FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ADVANCED INTEGRATIVE MEDICAL SCIENCE INSTITUTE, PLLC; SUNIL AGGARWAL, Doctor, MD, PhD, FAAPMR; ERINN BALDESCHWILER; MICHAL BLOOM, *Petitioners*, v. MERRICK B. GARLAND, Attorney General; D. CHRISTOPHER EVANS, in his official capacity as acting Administrator of the U.S. Drug Enforcement Administration; U.S. DRUG ENFORCEMENT ADMINISTRATION, *Respondents.*	No. 21-70544 OPINION

On Petition for Review of an Order of the Drug Enforcement Agency

Argued and Submitted September 2, 2021
Pasadena, California

Filed January 31, 2022

Before: Sandra S. Ikuta, Mark J. Bennett, and Ryan D. Nelson, Circuit Judges.

Opinion by Judge Ikuta

SUMMARY*

Drug Enforcement Agency

The panel dismissed, for lack of jurisdiction, a petition for review of the Drug Enforcement Administration ("DEA")'s letter sent in response to an attorney's letter seeking advice and guidance on how a physician could administer psilocybin to a terminally ill patient without incurring liability under the Controlled Substances Act ("CSA").

Specifically, the attorney's letter asked the DEA how the CSA would accommodate the Right to Try Act (amending the Food, Drug, and Cosmetic Act) to give patients the possibility of gaining access to new investigational drugs under certain circumstances. The DEA responded with a letter identifying the available exemptions in the CSA and indicating that the Right to Try Act did not create any additional exemptions.

The panel held that the DEA's response letter was not a final decision of the Attorney General under 21 U.S.C. § 877, and therefore the panel lacked jurisdiction to review it. Joining the D.C. Circuit, the panel applied the standard in *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997), which held

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

that two conditions must be satisfied for agency action to be final, in interpreting "final decision" in § 877. The first condition is that the agency action must mark the consummation of the agency's decisionmaking process; and the second condition is that the agency action must be one where rights or obligations have been determined, or from which legal consequences flow.

Considering the DEA's response letter, the panel concluded it was an informational letter of the sort that did not constitute final agency action under *Bennett*. First, the letter was the sort of advice letter that agencies prepare multiple times a year in dealing with the regulated community. There was no indication that the letter represented the consummation of a decisionmaking process. Second, the DEA letter did not lead to legal consequences for the prescribing physician. Rather, the letter provided straightforward guidance about the interaction of the Right to Try Act and the CSA. The panel concluded that the DEA letter did not meet either of *Bennett*'s conditions. Accordingly, an advice letter recognizing that Congress has not yet made an exception to the CSA to allow for the legal use of psilocybin for therapeutic purposes is not a final agency decision.

COUNSEL

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OPINION

IKUTA, Circuit Judge:

This appeal seeks to challenge a letter sent by the Drug Enforcement Administration (DEA) in response to an attorney's letter seeking advice and guidance on how a physician could administer psilocybin (a hallucinogenic substance) to a terminally ill patient without incurring liability under the Controlled Substances Act (CSA), 21 U.S.C. §§ 801–904. Specifically, the letter asked the DEA how the CSA would accommodate the Right to Try Act (RTT Act), 21 U.S.C. § 360bbb-0a, a 2018 enactment which amended the Food, Drug, and Cosmetic Act (FDCA) to give patients the possibility of gaining access to new investigational drugs under certain circumstances. The DEA responded in a letter identifying the available exemptions in the CSA and indicating that the RTT Act did not create any additional exemptions. In this context, we conclude that the

DEA's response letter was not "a final decision of the Attorney General," under 21 U.S.C. § 877, and therefore we lack jurisdiction to review it.[1]

I

A

The purpose of the FDCA is to protect consumers from various risks associated with drugs and biological products. 21 U.S.C. § 393(b)(2); *see also FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000). The FDA enforces the provisions of the FDCA through administrative proceedings, enforcement actions, and civil penalties. 21 U.S.C. §§ 331–337a. In general, before a new drug can be introduced into the market, the FDA must approve its new drug application or biologics license application, which must include data from clinical trials. 21 U.S.C. § 355. To get this process started, the sponsor of a clinical trial must submit an investigational new drug (IND) application to the FDA for permission to test the drugs on human subjects. *See* 21 C.F.R. § 312.2. Sponsors must provide specified information and comply with a long list of requirements to obtain approval of an IND application. *See* 21 C.F.R. § 312.23. If the application is approved, then the sponsor must embark on three phases of clinical trials. An individual may be able to access an investigational new drug through a clinical trial. 21 C.F.R. § 312.300. But in many cases an individual may be unable to do so if (for example) there is no ongoing clinical trial with that drug, any such trial is full, or

