears to confirm what the Letter makes plain: DEA has concluded it lacks authority to accommodate therapeutic use of Schedule I substances under state and federal RTT

because the federal RTT statute does not contain an explicit exemption to the CSA.

Yet DEA insists the Letter does not reflect the consummation of any decisionmaking process because Petitioners did not formally engage any established "routes" of "avenue[s]" of DEA decisionmaking. Resp. 20. DEA cites no authority for the proposition that finality hinges on the form of the request that prompted agency action. That is because the analysis rightly focuses on the *agency's* decision—not the technical phrasing of the prompt. Thus, even when an agency announces a legal conclusion on its own initiative (such as a rule), courts do not hesitate to hold that it is final agency action subject to judicial review. *Frozen Food Express v. United States*, 351 U.S. 40 (1956).

DEA's related argument that before Petitioners can obtain judicial review, they must petition for rulemaking or apply for registration and seek review of a denial, Resp. 20-21, fails for similar reasons. Aside from permitting DEA to delay or evade judicial review, what purpose is served by requiring terminally-ill patients to file numerous petitions and applications seeking relief that DEA has already determined it has *no authority* to entertain in the first place? The facts do not matter for resolving this pure legal dispute, but even assuming they did, considering Petitioners'

circumstances, forcing them through such a futile exercise would be Kafkaesque. As this Court explained in *San Francisco Herring Ass'n v. U.S. Department of the Interior*, 946 F.3d 565, 579 (9th Cir. 2019):

> [A] central rationale of the final agency action requirement is to prevent premature intrusion into the agency's deliberations; it is not to require regulated parties to keep knocking at the agency's door when the agency has already made its position clear.

Whitman v. American Trucking Ass'ns, 531 U.S. 457 (2001), is also instructive. There, the court recognized that "the agency ha[d] not dressed its decision with the conventional procedural accoutrements of finality." *Id.* at 479. Nevertheless, relying on the agency's "refus[al] in subsequent rulemakings to reconsider" the challenged interpretation, the court found that the agency's "own behavior … belies the claim that its interpretation is not final." *Id.* Likewise here, DEA's behavior—in the Letter and its brief before this Court—reveals no hint that its conclusion is tentative or interlocutory. Given the presumption favoring judicial review of agency action and the Supreme Court's repeated calls for a pragmatic approach to finality, DEA's attempt to elevate formalistic details about *Petitioners'* actions over the practical realities of its own denial must fail.

Moreover, DEA routinely renders final decisions under § 877 in letters. *John Doe, Inc. v. DEA*, 484 F.3d 561 (D.C. Cir. 2007) is one example. There, DEA provided notice of its denial of an importation permit via a letter that

was signed by the same official that signed the Letter in this case: the Deputy Assistant Administrator, DEA Office of Diversion Control. *Id.* at 564 n.3. Relying on *Ciba-Geigy Corp. v. USEPA*, 801 F.2d 430, 435 (D.C. Cir. 1986) the court concluded that the letter constituted a "final decision" under § 877 because it "staked out the agency's position clearly and gave no indication the agency's position was subject to further agency consideration or possible modification." *Id.* at 566 (quot. omitted). *See also, e.g., Palomo Farms, LLC/Hemport v. DEA*, No. 4:17-CV-169-BO, 2018 WL 2768676, at *2 (E.D.N.C. June 7, 2018).

Other considerations confirm that the Letter is DEA's final word.

First, consider who rendered the decision. *See Soundboard Ass'n v. FTC*, 888 F.3d 1261, 1272 (D.C. Cir. 2018) ("[P]recedent emphasizes the importance of who made a decision, and how an agency's regulations delineate responsibility for and the bindingness of such a decision."). The official that signed the Letter—the Deputy Assistant Administrator of DEA's Diversion Control Division—was chosen by the DEA Administrator to exercise the Administrator's delegated authority over all necessary functions with respect to the promulgation and implementation of most DEA regulations, including Part 1307. 28 C.F.R. § Pt. 0, Subpt. R, App., § 7. In other words, the Letter decision was not "the ruling of a subordinate official."

Abbott, 387 U.S. at 151. Also, DEA's Deputy Assistant Administrator expresses the views of the *DEA*, not his opinion or the views of staff members. SER-3 ("*DEA* appreciates the opportunity to address your request …"); ("*DEA* understands and appreciates the intent …"); *id.* ("*DEA* has no authority to waive …") (emphases added). That distinguishes this case from a case like *Soundboard*, where the Letter explained that it "reflect[ed] the views of staff members charged with enforcement" and had not been "approved or adopted" by the FTC. *Soundboard* 888 F.3d at 1265.

Second, whether DEA has authority to issue exceptions, exemptions or waivers to permit RTT use of an eligible investigational drug which happens to be a Schedule I substance, presents a pure legal issue that would not benefit from a more concrete setting or further factual development. Under the pragmatic approach, this is important. *See Ciba-Geigy*, 801 F.2d at 435 (pure legal issue favors ripeness). *See also Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 646 (6th Cir. 2004) (contrasting substantive issues addressed in agency letters with the threshold question of agency's authority to issue letters).

Finally, as was also the case in *Ciba-Geigy*, Petitioners would suffer serious hardship if review were postponed. 801 F.2d at 438. Now that DEA has closed off any possibility of an administrative exemption like those the

agency has issued in similar circumstances throughout its history, Petitioners' only remaining options are (1) to submit a petition for rulemaking or application for registration that DEA has already declared it lacks authority to entertain in the first place, or (2) to risk civil and criminal penalties for unlawful distribution and possession of controlled substances. The first option is a non-starter for reasons already discussed. And as for the second, courts have held that the fact that agency action that puts regulated parties between the rock and the hard place of complying with the agency's view of the law or risking serious civil or criminal liability, favors finality. *E.g.*, *Abbott*, 387 U.S. at 153 (risking "serious criminal and civil penalties for the unlawful distribution of 'misbranded' drugs" favored finality); *Ciba-Geigy*, 801 F.2d at 430 (similar).

In sum, the Letter contains DEA's final word on an important legal question. Nothing more is needed to satisfy *Bennett*'s first prong.

B. DEA's Letter Determined Rights, and Legal Consequences Flowed.

Hawkes, 136 S. Ct. 1807—a unanimous opinion the government never mentions in its brief—explains how courts should determine whether agency action meets *Bennett*'s second prong.

At issue in *Hawkes* was whether an "approved jurisdictional determination" from the U.S. Army Corps of Engineers qualified as final

agency action. *Id.* at 1811. An approved jurisdictional determination (JD) marks the Corps' determination that a property contains "waters of the United States" for purposes of the Clean Water Act, which imposes substantial criminal and civil penalties for discharging any pollutant into waters covered by the Act without a costly permit from the Corps. *See* 33 U.S.C. §§ 1311(a), 1319(c), (d), 1344(a). Approved JDs are binding on the government for five years. *Hawkes*, 136 S. Ct. at 1812.

To determine whether an approved JD is final agency action, the Court imagined how things would have been different had the Corps reached the opposite conclusion, issuing a negative JD. *Id.* at 1814. Had that happened, it explained, the Corps' determination that the property at issue did not contain waters of the United States would have been binding on the government for five years—creating what the Court called a "safe harbor" against government enforcement during that period. Such a consequence is enough to satisfy *Bennett*'s second prong. And because affirmative JDs effectively represent the denial of such a safe harbor, the Court reasoned, they, too, constitute final agency action. *Id.*

In so holding, the Court emphasized that it was adhering to the pragmatic approach it had long taken to finality. *Id.* at 1815 (citing *Abbott'*, 387 U.S. at 149; *Frozen Food Express*, 351 U.S. at 44-45). In *Frozen Food*

Express, for example, the Court held that an order specifying which commodities the Interstate Commerce Commission believed were exempt by statute from regulation, and which it believed were not, was final agency action. That was so, even though the Commission did not order anyone to do or refrain from doing anything. *Id.* (citing *Frozen Food Express*, 351 U.S. at 44).