[1] We **GRANT** the motions filed by Kathy L. Cerminara, Sylvia Law, Thaddeus Pope, and Rob Schwartz for leave to file an oversized amicus curiae brief (Dkt. 27, 30).

the patient does not meet the testing criteria.[2] Alternatively, a patient may attempt to access an investigational new drug through the FDA's expanded access program, but manufacturers are often reluctant to provide experimental drugs that may generate adverse event data.[3]

Because of restrictions on clinical investigations and difficulties associated with the expanded access program, Congress passed the RTT Act in 2018 to give certain patients access to investigational new drugs under certain circumstances, outside of a clinical trial setting. Pub. L. No. 115-176, 132 Stat. 1372 (2018). The RTT Act's primary function is to relieve qualifying individuals from regulatory requirements that would otherwise be imposed on eligible investigational drugs under the FCPA. The Act specifies that it was not intended to "establish a new entitlement" or a "positive right" in any individual. *Id.* § 3(1).

Under the RTT Act, the patient or physician must apply directly to the sponsor of the IND, and the FDA is not involved in approving or disapproving the patient's access. 21 U.S.C. § 360bbb-0a(d). The RTT Act applies to "[e]ligible investigational drugs provided to eligible patients in compliance with this section" and exempts them from specified statutory and regulatory provisions otherwise

[2] *See* Agata Bodie, *Expanded Access and Right to Try: Access to Investigational Drugs*, Congr. Res. Serv., R45414, at 3, available at https://crsreports.congress.gov/product/pdf/R/R45414 (updated Mar. 16, 2021).

[3] *Id.* at 4–6.

applicable to investigational drugs. *Id.* § 360bbb-0a(b).[4] An "eligible investigational drug" is an investigational drug that meets several criteria. *Id.* § 360bbb-0a(a)(2). An "eligible patient" is someone who has been diagnosed with a "life-threatening disease or condition," has "exhausted approved treatment options and is unable to participate in a clinical trial involving the eligible investigational drug" (as certified by a physician), and has provided written informed consent

[4] 21 U.S.C. § 360bbb-0a(b) provides, in full:

> Eligible investigational drugs provided to eligible patients in compliance with this section are exempt from sections 352(f) [directions for use and warning on label], 353(b)(4) [misbranding], 355(a) [necessity of effective approval of application], and 355(i) [exemptions of drugs for research; discretionary and mandatory conditions; direct reports to Secretary] of this title, section 351(a) of the Public Health Service Act [42 U.S.C. 262(a), covering biologics license], and parts 50 [protection of human subjects], 56 [institutional review boards], and 312 of title 21 [investigational new drug application], Code of Federal Regulations (or any successor regulations), provided that the sponsor of such eligible investigational drug or any person who manufactures, distributes, prescribes, dispenses, introduces or delivers for introduction into interstate commerce, or provides to an eligible patient an eligible investigational drug pursuant to this section is in compliance with the applicable requirements set forth in sections 312.6 [labeling of an investigational new drug], 312.7 [promotion of investigational new drug], and 312.8(d)(1) of title 21, Code of Federal Regulations [permitting a sponsor to recover only the direct costs of making its investigational drug available when charging for an investigational drug] (or any successor regulations) that apply to investigational drugs.

regarding the drug. *Id.* § 360bbb-0a(a)(1). Under the RTT Act, the sponsor of the drug is responsible for ensuring that the applicable criteria are met. *See id.* § 360bbb-0a(b).

The purpose of the CSA, 21 U.S.C. §§ 801–904, is to prevent the misuse of substances that threaten public health and welfare. *See* 21 U.S.C. § 801(1). To this end, the CSA makes it a crime to manufacture, distribute, or possess a controlled substance without authorization. 21 U.S.C. §§ 841(a)(1), 844(a). A "controlled substance" is defined as "a drug or other substance, or immediate precursor" included in a schedule established by the CSA. 21 U.S.C. § 802(6) (citing schedules defined by part B of the CSA, 21 U.S.C. § 811–814). The CSA categorizes controlled substances into five schedules based on safety, accepted medical use, and potential for abuse. *Id.* § 812(b). Schedule I drugs have "a high potential for abuse," "no currently accepted medical use in treatment in the United States," and "a lack of accepted safety for use . . . under medical supervision." *Id.* § 812(b)(1). Psilocybin is a hallucinogenic substance obtained from certain mushrooms, and is a Schedule I drug under the CSA. *Id.* § 812, Schedule I(c)(15).