Like the Commission's order in *Frozen Food Express*, the Corps' JD in *Hawkes* warned regulated parties that if they took certain actions, "they d[id] so at the risk of significant criminal and civil penalties." *Id.* at 1815. That satisfied *Bennett*'s second prong even though the JD merely "g[a]ve notice of how the [agency] interpreted the relevant statute." *Id.*

1. Under the pragmatic approach, DEA's Letter has direct and appreciable legal consequences.

Under the pragmatic approach outlined in *Hawkes*, DEA's Letter qualifies as final agency action. By concluding that it is without authority to grant an exemption or similar accommodation for RTT use, DEA foreclosed Petitioners' only avenue to legally access psilocybin under RTT laws. DEA correctly states that RTT does not abrogate CSA requirements; therefore, absent authorization from DEA, manufacture, possession, use, and/or dispensing of psilocybin is off limits under the CSA. Resp. 25.

Yet despite its undisputed history of recognizing and exercising its delegated authority to make exceptions to CSA restrictions, Br. 17-26, DEA inexplicably concludes that a similar exception to accommodate use of Schedule I substances under state and federal RTT is out of the question as a matter of statutory interpretation. This determination also "significantly and immediately alters the legal landscape for [ ] physicians." *Oregon v. Ashcroft*, 368 F.3d 1118, 1146-48 (9th Cir. 2004) (Wallace, J. dissenting): it affects legal rights by denying Petitioners and those similarly situated of a potential CSA waiver for RTT use; it discharges DEA's obligation to entertain any such request in the future; it determines who can apply for an RTT exemption (no one); and it determines the terms on which such applications will be considered (none). *See City of Fremont v. F.E.R.C.*, 336 F.3d 910, 914 (9th Cir. 2003) (agency order that determined who can apply for license and the "terms on which those applications will be considered" was final because it attached legal consequences to future proceedings).

While that should be the end of the matter, DEA's Letter has other "direct and appreciable legal consequences" as well.

First, like the JD in *Hawkes* and the Commission order in *Frozen Food Express*, DEA's interpretation puts Petitioners on notice that if they proceed to pursue treatments involving eligible investigational drugs, which

are Schedule I substances, under state and federal RTT, they do so at the risk of severe civil and criminal liability.

DEA attempts to evade this conclusion by invoking the "left the world just as it found it" principle. Resp. 21 (citing *Indep. Equip. Dealers Ass'n v. EPA*, 372 F.3d 420, 428 (D.C. Cir. 2004) (Roberts, J.)). But the letter in *Indep. Equip. Dealers Ass'n* merely restated a longstanding interpretation, and thus "tread no new ground." Here, in stark contrast, DEA cannot show its interpretation was "established" as a policy before now. Petitioners presented DEA question of first impression as to how it was going to accommodate the RTT, recently enacted in 2018.[1]

Second, any reasonable reader—whether a member of the regulated public or a member of DEA's staff—would conclude that the Letter means what it says: without an explicit statutory exemption from the requirements of the CSA, DEA lacks authority to accommodate use of Schedule I drugs for therapeutic purposes under state and federal RTT. *Gen. Elec. v. EPA*, 290 F.3d 377, 384 (D.C. Cir. 2002) ("To the applicant reading the Guidance Document the message is clear: in reviewing applications the Agency will not

[1] DEA's argument that "[a]ny restrictions on the petitioners' ability to access and use psilocybin flowed directly from the CSA and its implementing regulations," Resp. 22, fails for similar reasons.

be open to considering approaches other than those prescribed in the Document."). At the very least, this means that the permissibility of an exemption, exception, or waiver to the CSA's requirements for RTT purposes is a "closed question"—"at least for now." *POET Biorefining, LLC v. EPA*, 970 F.3d 392, 405 (D.C. Cir. 2020). This, too, is a legal consequence sufficient to satisfy *Bennett*'s second prong. *Id.*

2. *Hawkes* and *Frozen Food Express* refute DEA's arguments.

DEA insists that the Letter does not have the direct and appreciable legal consequences necessary to satisfy *Bennett*'s second prong for two reasons:

1. "[I]t did not order the petitioners to do anything or refrain from doing anything," and "it did not grant or deny a permit or a license," Resp. 21, and
2. It "simply … inform[ed] [the petitioners] of what the law, previously enacted or adopted, is," Br. 22 (quoting *Golden & Zimmerman, LLC v. Domenech*, 599 F.3d 426, 432-33 (4th Cir. 2010)).