Controlled substances may be used lawfully under limited circumstances. A person registered with the Attorney General may dispense controlled substances "to the extent authorized by their registration and in conformity with the other provisions of" the CSA. *Id.* § 822(b).[5] Because

[5] The Attorney General is authorized to interpret and apply the CSA. *Id.* § 871(b). The Attorney General has delegated his authority to the Administrator of the DEA, except for functions that do not relate to investigations or matters involving drugs or where otherwise reserved. 28 C.F.R. § 0.100.

substances in Schedule I are deemed to have no accepted medical use under the CSA, they can be produced, dispensed or possessed only in the context of research, and this research requires a special registration. *Id.* § 823(f); *see also* 21 C.F.R. §§ 1301.18, 1301.32. If an individual is registered as an approved researcher in controlled substances, the researcher is exempt from prosecution under federal, state, or local laws when acting within the scope of his registration "for offenses relating to possession, distribution or dispensing of those controlled substances within the scope of his exemption." 21 C.F.R. § 1316.24(a). The DEA is responsible for enforcing the registration requirements of the CSA. 28 C.F.R. § 0.100(a).

Any person or organization that produces or distributes prescription drugs that are also controlled substances must comply with the requirements of both the FDCA and the CSA.[6]

B

Dr. Sunil Aggarwal is co-director of the Advanced Integrative Medical Science Institute (AIMS) in Seattle, Washington. In January 2021, Kathryn Tucker, counsel to AIMS and Dr. Aggarwal, wrote a letter to the DEA Regulatory Section, stating that Dr. Aggarwal was registered by the DEA to prescribe controlled substances, and sought "additional registration" pursuant to the RTT Act "to obtain psilocybin, a Schedule I drug, for therapeutic use with

[6] Joanna R. Lampe, *The Controlled Substances Act (CSA): A Legal Overview for the 116th Congress*, Congr. Res. Serv., R45948, at 4, available at https://crsreports.congress.gov/product/pdf/R/R45948 (last updated Feb. 5, 2021).

terminally ill cancer patients suffering anxiety and/or depression." According to Tucker, "[t]his letter provides background information about the RTT, and we seek your guidance on how DEA will accommodate RTT so that Dr. Aggarwal and the AIMS Institute can obtain psilocybin for therapeutic use with terminally ill patients." The letter asserted that psilocybin qualified as an eligible investigational drug under the RTT Act, 21 U.S.C. § 360bbb-0a, and was the subject of an active IND application obtained by a company called Organix. The letter then stated:

> I look forward to your guidance as to how DEA will accommodate RTT so that Dr. Aggarwal and the AIMS Institute can obtain psilocybin for therapeutic use with terminally ill patients. The existing DEA forms do not appear to accommodate the RTT, which may be due to the fact that it was relatively recently enacted; hence it is confusing to use the existing forms for this purpose. Should Dr. Aggarwal seek registration as a "researcher," though his intention is therapeutic use as a palliative care clinician, treating terminally ill patients, not a "researcher" in the traditional sense? If not a researcher registration, how ought we proceed?
>
> In the interest of the terminally ill patients with refractory anxiety and/or depression, we hope DEA can promptly advise on how to proceed.

Before DEA responded, Tucker sent a follow-up email to DEA. This email stated:

> I recognize that DEA has not yet addressed how it will accommodate the Right to Try (RTT) law. As DEA works to determine this, it occurred to me that perhaps another way for it to do so would be to issue an exemption from prosecution from the CSA to Dr. Aggarwal for treating his patients with psilocybin under Right to Try . . . This approach would be something akin to what is provided for in 21 C.F.R. § 1316.24, Exemption from prosecution for researchers, although the use would be therapeutic rather than 'research' in the traditional sense . . .
>
> Please provide DEA's guidance on whether it would be preferable to proceed with a Petition for Exemption. I remind you that the patients are in advanced stage of cancer and time is of the essence to accommodate their rights under RTT.