Both arguments are squarely refuted by *Hawkes* and *Frozen Food Express*. As the Court explained in *Hawkes*, neither the Commission's order in *Frozen Food Express* nor the JD in *Hawkes* ordered anyone to do or refrain from doing anything. *Hawkes*, 136 S. Ct. at 1815. Nor did either agency action grant or deny a permit or license. Yet that did not stop the Court from concluding that those decisions constituted "final agency action."

Nor must an agency action announcing the agency's legal interpretation have legal consequences independent of the statute it interprets to be final. In its discussion of *Frozen Food Express*, the *Hawkes* Court explained that "[a]lthough the [Commission's] order 'had no authority except to give notice of how the Commission interpreted' the relevant statute, and 'would have effect only if and when a particular action was brought against a particular carrier,' we held that the order was nonetheless immediately reviewable." *Hawkes*, 136 S. Ct. at 1815. That was because the Commission's order "warn[ed] every carrier, who does not have authority from the Commission to transport those commodities, that it does so at the risk of incurring criminal penalties." *Id.* (quot. omitted). For the same reason, the Court did not hesitate to declare the JD final agency action even though it, too, lacked any independent legal consequence. *Id.*

The government's chief authority, *Bennett*, relied on *Port of Bos. Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic*, 400 U.S. 62, 70-71 (1970) for the "rights or obligations have been determined," or from which "legal consequences will flow" language. *Bennett*, 520 U.S. at 178. In stating this language, *Port of Boston* rejected the argument that a Commission order about dockside storage fees "lacked finality because it had no independent effect on anyone." 400 U.S. at 70-71. That argument had the

"hollow ring of another era." *Id.* Instead, it acknowledged agency actions "that have no independent coercive effect are common" and emphasized that it had found such actions final and reviewable. *Id.*

Put simply, if an agency's decision that it has authority to regulate conduct based on legal interpretation is a decision from which legal consequences flow, then an agency's decision that it lacks such authority based on legal interpretation should receive the same treatment. *Cf. Hawkes*, 136 S. Ct. at 1814.

C. Unique Features of § 877 Favor Finality.

DEA focuses on whether the Letter is "final agency action" under § 704 of the APA. Resp. 19-23. But because this case arises under § 877 of the CSA, the question is actually whether the Letter is "agency action made reviewable by [that] statute." 5 U.S.C. § 704.

DEA sees "no reason" why "the word 'final' in § 877 should be interpreted differently than the word 'final' in the APA." Resp. 20 at n.5 (quoting *John Doe*, 484 F.3d at 566, n.4). Petitioners agree as to *Bennett*'s first factor relating to precluding review of tentative or interlocutory decisions. *See Whitewater Draw Nat. Res. Conservation Dist. v. Mayorkas*, No. 20-55777, 2021 WL 3027687, at *7 (9th Cir. July 19, 2021) (noting that *Bennett*'s first prong is directed to whether the challenged act is "*final* agency

action" while *Bennett*'s second prong is directed to whether the challenged act is "final agency *action*"). But a "final agency *action*" is not necessarily the same as a "final *decision*" in every respect under the pragmatic approach to finality the Supreme Court requires. *See Hawkes*, 136 S. Ct. at 1813 (noting that "generally" two conditions "must be satisfied for agency action to be 'final' under the APA").

In this case, this distinction is important. In § 877, Congress identified three specific types of terminal acts or events that constitute "final decisions" subject to judicial review: final (1) determinations, (2) findings, and (3) conclusions. Congress could have used the default APA "agency action" language or otherwise qualified review in the manner DEA proposes. Instead, however, it used precise words whose plain meaning sweeps broadly, agnostic as to the type of proceedings in which a final conclusion or determination might arise. This intentional variation and breadth must be given meaning. *See Woods v. DEA*, 283 F. Supp. 3d 649, 657 (W.D. Tenn. 2017).

Even adopting DEA's characterization of the Letter, review is proper under § 877. DEA says its Letter informed Petitioners of its view of the law. Resp. 31. That is a legal "conclusion" about the CSA's scope. Black's Law Dictionary (11th ed. 2019) (defining conclusion to mean "judgment arrived

at by reasoning; an inferential statement"). And in *Ashcroft*, 368 F.3d at 1120, this Court held that an interpretive rule delineating the scope of a CSA regulation was a "final determination" subject to § 877. 368 F.3d 1118, 1146-48 (Wallace, J. dissenting) (addressing jurisdiction under § 877 in greater detail). Thus, even if the Letter is not' a typical "final agency *action*," judicial review is available under the plain text of § 877, which covers a broader array of DEA determinations and conclusions, provided they are neither tentative nor interlocutory.

Sound policy reasons and the pragmatic approach to finality support this interpretation. CSA violations carry stiff criminal penalties, the repercussions of which can last a lifetime and ruin careers. Thus, providing for judicial review of DEA's definitive determinations, findings, and conclusions about the CSA's metes-and-bounds squares with the general notion underlying the pragmatic inquiry the Court described in *Abbott* three years before the CSA's enactment. *Abbott*, 387 U.S. at 153. These interpretations almost necessarily effect the day-to-day business of regulated entities.

This statutory context distinguishes this case from garden-variety agency letter cases. Nonetheless, DEA invokes the slippery slope: agencies send advice letters "countless times per year in dealing with the regulated

community." Resp. 23. If every recipient could sue on receiving such letters, the argument goes, the administrative process would breakdown. *Id.*

This slippery slope notion lacks merit for at least two reasons. First, because a special review provision (§ 877) controls here, judicial review in this case does not necessarily command similar treatment in cases arising under other statutes. Second, DEA's policy argument gets things backwards: if agencies could dodge judicial review of their authoritative legal interpretations, determining important public health issues by slipping them into letters "advising" regulated parties, the presumption favoring judicial review of agency action "would not be much of a presumption at all." *Sackett v. EPA*, 566 U.S. 120, 129 (2012).

II. RTT Requires DEA to Regulate and Accommodate, Not Abdicate.

Petitioners' brief made two points in response to DEA's assertion that it lacked authority to permit RTT use of Schedule I substances. First, based on statutory text, judicial precedent, and past practice, DEA has such authority. Second, in light of § 902, DEA must accommodate RTT eligible uses of Schedule I drugs. In so doing, it may, of course, impose controls consistent with its mission to prevent abuse and diversion.

DEA's Response largely avoids Petitioners' arguments, instead refuting other arguments or falling back on hyperbole. For example, Petitioners never

argued that RTT supersedes the CSA, nor do Petitioners seek to reschedule psilocybin. We take up these responses in turn.

A. The CSA Must Be Construed to Permit DEA to Authorize RTT Use.

Much of DEA's Response hinges on the notion that Petitioners argue that RTT itself provides an exemption from the CSA. Resp. 24 ("In arguing to the contrary …"). Not quite.

1. In interpreting and applying the CSA, § 902 provides a rule of construction that DEA must follow.

RTT does not itself provide a broad exemption from the CSA. Indeed, that is the point of this lawsuit. Because the RTT law does not provide an express statutory exemption for the CSA, Petitioners sought the agency's position on how they could obtain DEA's permission in the form of a waiver, exception, or exemption to access a Schedule I drug for RTT therapeutic use, just as access to Schedule I substances is permitted in other contexts, for example religious use. Br. 18-19. DEA responded by concluding it has no authority to allow RTT access through any similar avenue.

The issue is thus not whether RTT supersedes CSA, but whether DEA has authority (indeed duty) to permit therapeutic use of Schedule I drugs in accordance with the RTT. This is where § 902 factors in. DEA's Letter disclaiming authority to accommodate use of Schedule I drugs for RTT-

compliant purposes rests on an impermissible construction of the CSA, namely that a drug's placement in Schedule I forbids a lawful use sanctioned under state law and the FDCA's RTT amendment. Boiled down, DEA has construed the CSA to "supersed[e] the provisions of the [FDCA]," which is precisely the opposite of what § 902 commands. Resp. 40.

DEA never directly confronts this argument. First, it notes that § 902 "does not suggest—and has never been understood to suggest—that the restrictions on Schedule I drugs improperly supersede provisions of the FDCA or that the provisions of the FDCA take precedence over the restrictions of Schedule I." Resp. 25. But of course, that is so because, to Petitioners' knowledge, no court has ever had occasion to apply § 902. As Petitioners explained, until the Letter, DEA consistently interpreted the CSA by paying homage to the FDCA in all respects. *See e.g.*, Br. 63-66. Not surprisingly, since 1970, the most a court has said about § 902 is an afterthought in a footnote. *See Am. Pharm. Ass'n v. Mathews*, 530 F.2d 1054, 1055 (D.C. Cir. 1976). DEA's determination in the Letter marks an unexplained departure from an otherwise consistent policy and practice, and one that is contrary to the rule of construction laid down in § 902. Br. 63-66.