A week later, Thomas Prevoznik, Deputy Assistant Administrator, Diversion Control Division of the DEA responded in a letter addressed to Tucker.[7] The letter first

[7] The Diversion Control Division's mission "is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs." DEA, Diversion Control Division, available at https://www.dea.gov/operational-division/diversion.

acknowledged that Dr. Aggarwal "seeks additional authorization or additional registration (from DEA)" pursuant to the RTT Act, and "ask[s] DEA for guidance on how DEA will accommodate the RTT."

In response, Prevoznik stated that "the RTT does not waive the requirements of any provision of the Controlled Substances Act (CSA) or its implementing regulations." Prevoznik set out the full text of the RTT exemption section, 21 U.S.C. 360bbb-0a(b), which does not mention the CSA.[8] Prevoznik then stated that "absent an explicit statutory exemption to the Controlled Substances Act (CSA), DEA has no authority to waive any of the CSA's requirements pursuant to the RTT."

Turning to the CSA, Prevoznik provided guidance on the applicable exemptions. First, he stated that "[a] potential avenue for Dr. Aggarwal to pursue is to apply for a schedule I researcher registration with DEA to conduct research with psilocybin, a schedule I controlled substance," and noted that "[t]he procedures for such application are outlined in 21 U.S.C. 823(f), 21 CFR 1301.18, and 21 CFR 1301.32." In response to Tucker's inquiry "as to the possibility of DEA issuing an exemption from prosecution to Dr. Aggarwal" that was "akin to the exemption provided for in 21 CFR 1316.24," Prevoznik stated that the § 1316.24 exemption "applies to individuals already registered with DEA to engage in research in controlled substances," and would not be applicable to Dr. Aggarwal, who did not have registration for researching in psilocybin. The letter concluded that should "Dr. Aggarwal obtain a schedule I researcher registration from DEA, he may then petition the DEA Administrator for

[8] *See* n.3, *supra*.

a grant of exemption from prosecution following the procedure set forth in 21 CFR 1316.24(b)."

Dissatisfied with this response, AIMS, Dr. Aggarwal, and two patients (we refer to AIMS and Dr. Aggarwal individually when appropriate, and collectively as AIMS) who were seeking to obtain psilocybin from Organix under the RTT Act, brought an action in our court pursuant to 21 U.S.C. § 877, a provision allowing judicial review of final decisions of the Attorney General.

II

As a threshold matter, we must determine whether 21 U.S.C. § 877 gives us jurisdiction to review the DEA letter. We have jurisdiction to determine our own jurisdiction, *In re Gugliuzza*, 852 F.3d 884, 889 (9th Cir. 2017), and review questions regarding our jurisdiction de novo, *Sandoval-Luna v. Mukasey*, 526 F.3d 1243, 1245 (9th Cir. 2008) (per curiam) (citations omitted). "It is to be presumed that a cause lies outside [of federal courts'] limited jurisdiction, and the burden of establishing the contrary rests upon the party asserting jurisdiction." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994) (citations omitted).

A

Section 877 states that "[a]ll final determinations, findings, and conclusions of the Attorney General under [21 U.S.C. §§ 801–904] shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may

obtain review of the decision" in the appropriate court of appeals.[9]

The term "final" is not defined in the statute. However, "statutes addressing the same subject matter" generally should be interpreted consistently with each other. *Wachovia Bank v. Schmidt*, 546 U.S. 303, 305 (2006); *see also United States v. Stewart*, 311 U.S. 60, 64 (1940) ("[A]ll acts *in pari materia* are to be taken together, as if they were one law."). This interpretive principle is often applied when the language in an earlier act is the same as, or similar to, the language in the later act. *See, e.g., Oscar Mayer & Co. v. Evans*, 441 U.S. 750, 756 (1979) (interpreting language in the Age Discrimination in Employment Act by considering interpretation of similar language in Title VII of the Civil Rights Act). Applying this principle, we look to the Supreme Court's definition of "final" in the context of determining when decisions or actions of administrative agencies are "final" for purposes of judicial review. In construing the Administrative Procedure Act (APA), which provides courts

[9] 21 U.S.C. § 877 states, in full:

> All final determinations, finding, and conclusions of the Attorney General under this subchapter [21 U.S.C. §§ 801–904, Control and Enforcement] shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

with jurisdiction to review "final agency actions," 5 U.S.C. § 704, the Court held that "[a]s a general matter, two conditions must be satisfied for agency action to be 'final.'" *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997). The first condition is that "the action must mark the 'consummation' of the agency's decisionmaking process," and "must not be of a merely tentative or interlocutory nature." *Id.* at 177–78 (citation omitted). The second condition that must be satisfied for agency action to be "final" is that "the action must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Id.* at 178 (citation omitted).