DEA also claims that Petitioners are using § 902 to argue that restrictions on Schedule I drugs "improperly supersede provisions of the

FDCA," Resp. 25; that the provisions of the "FDCA take precedence over the restrictions of Schedule I"; and that RTT "rescind[s] portions of the CSA." Resp. 29. None of this is correct. Fairly read, Petitioners argue that § 902 provides a mandatory rule of construction that governs how DEA must interpret the CSA. *E.g.*, Br. 40 ("Section 902's unambiguous aim is to prohibit any construction of the CSA that would interfere with the FDCA"). Absent some express prohibition, DEA cannot construe the CSA—and its restrictions on Schedule I drugs specifically—as forbidding RTT use under the FDCA, as it does in its Letter. Indeed, because DEA does not and cannot regulate medical practice, it must accommodate RTT uses. Yet it can, in its discretion, impose controls to prevent diversion—just as it has done with Schedule I research and in other contexts. *See e.g.*, Br. 18-19 (religious use).

Rather than apply § 902 as it is written, DEA asks this Court to embrace the notion that the FDCA and CSA occupy "complementary spheres" and that the provisions of the FDCA "do not take precedence over the restrictions of Schedule I." Resp. 25. That argument fails to appreciate that RTT is a unique single-subject statute that carves out a "niche" within the FDCA to sweep aside federal obstacles to accessing certain investigational drugs. Section 902 also indicates that in the event of an interpretive conflict, the CSA must yield.

"Congress has spoken" in § 902. Just as in *Judge Rotenberg*, 2021 WL 2799891, at *7, this Court "must "assume that [Congress] says what it means and that the statute means what it says." *Id.* And "[i]n this case, the statute says that the [DEA] is not to construe its statute so as to interfere with the [FDCA]," including RTT. *See id.*

2. The nub: does the CSA permit DEA to allow discrete therapeutic uses of Schedule I drugs?

Boiled down, this case presents a question of statutory construction: what does it mean for a controlled drug to be placed in Schedule I of the CSA?

Citing the text, regulations, and precedent, Petitioners say a drug's placement in Schedule I does not categorically foreclose DEA from permitting its discrete, non-prescription use under RTT. The CSA clearly forecloses prescription use of Schedule I drugs. *See* 21 U.S.C. § 829. But use under RTT is not prescription use. Permitting RTT use of a Schedule I drug is thus consistent with the CSA's text, which never expressly or impliedly prohibits such permission. *See* Br. 54. Moreover, DEA's authority to permit exceptional uses, despite Schedule I classification, is the clear import of the discussion in *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 432-35 (2006) ("[T]he Government's mere invocation of the general characteristics of Schedule I substances, as set forth in the Controlled Substances Act, cannot carry the day."). And because RTT amends and

resides in the FDCA, some form of accommodation is the outcome § 902 mandates.

DEA has a different read. When it says it has no authority to permit therapeutic uses of Schedule I drugs for RTT use, what it really means is that the Schedule I classification itself precludes it from using its delegated authority to permit RTT therapeutic use. Hence, when it speaks of RTT use "superseding" Schedule I restrictions, it assumes that somewhere in the CSA lie "restrictions of Schedule I" substances or "Schedule I prohibitions" that prohibit the discrete therapeutic use Petitioners advocate.

But where are these Schedule I prohibitions? DEA never shows us because they do not exist. In fact, the CSA's structure departs radically from DEA's portrayal. Sections 841(a) and 844 prohibit the use of *all* controlled drugs, regardless of schedule, "[e]xcept as authorized by this subchapter." Then, throughout the Act, various provisions authorize certain activities or conduct depending on schedule. *E.g.*, § 823 (registrations). *See also, generally*, *United States v. Akinyoyenu*, 199 F. Supp. 3d 106, 111-16 (D.D.C. 2016) (Boasberg, J.) (discussing many other CSA provisions or mechanisms that authorize actions involving controlled substances). Nothing in the CSA says that §§ 823 and 829 are the sole means of authorization. So, while nothing in the CSA *permits* use of Schedule I drugs outside of research,

nothing creates the "Schedule I prohibitions" or "restrictions" on which the government relies either.

DEA emphasizes that Schedule I drugs are deemed to have "no currently accepted medical use in treatment in the United States." Resp. 31. That 'is true, and as a result, Schedule I drugs cannot be prescribed under § 829. But whether a drug has a statutory classification that depends on "currently accepted medical use" or is available for prescription says nothing about whether a practitioner may provide Schedule I substances for therapeutic uses *outside* of the prescription context. Indeed, that is the premise of RTT and this lawsuit—to allow practitioners to obtain and provide investigational drugs to dying patients when those drugs have been proven safe but have not yet completed the approval process, hence do not (yet) have currently accepted medical uses.

DEA also states that "all access is denied" to Schedule I substances "except for specifically approved research projects." Resp. 31. But its string cite provides no textual support for this claim. It cites § 823(f), which provides a process to register practitioners wishing to conduct research with Schedule I substances. Certainly, § 823(f) establishes that, in general, practitioners can only register to dispense controlled substances in Schedules II-V. And it also provides a procedure for registering practitioners

to research Schedule I drugs. But where does § 823(f) (or any other CSA provision) say "schedule I drugs can only be used for research and no other purpose"? No such statement exists, and any such statement would be directly contrary to precedent and past practice.

Because nothing in the CSA expressly says what DEA wants it to say, § 902 and other tools of construction, like the federalism canon and avoidance, resolve this case. The provisions at issue here are not "unambiguous," Resp. 32, thus tools of statutory construction matter. Because no conflict inherently or even impliedly exists between RTT and the CSA, these principles control. The proper construction must avoid creating a conflict (1) with the FDCA, and (2) with the States.

DEA cites one case to support its contrary interpretation, *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 489-90 (2001) (cited at Resp. 31), which Petitioners previously distinguished. Br. 54-55. *OCBC* resolves the question of whether, before RTT, medical necessity arising under state law could provide a defense to a federal CSA violation for manufacturing marijuana. Specifically, *OCBC* held that an implied common law medical exception with roots in state law could not be "read into" § 841(a) as a defense. *Id.* But it never comes close to addressing the issues in this case: whether DEA has authority to create other exceptions, waivers, or

exemptions for therapeutic use, and whether it must accommodate a use codified in the FDCA. And because *OCBC* was decided more than 15 years before the federal RTT statute was added to the FDCA, the *OCBC* Court could not address it.

B. DEA's Arguments Regarding RTT's "No-Liability" Protections Fail.

Much of DEA's Response focuses on invoking slippery-slope logic in response to the federal RTT's no-liability protections. Resp. 26-29. These arguments are misguided.

While DEA starts with text, it loses focus of key language. According to DEA, because the exception shields liability "reckless or willful misconduct, gross negligence, or an intentional tort," Resp. 26, RTT only exempts civil liability. Unfortunately, it loses focus of the text preceding that phrase: "nothing in this section shall be construed to modify or otherwise affect the right of any person to bring a *private* action under any State or Federal product liability, tort, consumer protection, or warranty law." 132 Stat. at 1374 (emph. added). If, as DEA argues, the liability shield of paragraph (1) only applies to private litigation, Congress would not have needed to include the qualifying word "private" in paragraph (3). That it did strongly suggests paragraph (1) reaches both public and private causes of action. *See Loughrin v. United States*, 573 U.S. 351, 358 (2014) (repeating "cardinal principle" that

courts "must give effect, if possible, to every clause and word of a statute"). And as the legislative history and thrust of RTT show, the point of the law was to remove use of certain investigational drugs from FDA oversight, which would include civil *and criminal* FDCA infractions. *See* States Br. at 6-7. The text thus either favors the reading advocated by Petitioners and the States, or it is genuinely ambiguous.[2]