The Court has applied this interpretation of "final" outside of the APA context. For instance, in *Whitman v. American Trucking Ass'ns*, the Court had to interpret the word "final" in § 307(b)(1) of the Clean Air Act, 42 U.S.C. § 7607(b)(1), which gives a court jurisdiction over "any . . . nationally applicable regulations promulgated, or final action taken" by the Environmental Protection Agency (EPA). 531 U.S. 457, 478 (2001). Although § 307(b)(1) used different language than § 704 ("final action" rather than "final agency actions"), the Court stated that the phrase "'final action' . . . bears the same meaning in § 307(b)(1) that it does under the Administrative Procedure Act (APA), 5 U.S.C. § 704." *Id.* (citation omitted). The Court explained that "[t]he bite in the phrase 'final action" . . . is not the word 'action,' which is meant to cover comprehensively every manner in which an agency may exercise power," but "[i]t is rather in the word "final," which requires that the action under review "mark the consummation of the agency's decisionmaking process." *Id.* (quoting *Bennett*, 520 U.S. at 177–178). Accordingly, the agency's action is "'final' and thus reviewable" when the

agency "has rendered its last word on the matter in question." *Id*. (citation omitted).[10]

We have likewise applied *Bennett*'s interpretation of "final" to uses of the word "final" in other statutes providing jurisdiction over agency action. Thus in *U.S. West Commc'ns, Inc. v. Hamilton*, we concluded that the term "final order" under the Hobbs Act was "analytically equivalent" to the term "final agency action" under the APA. 224 F.3d 1049, 1054–55 (9th Cir. 2000). Therefore, we held that "*Bennett* governs our understanding of 'final order' for the purposes of the Hobbs Act." *Id.* Applying *Bennett*'s interpretation, we determined that an order was final, because it was "neither tentative nor interlocutory" and it "determine[d] rights and [gave] rise to legal consequences." *Id.* at 1055.

Although we have not expressly applied *Bennett* in interpreting "final decision" in § 877, we have applied similar reasoning in that context. *See Hemp Indus. Ass'n v. DEA*, 333 F.3d 1082, 1085 (9th Cir. 2003). In *Hemp*, the DEA published a rule that banned the sale of certain products containing hemp products in the Federal Register. *Id.* at 1084–85. Implicitly applying *Bennett*'s second condition, we concluded that the rule was "final" for purposes of our jurisdiction under § 877 because it imposed "obligations and sanctions in the event of violation." *Id*. at 1085; *see also Oregon v. Ashcroft*, 368 F.3d 1118, 1120 (9th Cir. 2004)

[10] *Whitman* also determined that because the "special judicial review provision" of the Clean Air Act provides for preenforcement review, the rule had sufficient "concrete effects" for enforcement. *Id.* at 480–81 (citation omitted).

(holding that the court had jurisdiction under § 877 to review a rule that "orders sanctions for violations of its provisions").

As these cases indicate, *Bennett*'s conclusion that an agency action is final if it is not interim or tentative but has concrete effects and legal consequences is equally applicable in construing other statutes authorizing review of agency action. We conclude that this interpretation is applicable to our analysis of § 877, because the word "final" in this context is "analytically equivalent" to the meaning of the same word in the APA. *Hamilton*, 224 F.3d at 1054–55. We therefore join the D.C. Circuit, which reached the same conclusion. *See John Doe, Inc. v. DEA*, 484 F.3d 561, 566 n.4 (D.C. Cir. 2007). In *John Doe*, the D.C. Circuit held that it had jurisdiction under § 877 to review the DEA's denial of an application for a permit. *Id.* at 567. *John Doe* explained that *Bennett* "firmly support[s] a finding of finality" because the DEA "affirmatively denied Doe's permit application," thus marking the culmination of its decisionmaking process, and also established "legal consequences by prohibiting importation." *Id.* at 566–67 (citation omitted). Our conclusion is also consistent with the Sixth Circuit's analysis. *See Miami-Luken, Inc. v. DEA*, 900 F.3d 738, 743 (6th Cir. 2018). Although the Sixth Circuit primarily relied on the Supreme Court's interpretation of 28 U.S.C. § 1291 (providing jurisdiction over "final decisions" of district courts) in interpreting § 877's finality requirement, the Sixth Circuit stated that its analysis was "bolstered by the Supreme Court's analysis" of the APA in *Bennett*. *Id.* at 742 n.4.[11]

[11] We agree with *Miami-Luken* that interpretations of the word "final" in 28 U.S.C. § 1291 can also shed light on the use of the word "final" in § 877.

B

When applying *Bennett*'s two conditions to a communication made by an agency, courts differentiate between an informational document that merely provides the agency's interpretation of a statute, *see City of San Diego v. Whitman*, 242 F.3d 1097 (9th Cir. 2001), and a decision that determines how a statute or regulation applies to facts for enforcement purposes, *see U.S. Army Corps. of Eng'rs v. Hawkes Co.*, 578 U.S. 1129 (2016).

1

An agency's informational document, in which "an agency merely expresses its view of what the law requires of a party," is not a final agency action. *Indep. Equip. Dealers Ass'n v. EPA*, 372 F.3d 420, 427–28 (D.C. Cir. 2004). In *City of San Diego*, for instance, we determined that a letter written by the EPA, stating it planned to apply the Ocean Pollution Reduction Act to the City's future application for renewal of its wastewater discharge permit, was not final agency action. 242 F.3d at 1098. First, the letter did not mark the consummation of the agency's decisionmaking process, the first *Bennett* condition. *Id.* at 1101. Rather, we held that the agency's decisionmaking process on the City's application would "not even begin until the City files its application," and the agency's process would not be completed until the City had exhausted the appeal process. *Id.* at 1101. Second, the letter did not lead to legal consequences for the City, the second condition of *Bennett*, because the letter "simply responds to the City's request for 'assistance' on the issue" of whether the EPA would apply a specified statute to its application, and "only 'encourage[s]' the City to submit its

application in accordance with the EPA's interpretation" of the statute. *Id.*

Similarly, we held that an agency's informational manual on compliance with the National Environmental Policy Act (NEPA) was not a final agency action. *Whitewater Draw Nat. Res. Conservation Dist. v. Mayorkas*, 5 F.4th 997 (9th Cir. 2021), *cert. denied sub nom. Whitewater Draw v. Mayorkas*, No. 21-574, 2021 WL 5869442 (U.S. Dec. 13, 2021) (9th Cir. July 19, 2021). First, the manual was not the culmination of the agency's decisionmaking process because it merely "facilitates the *beginning* of the NEPA review process for proposed" agency action. *Id.* at 1008. Second, it did not lead to legal consequences, because the informational manual "is not itself a decision that any particular [agency] action requires or does not require" an environmental impact statement, and the guidance provided by the manual "would be subsumed in any final rule issued by [the agency] on a particular matter." *Id.* (citation omitted).

In considering *Bennett*'s second condition, we have emphasized that an agency action is not final where the agency merely "expresses its view of what the law requires." *Fairbanks N. Star Borough v. U.S. Army Corps of Eng'rs*, 543 F.3d 586, 594 (9th Cir. 2008) (citation omitted). This is because in a later enforcement action, the regulated party "would face liability only for noncompliance with the underlying statutory commands, not for disagreement with the agency's determination." *Id.* (citation omitted). "Absent some identifiable effect on the regulated community, an agency works no legal effect merely by expressing its view of the law." *Valero Energy Corp. v. EPA*, 927 F.3d 532, 536 (D.C. Cir. 2019) (citation omitted).

2

By contrast, a decision document that marks the conclusion of an agency's decisionmaking process and has legal consequences for the regulated party is a final agency action. In *Hawkes*, 578 U.S. 590, the Supreme Court considered a determination issued by the Army Corps of Engineers giving its definitive view on whether a particular piece of property contained wetlands (called an approved jurisdictional determination, or JD). The Court held first that "an approved JD clearly mark[s] the consummation of the Corps' decisionmaking process" (the first *Bennett* condition) because "it is issued after extensive factfinding by the Corps regarding the physical and hydrological characteristics of the property . . . and is typically not revisited if the permitting process moves forward." *Id.* at 597–98 (cleaned up). The Court also held that a JD meets the second *Bennett* consideration, because it gives rise to "direct and appreciable legal consequences." *Id.* at 598 (citing *Bennett*, 520 U.S. at 178). An approved JD stating that a party's property does not contain jurisdictional waters "both narrows the field of potential plaintiffs and limits the potential liability a landowner faces for discharging pollutants without a permit." *Id.* at 599. And a positive JD (a determination that there are wetlands on the property) also has legal consequences, because it represents "the denial of the safe harbor that negative JDs afford." *Id.* (citation omitted).