DEA's refutation of the States' argument is unpersuasive. Resp. 27, n.7 (arguing that "cause of action" in statute does not include criminal or administrative enforcement). "Cause of action" is not unambiguous. *See Johns-Manville Corp. v. United States*, 855 F.2d 1556, 1560 (Fed. Cir. 1988). Congress and the courts routinely understand the generic phrase "cause of action" to include criminal causes of action. *See, e.g.*, *Bartnicki v. Vopper*, 200 F.3d 109, 115 (3d Cir. 1999) (referring to "civil and criminal causes of action"); *Morse v. Comm'r*, 419 F.3d 829, 834 (8th Cir. 2005) ("'The government may have both a civil and a criminal cause of action as a result of a single factual situation'") (quoting *United States v. Barnette*, 10 F.3d 1553, 1562 (11th Cir. 1994)); 17 U.S.C. § 507(a) (using "cause of action" to refer to a criminal cause of action); States Br. at 15-6. Indeed, Congress

[2] *United States v. Moore*, 423 U.S. 122, 145 (1975), on its own terms, does not apply because here, there is genuine ambiguity.

knows how to limit "cause of action" to a specific type of proceeding by saying so—usually in the statute itself. *See* Resp. 27 n.7 (noting that Congress has used the word "criminal" preceding "causes," "actions," or "causes of action").

DEA forewarns a world where, if it cannot arrest practitioners who administer clinically safe but investigational drugs to dying patients, it will be "powerless to prevent an unscrupulous doctor from obtaining schedule I substances." Resp. 28. This is rank hyperbole. Even if RTT precludes criminal liability, DEA retains broad authority to enforce the CSA in other ways. While RTT provides a liability shield, nothing stops DEA from revoking an "unscrupulous" practitioner's registration and shutting down her practice if DEA believes she has violated the CSA. Hence, why Dr. Aggarwal inquired about authorization. Removing federal criminal liability simply reverts policing this niche to the States, subject to RTT's terms. This vision is entirely consistent with federalism principles and the movement underlying RTT: to revert a sensitive matter that is traditionally locally regulated back to the States.

Rather than support its position, DEA's parade of horribles bolsters the result Petitioners advocate: diversion control, not prohibition. DEA must allow access to investigational drugs under RTT but may control use of

Schedule I drugs to prevent the diversion it supposedly fears. What DEA foretells flows from its prohibitory stance based on its impermissible medical judgment, contrary to that of the States and Congress, that Schedule I drugs without accepted medical uses categorically have nothing to offer in an RTT paradigm. If DEA acted as a regulator focused on abuse and diversion, as Congress intended, the "unscrupulous doctor" would not be a serious issue.

C. DEA's Remaining Remarks Do Not Change the Analysis.

DEA's other arguments or statements do not merit deep consideration.

DEA argues that "petitioners do not seek psilocybin to treat the life-threatening disease that triggers 'eligible patient' status under [RTT]." Resp. 28. DEA does not explain this point, but in any case, it is not before the Court. Whether Petitioners are RTT eligible goes to the merits of an exemption or waiver request, not whether an exemption or waiver is possible. For the same reasons, whether the treatment-resistant anxiety or depression with which the terminally-ill Petitioners suffer are "common conditions" is questionable, but a point best saved for another day. It is simply irrelevant to the legal issues in this case. And how DEA's discussion of supply and demand or the narcotics trade intersects with the question of DEA's legal authority to permit discrete therapeutic uses of Schedule I drugs for RTT use is equally unclear, at best.

DEA also portrays this lawsuit as a backdoor rescheduling effort, Resp. 34-35, which again misapprehends Petitioners' argument. If DEA registered Dr. Aggarwal and permitted him to obtain psilocybin under RTT for that discrete purpose, the drug would remain in Schedule I in every respect. Psilocybin would not be available for prescription generally (like Schedule II drugs) under § 829. Put simply, permitting RTT therapeutic use of a Schedule I drug does not change the drug's statutory classification any more than permitting peyote use in religious ceremonies reschedules peyote. *See* 42 U.S.C. § 1996a.

Finally, DEA's contention that "[a]pplication of the CSA to restrict the use of psilocybin by patients with life-threatening conditions furthers the CSA's main objectives 'to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances'," Resp. 29, while revealing, is simply not worthy of discussion.

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), I certify that:

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 6,863 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief com-plies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionately spaced typeface using Microsoft Word Georgia 14-point font.

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CERTIFICATE OF SERVICE

I hereby certify that on July 23, 2021, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

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