According to *Hawkes*, this conclusion "tracks the pragmatic approach" adopted in *Frozen Food Express v. United States*, 351 U.S. 40 (1956), which was decided before the Court formalized its approach in *Bennett*. 578 U.S. at 599. In *Frozen Foods*, after a decisionmaking process that included a public hearing, the Interstate Commerce

Commission (Commission) issued a report and order to establish which commodities were exempt from regulation. *Id.* at 41–42. The Court determined the order was effectively a declaratory rule with legal consequences, and therefore constituted final agency action. *Id.* at 45. The Court explained that the Commission's ruling that a commodity was not exempt had "an immediate and practical impact" on the regulated community, in that it "warns 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.* at 44.

We have likewise distinguished between "an agency letter to a single entity that was purely informational in nature and compelled no one to do anything," which is not final agency action, and an agency's "application and enforcement" of an order warning the regulated community not to take prohibited actions "on pain of fines and imprisonment," which qualifies as a final agency action. *San Francisco Herring Ass'n v. Dep't of the Interior*, 946 F.3d 564, 577 (9th Cir. 2019) (cleaned up). In *San Francisco Herring Ass'n*, the National Park Service issued a series of enforcement orders stating it had jurisdiction over the Golden Gate National Recreation Area (GGNRA), and announcing its intention "to enforce the prohibition on commercial fishing" in those waters. *Id.* at 578. "Subsequently, and critically, the Park Service then put its declared position into action when its uniformed officers and California wardens (allegedly acting at the federal government's direction) took to the waters to order herring fishermen to stop fishing in the GGNRA." *Id.* We concluded that the Park Service's enforcement orders were final agency action. We explained that "[t]he Park Service had arrived at a definitive position, fulfilling the first *Bennett* requirement of being the consummation of agency decisionmaking

regarding that issue." *Id.* (citation omitted). The orders also had legal consequences, satisfying *Bennett*'s second requirement, because "there is no dispute that based on the Park Service's position, persons who engaged in commercial fishing in the GGNRA could be punished through fines and imprisonment," and such "exposure to the risk of significant criminal and civil penalties." *Id.* at 580 (citing *Hawkes*, 578 U.S. at 600); *see also Hemp Indus. Ass'n*, 333 F.3d at 1085 (holding that an interpretive rule issued by the Attorney General pursuant to the CSA is a "final determination" for jurisdictional purposes because the rule "impos[es] obligations and sanctions in the event of violation [of its provisions]").

In short, in considering whether an agency's informational document is a final agency action, we take a "pragmatic approach." *Hawkes*, 578 U.S. at 599 (citation omitted). If the informational document is more analogous to the "the type of workaday advice letter that agencies prepare countless times per year in dealing with the regulated community," *Indep. Equip. Dealers Ass'n*, 372 F.3d at 427, and is little more than a restatement of statute and regulations in a response to a "request for assistance," *City of San Diego*, 242 F.3d at 1100, it is not the consummation of a decisionmaking process or an order from which "legal consequences will flow," *Bennett*, 520 U.S. at 178. By contrast, if the informational document "is issued after extensive factfinding," *see Hawkes*, 578 U.S. at 597, or after a public hearing, *see Frozen Foods*, 351 U.S. at 41, or after "a series of formal written notices," *San Francisco Herring Ass'n*, 946 F.3d at 567, and thus indicates the agency's determination that a regulated party disobeys the order at its peril of incurring criminal penalties or sanctions, *id.*, it satisfies the *Bennett* conditions and is a final agency action.

III

Considering Prevoznik's letter in light of this standard, we conclude it is an informational letter of the sort that does not constitute final agency action under *Bennett*.

First, the letter is "the type of workaday advice letter that agencies prepare countless times per year in dealing with the regulated community," *Indep. Equip. Dealers Ass'n*, 372 F.3d at 427. The letter was a response to a request for assistance and advice as to whether a physician who was relieved of certain FCPA registration requirements for the use of psilocybin under the RTT Act could also be relieved from the requirements of the CSA. There is no indication that the response to Tucker's request for advice was preceded by agency factfinding or a public hearing, or that the DEA otherwise engaged in a decisionmaking process resulting in the response letter.

Despite the lack of indicia that the letter represented the consummation of a decisionmaking process, AIMS argues that we should deem it to establish the DEA's settled views that the DEA lacked authority to accommodate therapeutic use of Schedule I substances under state and federal RTT Acts. To support this claim, AIMS argues it is critical that the letter was signed by the Deputy Assistant Administrator of Diversion Control, who has authority over the promulgation and implementation of many DEA regulations, *see* 28 C.F.R. Pt. 0, Subpt. R., App. § 7; 21 C.F.R. §§ 1301.18, 1301.32. We disagree. Whatever his authority as Deputy Assistant Administrator to promulgate regulations or grant waivers, there is no indication that Prevoznik exercised that authority in signing the letter. Tucker asked only for advice and guidance; she did not request or propose

that the DEA promulgate regulations to harmonize the CSA with the DEA or apply for relief from CSA provisions. Therefore, in informing Tucker that the RTT Act itself gave the DEA no authority to waive CSA's requirements, Prevoznik did not grant or deny any request or make any final decision. In sending the response letter, the DEA's decisionmaking process had not yet begun. *Cf. Indep. Equip. Dealers Ass'n*, 372 F.3d at 428. Accordingly, Prevoznik's letter does not meet *Bennett*'s first condition.

Second, the letter does not lead to legal consequences for Dr. Aggarwal. Rather, the letter provided straightforward guidance about the interaction of the RTT Act and the CSA. It stated that "absent an explicit statutory exemption to the Controlled Substances Act (CSA) DEA has no authority to waive any of the CSA's requirements *pursuant to the RTT*" and then set out the entire text of RTT's exemption provision, 21 U.S.C. § 360bbb-0a(b), which did not give the DEA authority to waive CSA requirements. Second, the letter stated that the CSA provides an exemption from criminal liability only for researchers who register to conduct research with Schedule 1 controlled substances. This is likewise a straightforward statement of Prevoznik's "view of what the law requires," *Fairbanks*, 543 F.3d at 594. These statements do not impose legal consequences on Dr. Aggarwal. Should Dr. Aggarwal obtain psilocybin for his patient, he "would face liability only for noncompliance" with the CSA, and "not for disagreement with the agency's determination," *id*.[12]

[12] Thus, AIMS's reliance on the D.C. Circuit's decision in *John Doe*, 484 F.3d at 566, to support its claim that we have jurisdiction under § 877 is misplaced. Prevoznik's letter did not grant or deny any request, nor impose any legal consequence on Dr. Aggarwal. In *John Doe*, by

AIMS argues that Prevoznik's letter had legal consequences for Dr. Aggarwal and AIMS because it foreclosed their only avenue to access psilocybin under RTT Act laws. Further, AIMS argues that Prevoznik's letter put them on notice that if they attempt to obtain psilocybin under the RTT Act they are at risk of civil and criminal liability under the CSA. But this risk was not created by Prevoznik's letter, which did no more than point to the plain language of existing law. In short, AIMS's issue is not with the DEA's letter, but with the CSA's criminalization of psilocybin use, subject to narrow exemptions. An advice letter recognizing that Congress has not yet made an exception to the CSA to allow for the legal use of psilocybin for therapeutic purposes is not a final agency decision.[13] Accordingly, the letter does not meet *Bennett*'s second condition.[14]

DISMISSED.

contrast, the DEA "affirmatively denied Doe's permit application," and thus established "legal consequences by prohibiting importation." *Id*.

[13] Supporters of decriminalization of psilocybin for therapeutic use have recognized that a legislative approach is necessary. In November 2020, Oregon passed Ballot Measure 109, which legalized psilocybin for therapeutic use, and several cities have made enforcement of psilocybin use low priority. Mason M. Marks, *Controlled Substance Regulation for the Covid-19 Mental Health Crisis*, 72 Admin. L. Rev. 649, 654, 708–10 (2020).

[14] Because we determine that the Prevoznik letter was not final agency action, we need not address the question whether the letter was a decision "of the Attorney General," as required by § 877.